

Impact of service-delivery model and hearing aid technology on patient outcomes

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Barriers to hearing aid (HA) use

- HA is the primary intervention for age-related hearing loss
- However, the adoption rate of HAs is low.
- Affordability and accessibility issues

Over-the-counter (OTC) HAs

- OTC HAs: To address affordability and accessibility issues
- **Preset-based** and **Self-fitting OTC HAs**
- Traditional HAs: **Prescription HAs**

AUD vs. OTC

- Humes et al. (2017) and De Sousa et al. (2023)
 - Randomized controlled trial
- **AUD = OTC**
 - Retrospective self-reports: PHAB, APHAB, HHIE, IOI-HA
 - Speech tests: CST, QuickSIN, DIN
- **AUD > OTC**
 - HA Satisfaction: HASS



JAMA Otolaryngology-Head & Neck Surgery | [Original Investigation](#)

Effectiveness of an Over-the-Counter Self-fitting Hearing Aid Compared With an Audiologist-Fitted Hearing Aid
A Randomized Clinical Trial

Karina C. De Sousa, PhD; Vinaya Manchaiah, PhD; David R. Moore, PhD; Marien A. Graham, PhD; De Wet Swanepoel, PhD

AUD vs. OTC

- OTC outcome is similar to or slightly poorer than AUD outcome
 - OTC is an effective intervention.
 - Professional services have little or no contribution to patient outcome.
- Retrospective self-reports may not be sensitive.
- In-situ self-reports (Ecological Momentary Assessment; EMA) are more sensitive than retrospective self-reports (Wu et al., 2020).

Comparison of In-Situ and Retrospective Self-Reports on Assessing Hearing Aid Outcomes

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Ruth Bentler¹

J Am Acad Audiol 2020;31:746–762.

High-end vs. Low-end HAs

- High-end HAs
 - More advanced technologies
 - More expensive
 - Should yield better outcomes to justify the high cost
- Cox et al. (2014), Wu et al. (2019)
 - Cross-over field trials
 - **Real world: High-end = Low-end**

Impact of Advanced Hearing Aid Technology on Speech Understanding for Older Listeners with Mild to Moderate, Adult-Onset, Sensorineural Hearing Loss

Robyn M. Cox Jani A. Johnson Jingjing Xu

School of Communication Sciences and Disorders, University of Memphis, Memphis, Tenn., USA

Efficacy and Effectiveness of Advanced Hearing Aid Directional and Noise Reduction Technologies for Older Adults With Mild to Moderate Hearing Loss

Yu-Hsiang Wu,¹ Elizabeth Stangl,¹ Octav Chipara,² Syed Shabih Hasan,² Sean DeVries,³ and Jacob Oleson³

High-end vs. Low-end HAs

- High-end and Low-end HAs yield similar real-world outcomes.
 - In the AUD model
- How about OTC+ and OTC?
- In AUD, if we well instruct participants on how and when to use advanced features, would High-end outperforms Low-end?
 - Instructions not doable in a cross-over design with blinding

AUD

OTC+

OTC

High-end HA

- Prescription HA
- Hearing evaluation
- Device personalization
- Device orientation
- Counseling
- Follow-up

- OTC HA
- Hearing evaluation and device selection
- Device orientation
- Counseling
- Follow-up

- OTC HA
- No professional service

Low-end HA

- Prescription HA
- Hearing evaluation
- Device personalization
- Device orientation
- Counseling
- Follow-up

- OTC HA
- Hearing evaluation and device selection
- Device orientation
- Counseling
- Follow-up

- OTC HA
- No professional service

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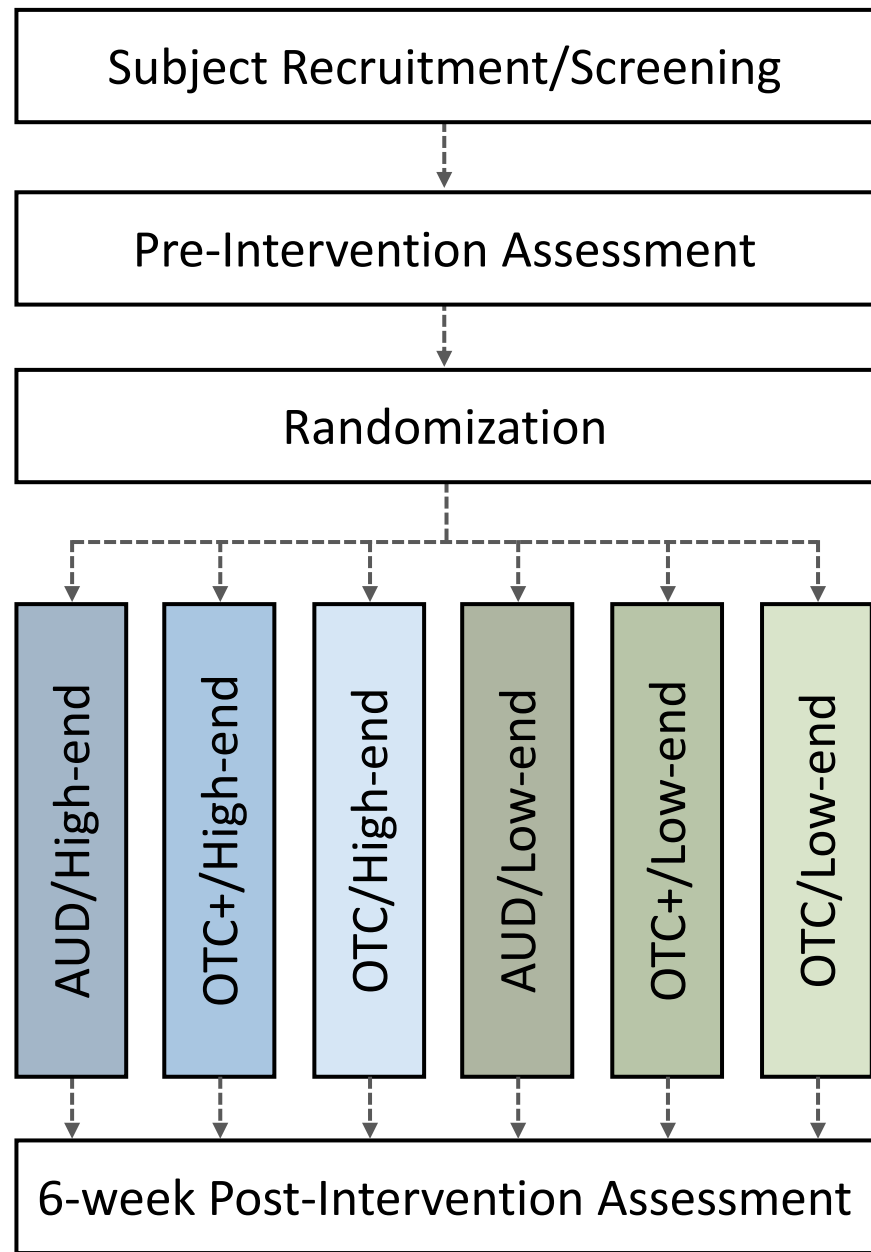


Dr. Larry Humes

Methods and Materials

Study design

- A two-site (Iowa and Vanderbilt) randomized controlled trial
- Blinding:
 - Participants were only aware to the services and HA technologies they received
- Subject inclusion criteria
 - Between 55 and 85 years old
 - Bilateral, SNHL with 3PTA (0.5, 1, and 2 kHz) > 25 dB HL but ≤ 65 dB HL
 - No prior HA experience



- Hypothesis:
 - $AUD > OTC+ > OTC$
 - High-end $>$ Low-end
- Power analysis:
 - N=40 each group

AUD

OTC+

OTC

High-end HA

AUD
High-end

OTC+
High-end

OTC
High-end

Low-end HA

AUD
Low-end

OTC+
Low-end

OTC
Low-end

AUD

OTC+

OTC

Prescription HAs (BTE)

	Signal Processing Channels	Hearing Programs	Extended dynamic range	Extended bandwidth	Impulse noise reduction	Narrow Directionality	Spatial noise reduction	Reverb reduction	Wind noise reduction	Smart phone app
High-end HA	48	6	Yes	Yes	Yes	Yes	Yes	Yes	Yes	More functions
Low-end HA	12	4	No	No	No	No	No	No	No	Fewer functions

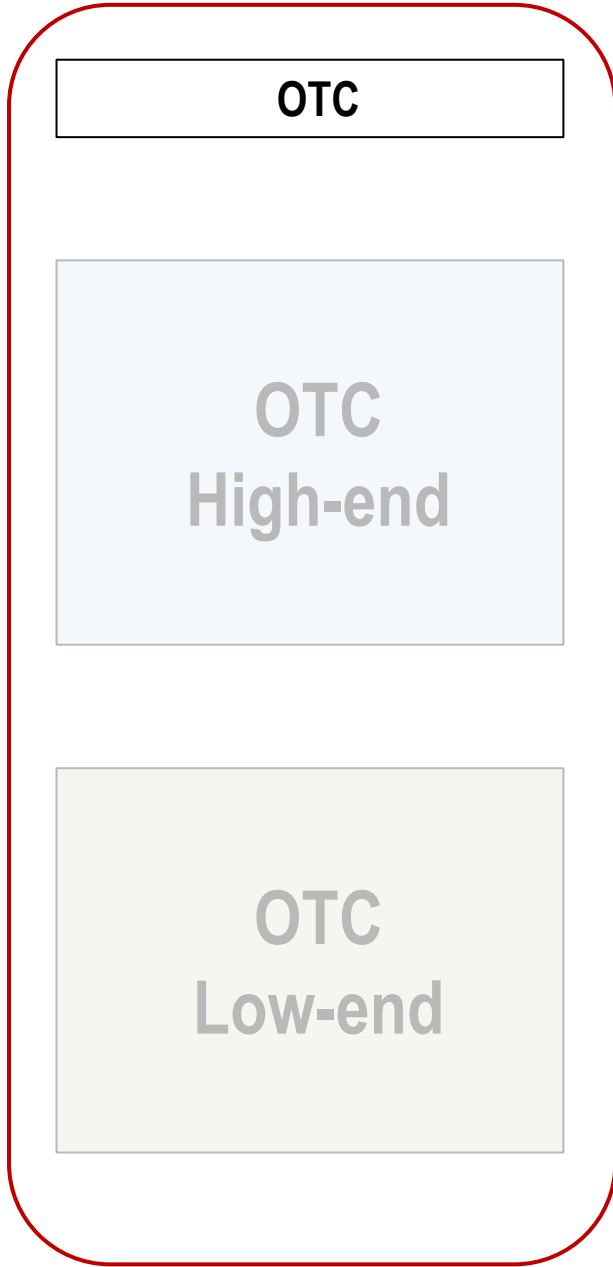
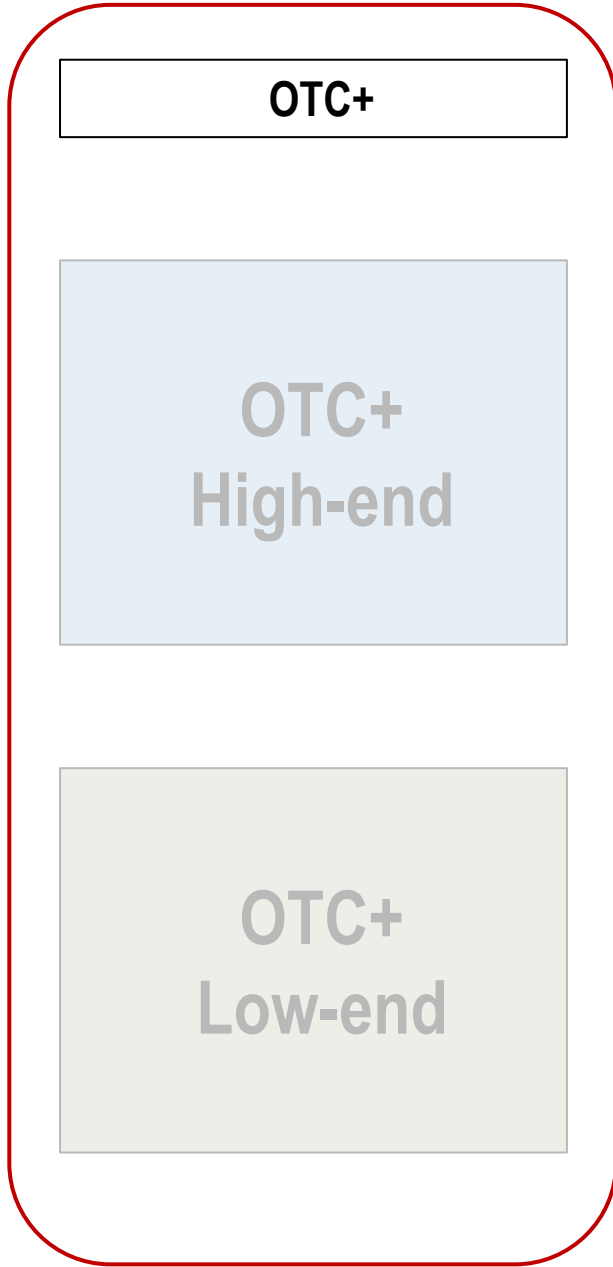
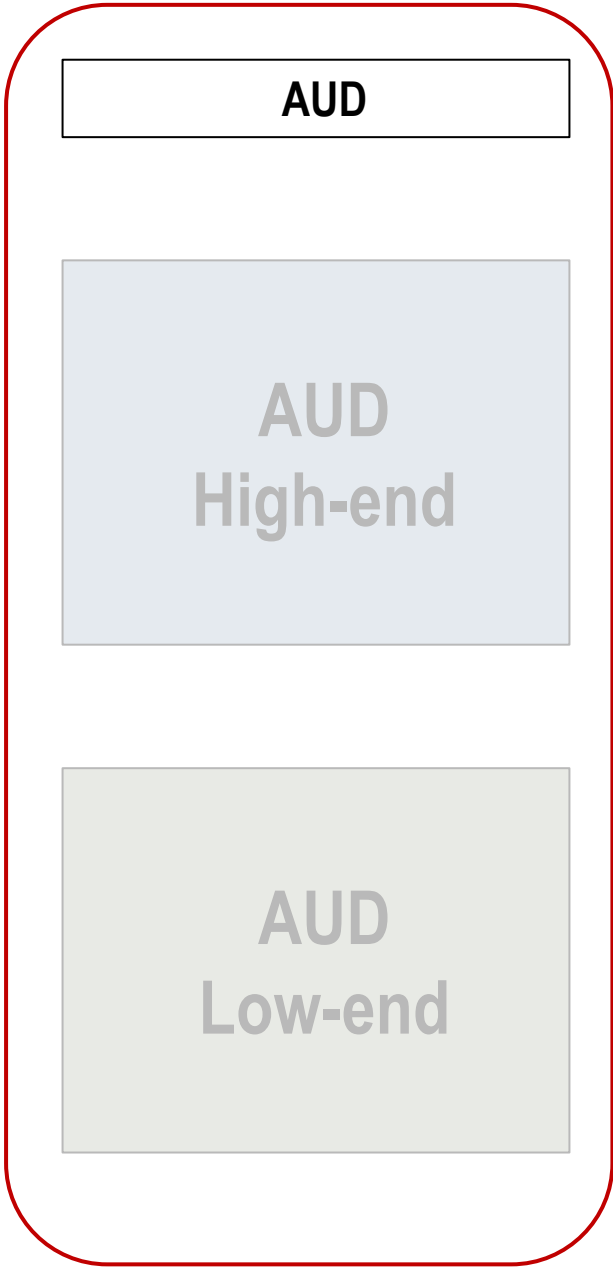
LOW END

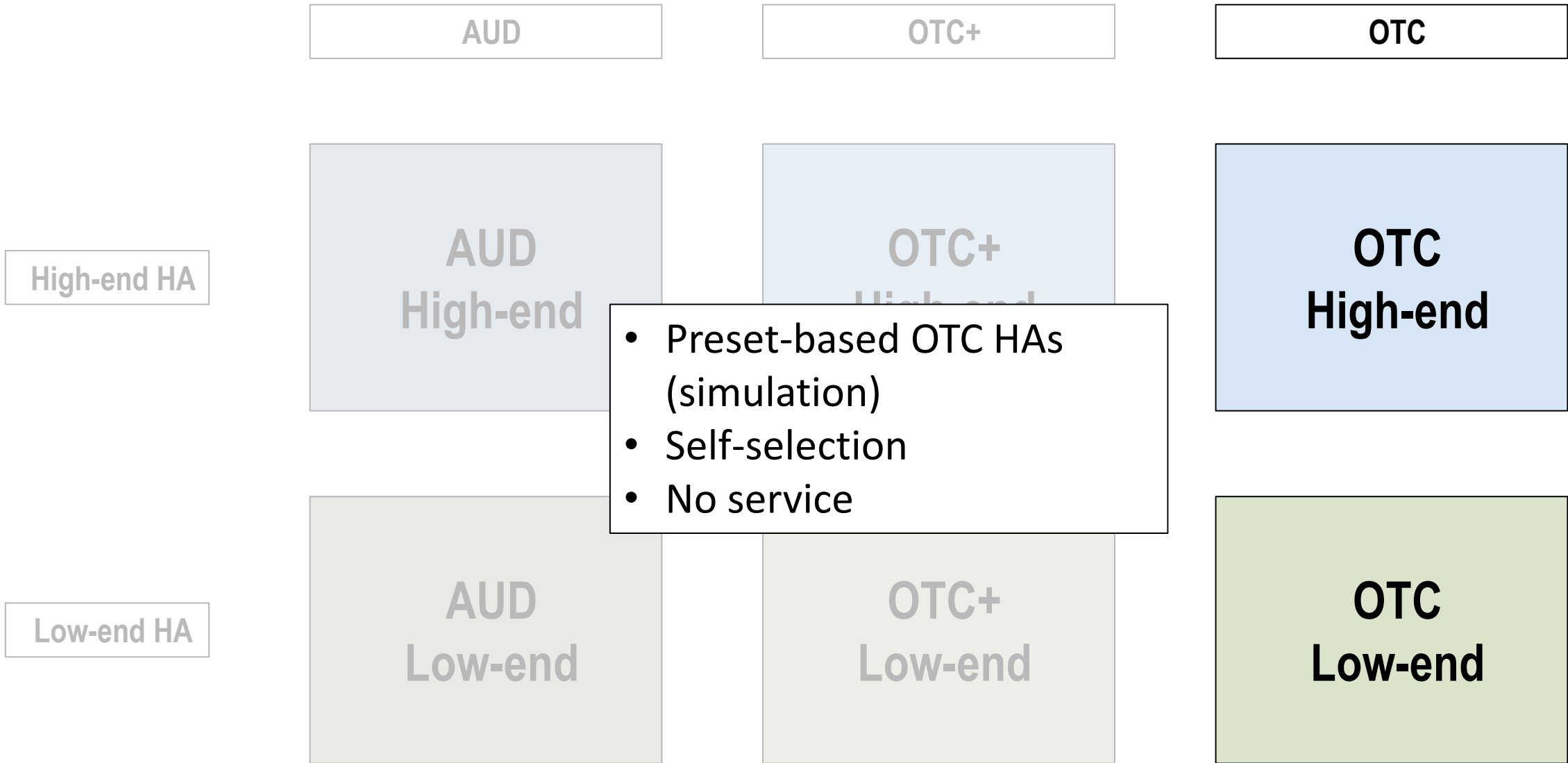
LOW END

LOW END

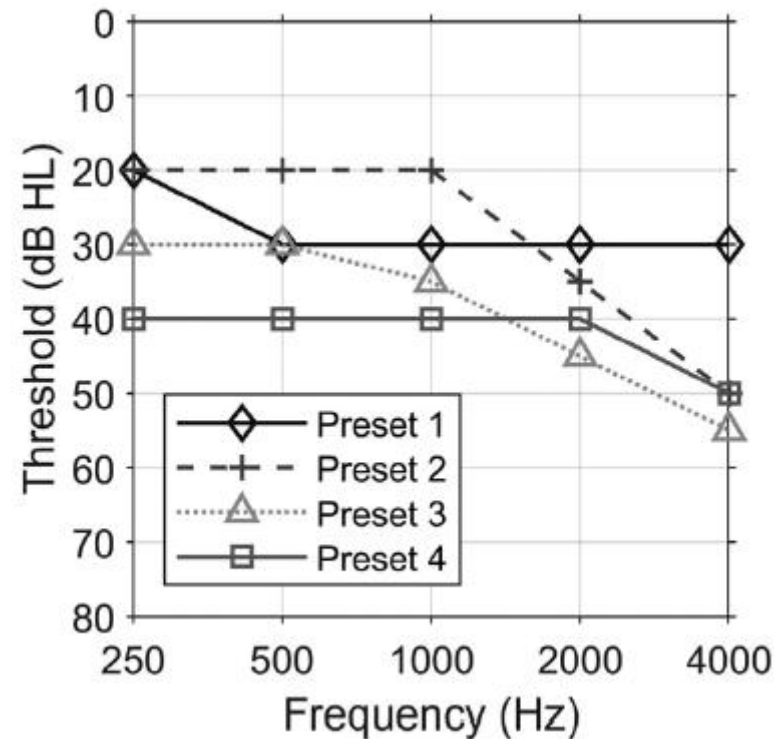
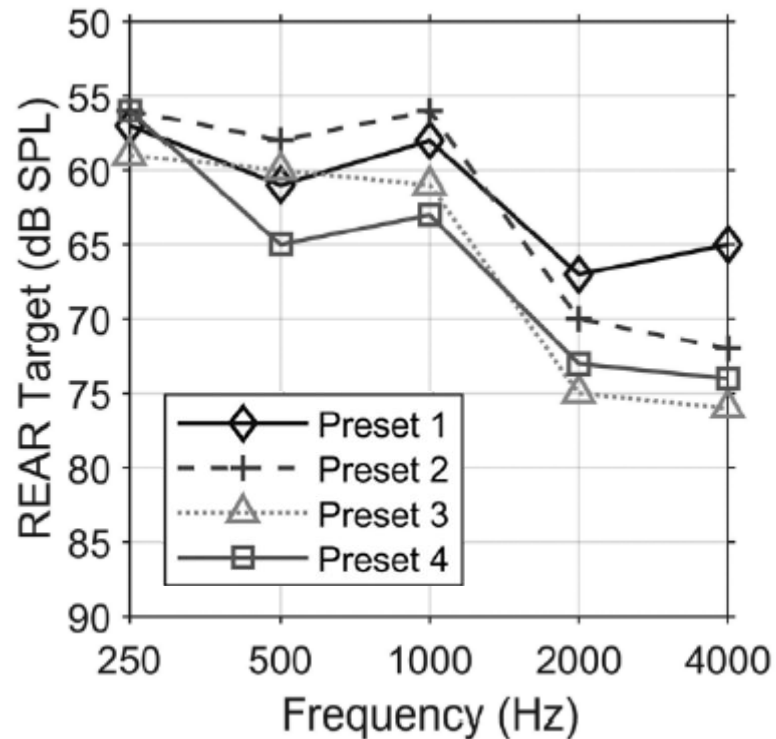
High-end HA

Low-end HA





Preset-based OTC HA



	Dome
Preset 1	Open
Preset 2	Open
Preset 3	Closed
Preset 4	Closed



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Research Article

Efficacy and Effectiveness of Evidence-Based Non-Self-Fitting Presets Compared to Prescription Hearing Aid Fittings and a Personal Sound Amplification Product

Soumya Venkitakrishnan,^a Dana Urbanski,^b and Yu-Hsiang Wu^c

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Research Article

Toward a New Evidence-Based Fitting Paradigm for Over-the-Counter Hearing Aids

Dana Urbanski,^a Helin Hernandez,^b Jacob Oleson,^b and Yu-Hsiang Wu^a

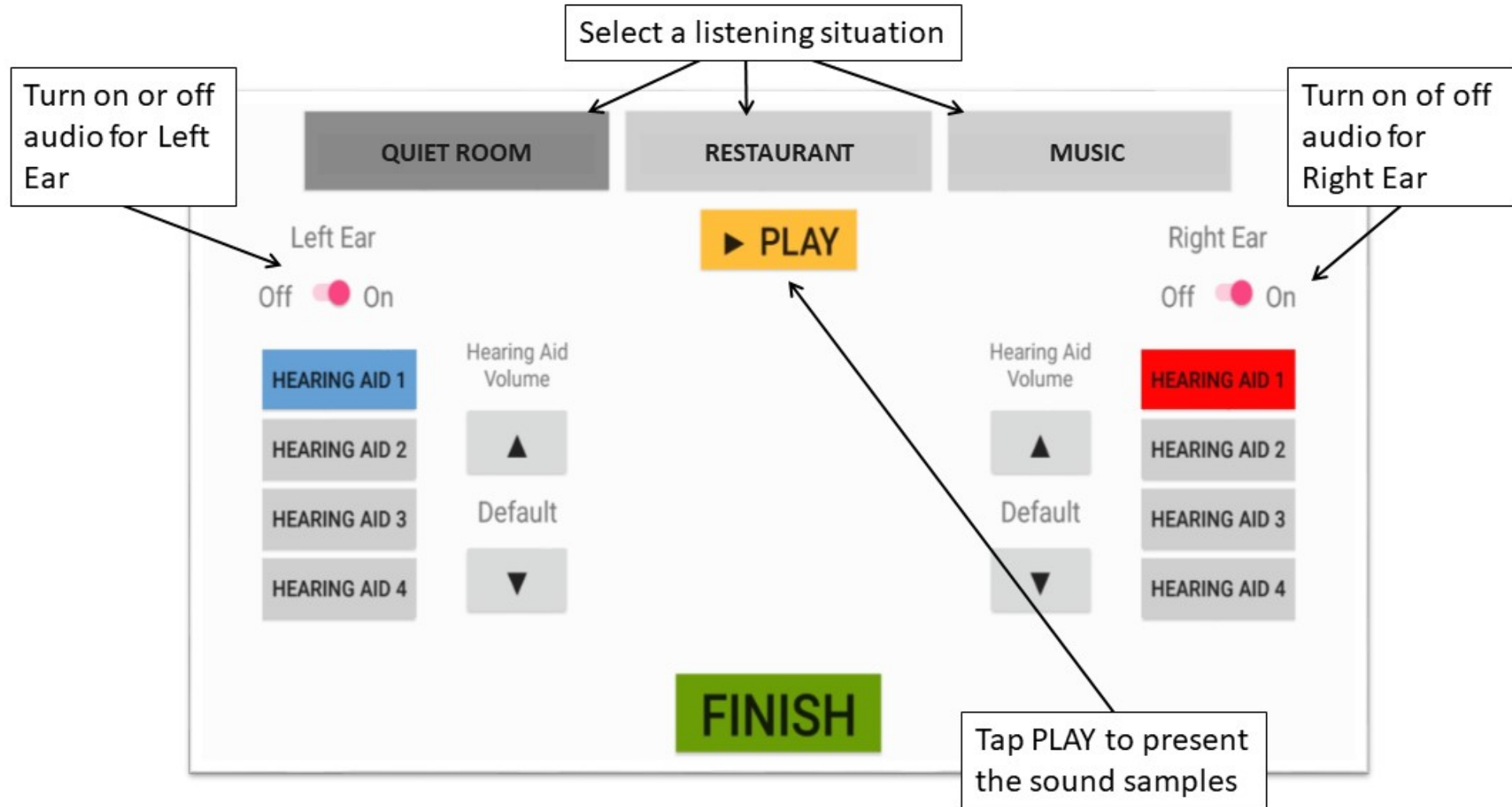
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Research Article

Common Configurations of Real-Ear Aided Response Targets Prescribed by NAL-NL2 for Older Adults With Mild-to-Moderate Hearing Loss

Justin Jensen,^a Dhruv Vyas,^b Dana Urbanski,^a Harinathi Garudadri,^a Octav Chipara,^b and Yu-Hsiang Wu^a

HA selection kiosk



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AUD

OTC+

OTC

AUD

**OTC+
High-end**

OTC
High-end

- High
- Preset-based OTC HAs (simulation)
 - Preset and earpiece selection
 - Orientation and demonstration
 - 30-minute fitting, two 15-minute follow-up visits

Low-end HA

AUD
Low-end

**OTC+
Low-end**

OTC
Low-end

AUD

OTC+

OTC

High-end HA

**AUD
High-end**

Low-end HA

**AUD
Low-end**

- Prescription HAs
- Measures:
 - Loudness Discomfort Level (LDL)
 - Acceptable Noise Level (ANL)
 - Client Oriented Scale of Improvement (COSI)
 - QuickSIN
- Device personalization
- Probe-microphone measures
- Orientation and demonstration
- And more...

Outcome measures

- Primary outcome: **Glasgow Hearing Aid Benefit Profile (GHABP)**

Handicap	HA use	HA Benefit	Disability	HA satisfaction
In this situation, <u>with your hearing aid</u> , how much does any difficulty in this situation worry, annoy or upset you?	In this situation, what proportion of the time do you wear your hearing aid?	In this situation, how much does your hearing aid help you?	In this situation, <u>with your hearing aid</u> , how much difficulty do you <u>now</u> have?	For this situation, how satisfied are you with your hearing aid?
0__ N/A 1__ Not at all 2__ Only a little 3__ A moderate amount 4__ Quite a lot 5__ Very much indeed	0__ N/A 1__ Never/Not at all 2__ About ¼ of the time 3__ About ½ of the time 4__ About ¾ of the time 5__ All the time	0__ N/A 1__ Hearing aid no use at all 2__ Hearing aid is some help 3__ Hearing aid is quite helpful 4__ Hearing aid is a great help 5__ Hearing is perfect with aid	0__ N/A 1__ No difficulty 2__ Only slight difficulty 3__ Moderate difficulty 4__ Great difficulty 5__ Cannot manage at all	0__ N/A 1__ Not satisfied at all 2__ A little satisfied 3__ Reasonably satisfied 4__ Very satisfied 5__ Delighted with aid
Unaided			Unaided	

EMA-GHABP

Smartphone-based EMA

AudioSense+

Start Survey

Vibrate/Sound

Snooze 30 minutes

Settings

Exit

AudioSense+

TV/Volume set for others

For this situation, how satisfied were you with the hearing aids?

Not satisfied at all

A little satisfied

Reasonably satisfied

Very satisfied

Delighted with hearing aids

Retro-GHABP

Retrospective questionnaire



Secondary outcome measures

	Unaided	Aided
• Profile of Hearing Aid Performance (PHAP)	X	X
• Hearing Handicap Inventory for the Elderly (HHIE) or Adults (HHIA)	X	X
• Satisfaction with Amplification in Daily Life (SADL)		X
• As-worn Connected Speech Test (CST)	X	X
• Speech from 0 degree, noise from 180 degree		
• 3 dB SNR		

Results

Subject recruitment and retention

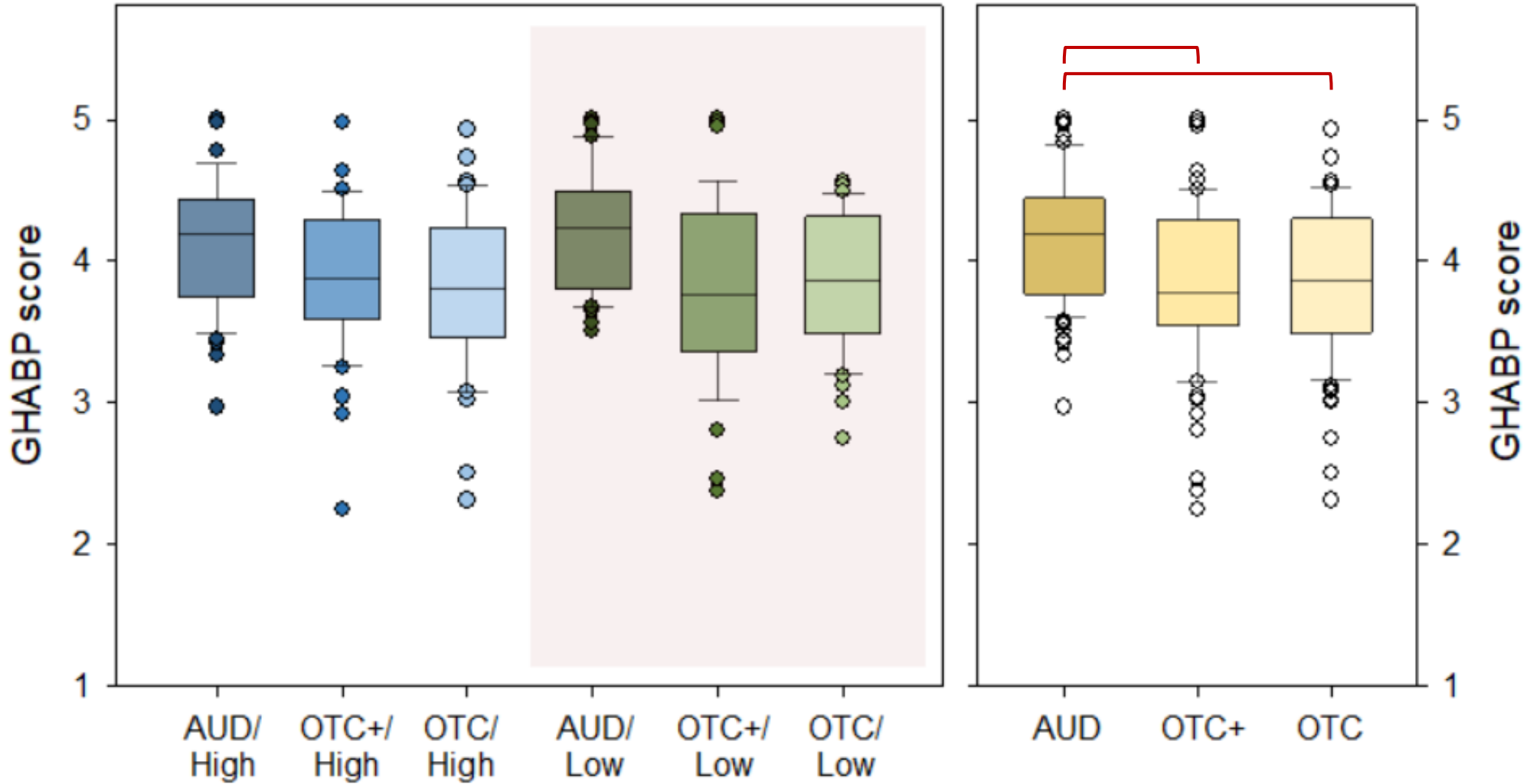
- From February 2019 to December 2023
- Assessed for eligibility: n = 511

		AUD/ High	OTC+/ High	OTC/ High	AUD/ Low	OTC+/ Low	OTC/ Low	Total
Completed		43	41	42	40	39	40	245
Withdrawals	COVID	2	3	4	3	1	2	15
	Disliked hearing aids	1	1	4	1	2	3	12
	Health concern	2	0	0	1	2	2	7
	Lost to follow-up/unknown	0	0	0	0	1	0	1
	Protocol Error	1	0	1	0	1	5	8
	Time/distance concern	0	0	1	0	0	1	2

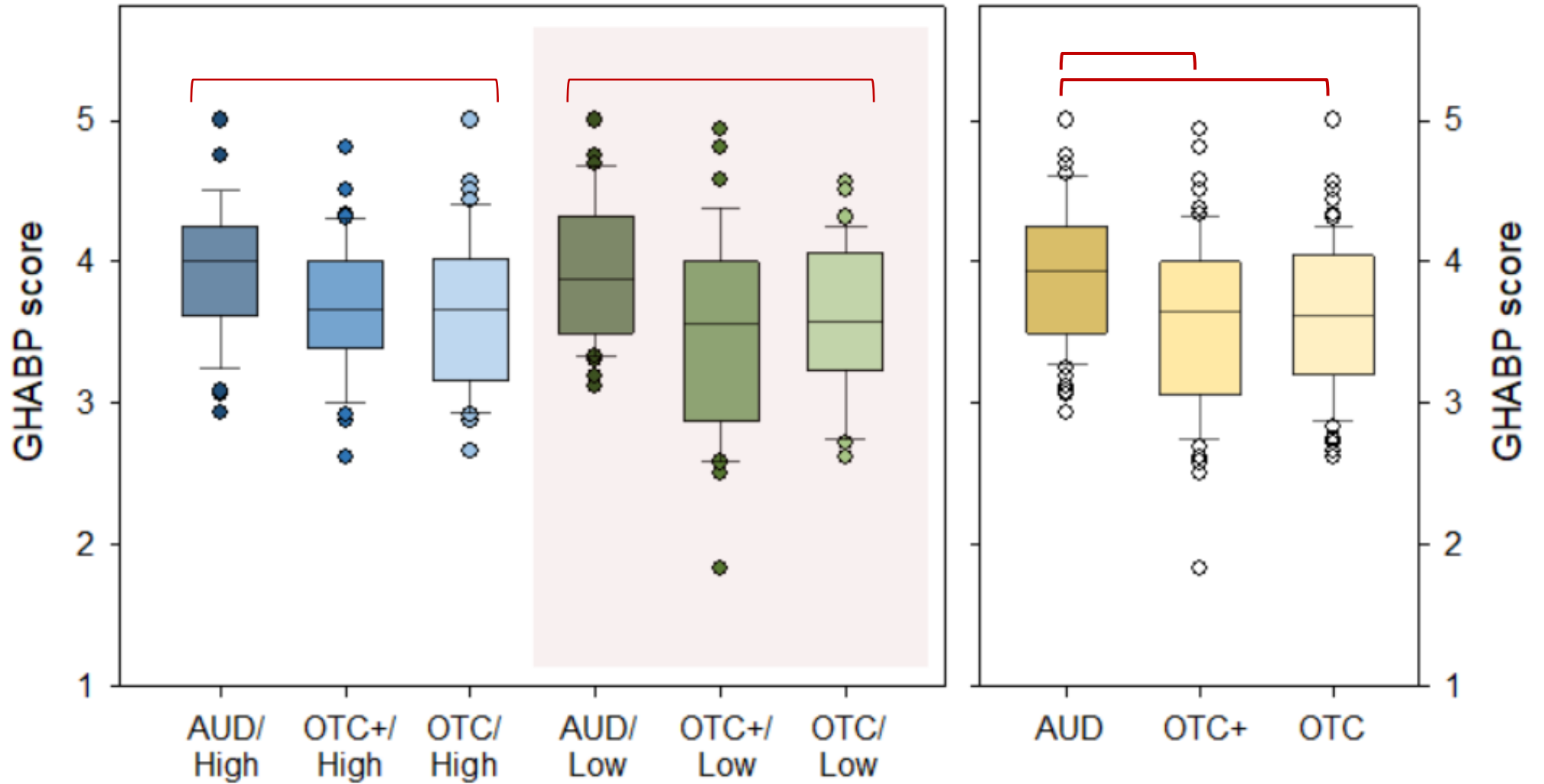
Subject characteristics (n=245)

	AUD/ High	OTC+/ High	OTC/ High	AUD/ Low	OTC+/ Low	OTC/ Low
Age	66.3	68.6	67.7	67.5	69.1	69.5
Female	51%	50%	51%	48%	43%	50%
College degree or higher	40%	48%	37%	45%	38%	40%
MOCA score	25.9	26.1	26.1	25.9	25.4	25.8
3PTA (dB HL)	31.2	31.8	30.0	31.4	30.9	30.7

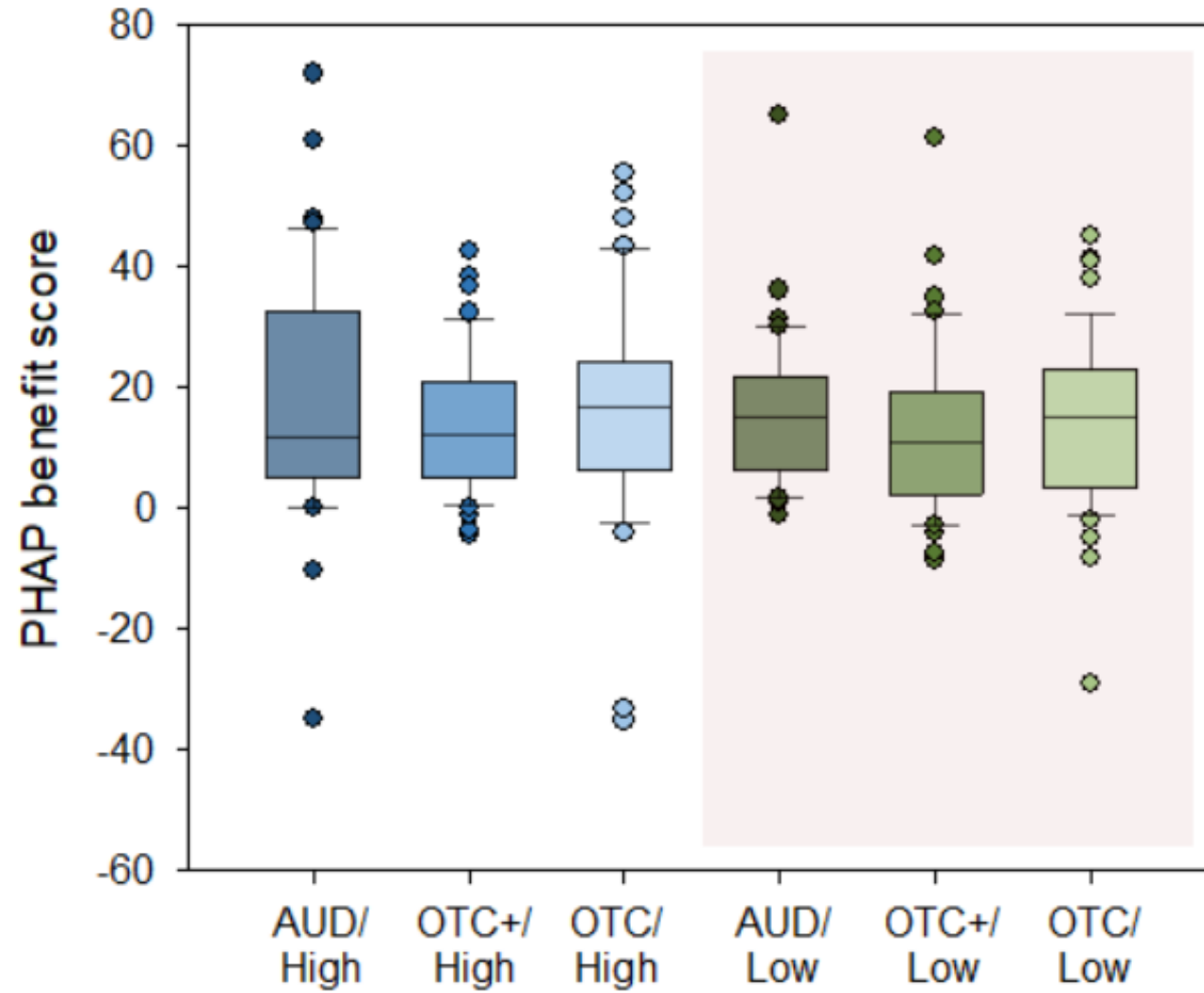
EMA-GHABP (control for unaided score and site; 8,631 aided surveys)



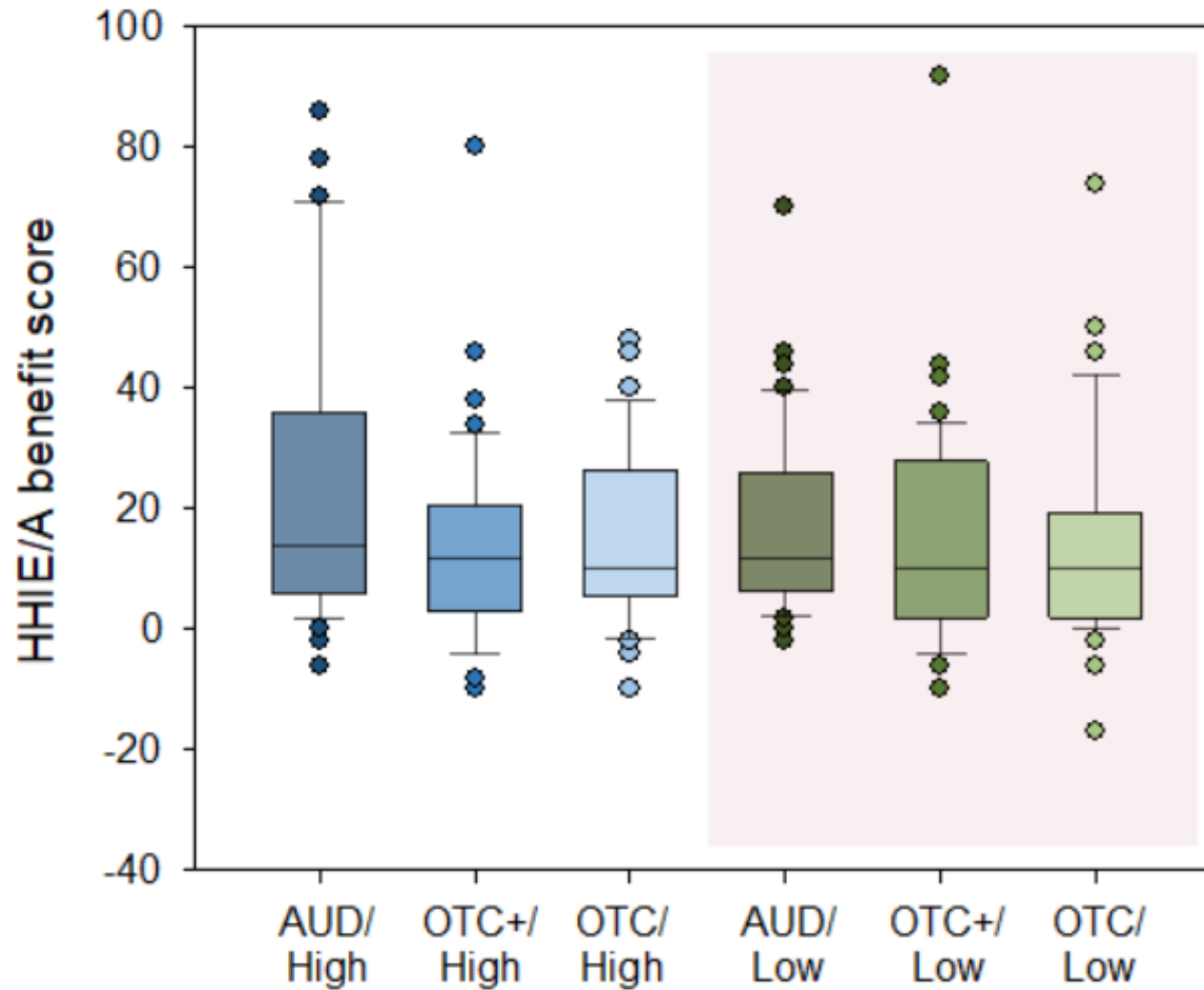
Retro-GHABP (control for unaided score and site)



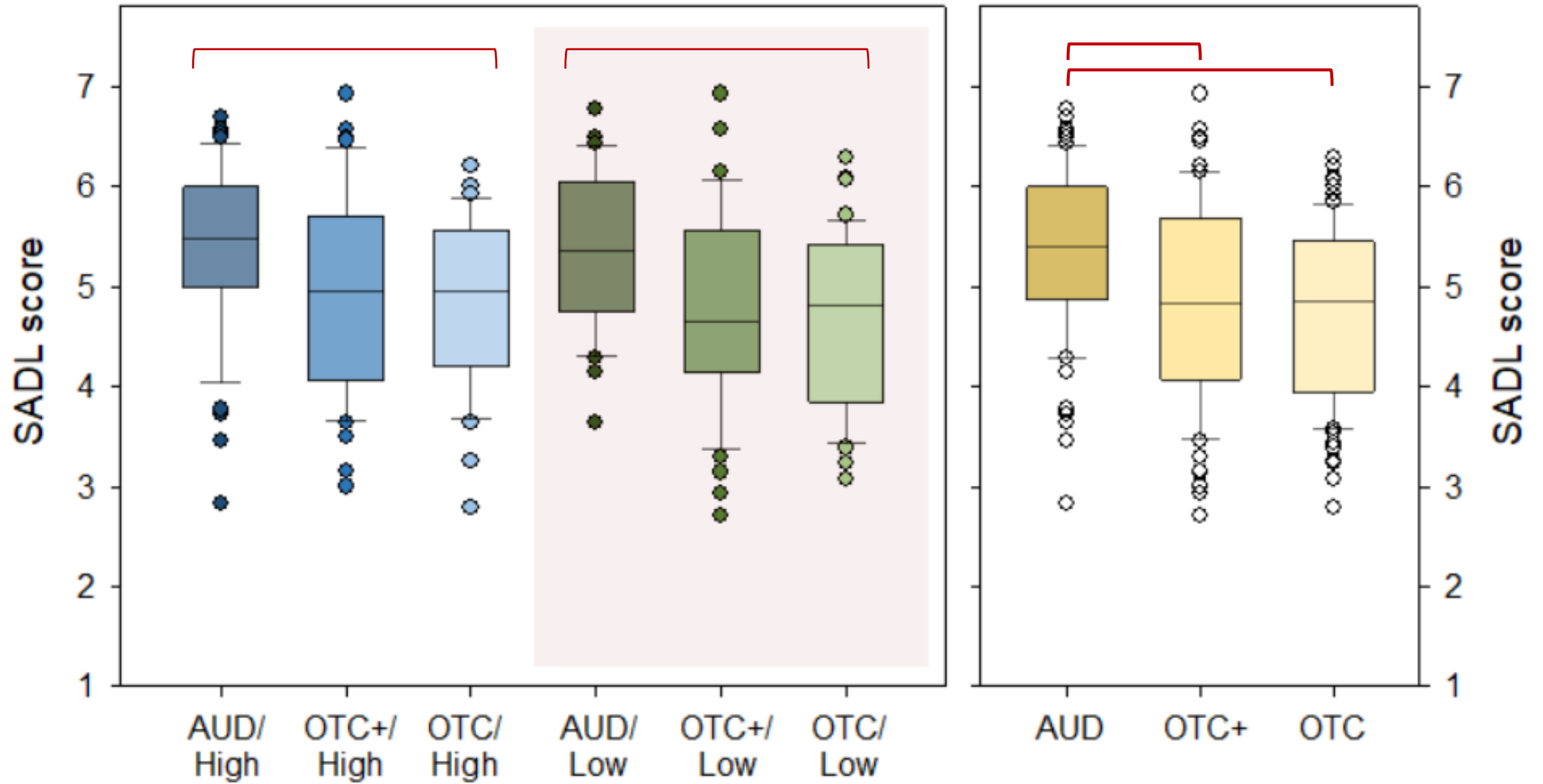
PHAP (benefit score, control for site)



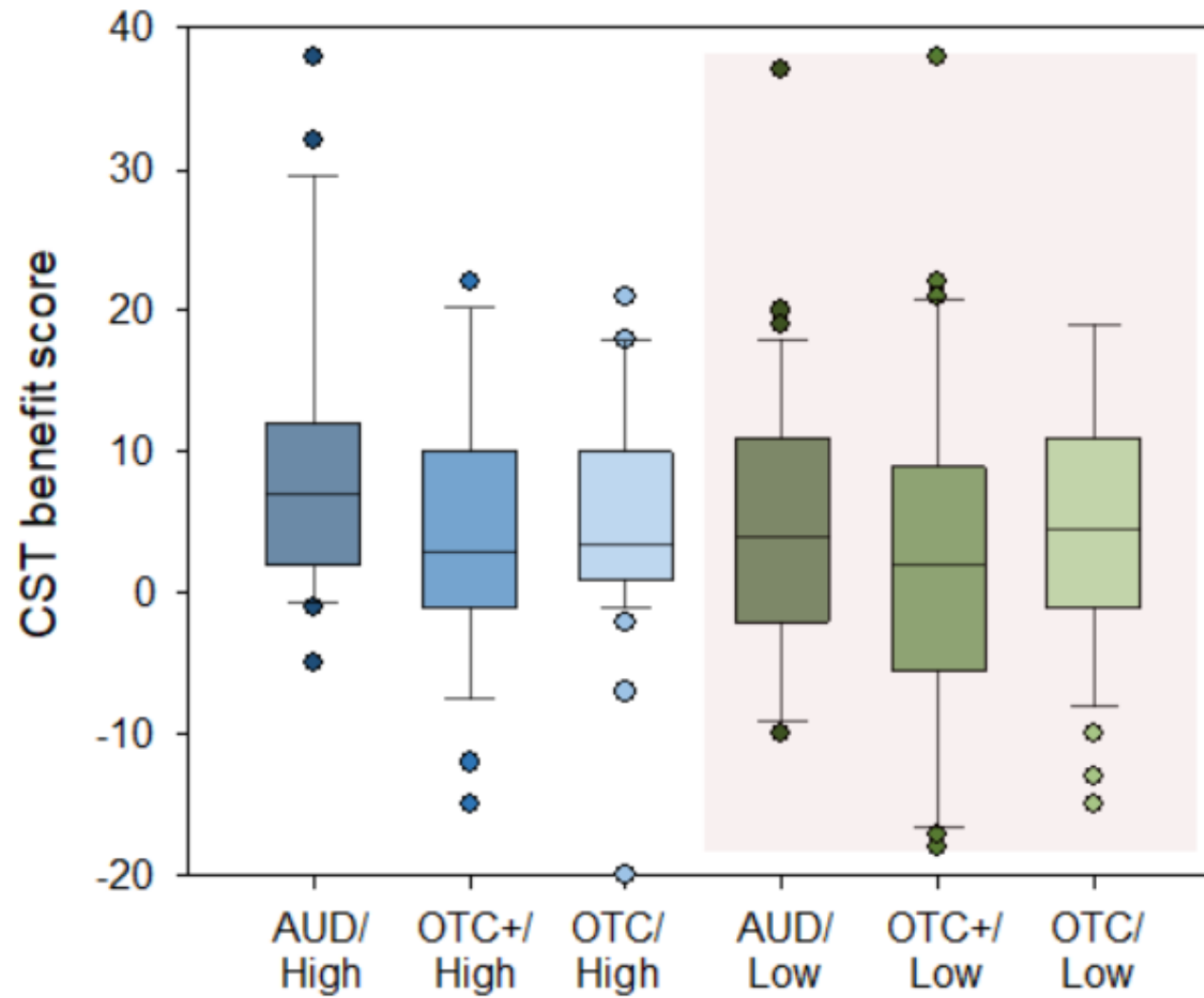
HHIE/A (benefit score, control for site)



SADL (control for site)



CST (benefit score, control for site)



Discussion and Conclusions

Summary

- GHABP: **AUD > OTC+ = OTC**
 - Both EMA- and Retro-GHABP
- Secondary outcomes:
 - PHAP, HHIE/A, CST: **AUD = OTC+ = OTC**
 - SADL: **AUD > OTC+ = OTC**
- All outcomes:
 - **High-end = Low-end**



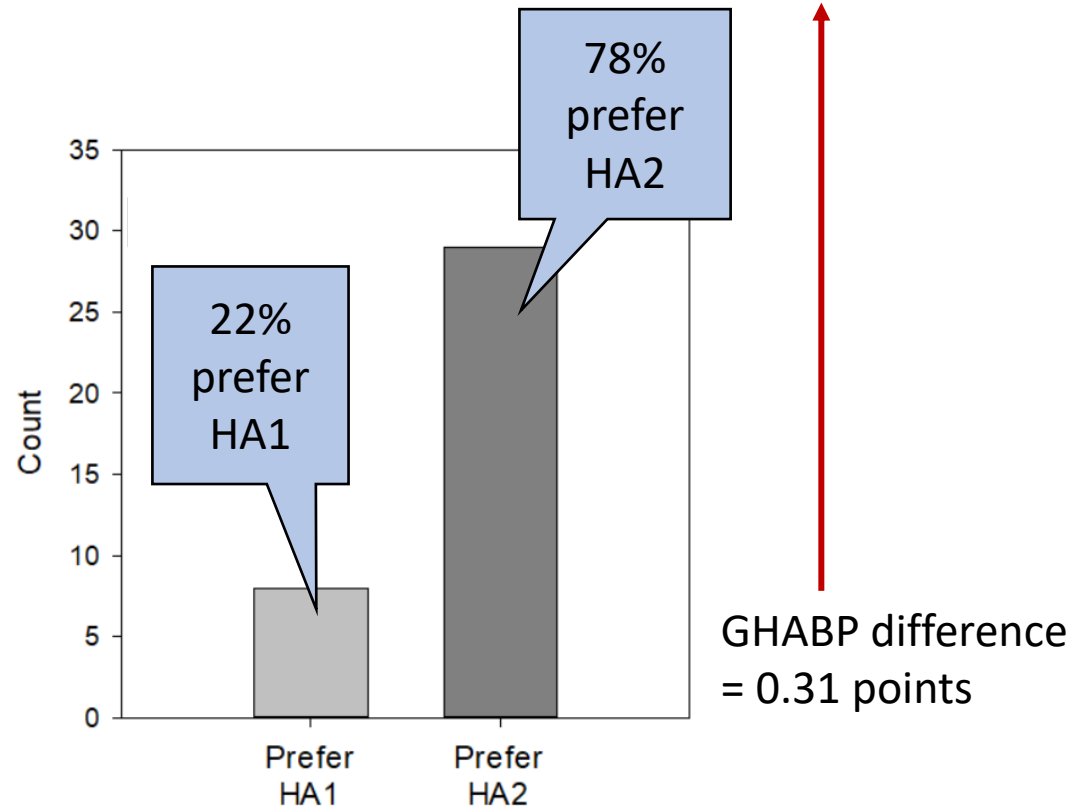
New findings



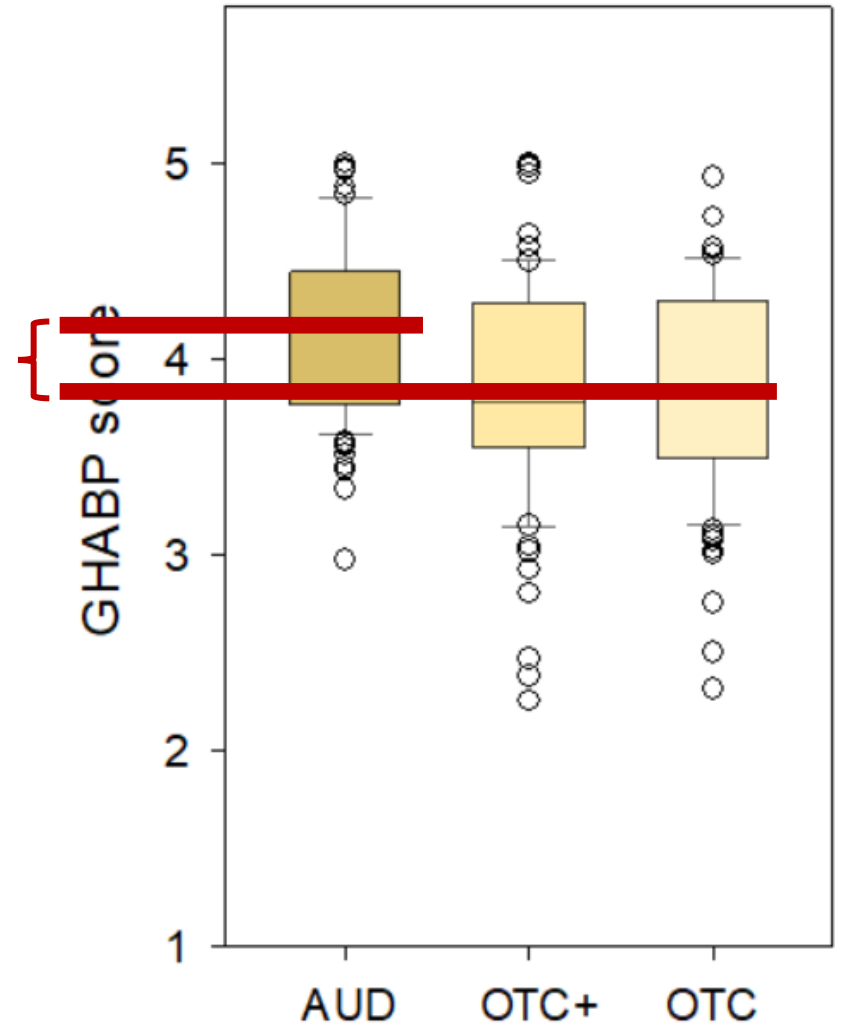
Consistent with the literature

AUD > OTC+ = OTC

- GHABP difference = 0.33 points



GHABP difference = 0.31 points

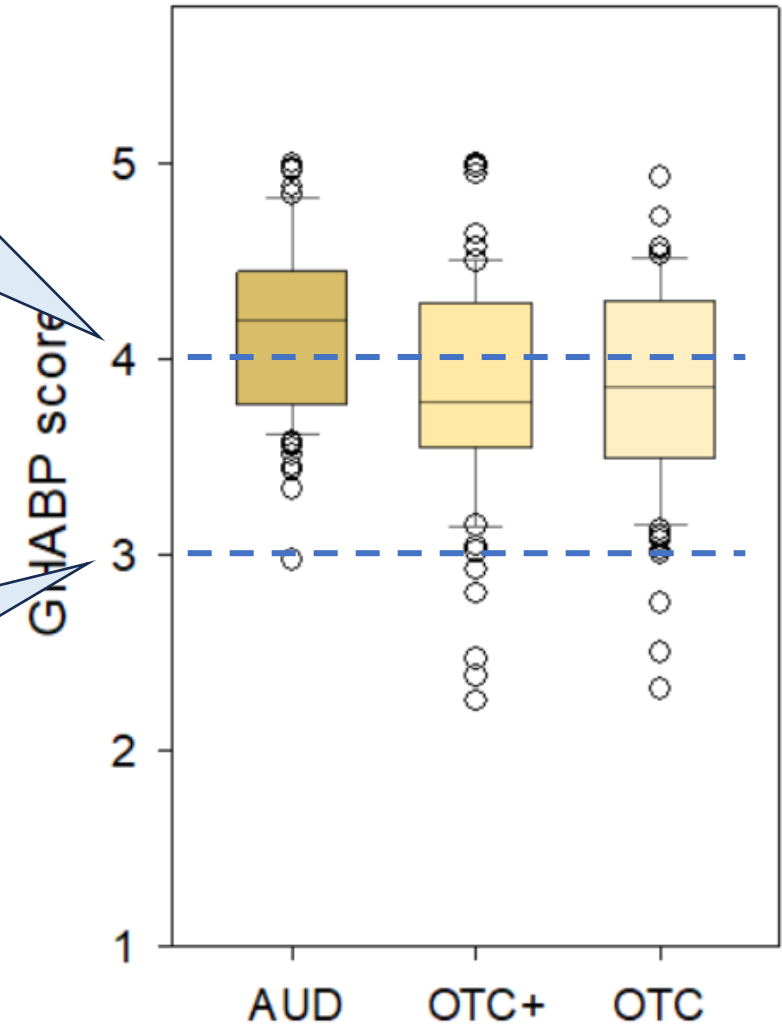


AUD > OTC+ = OTC

- OTC+ and OTC are effective.

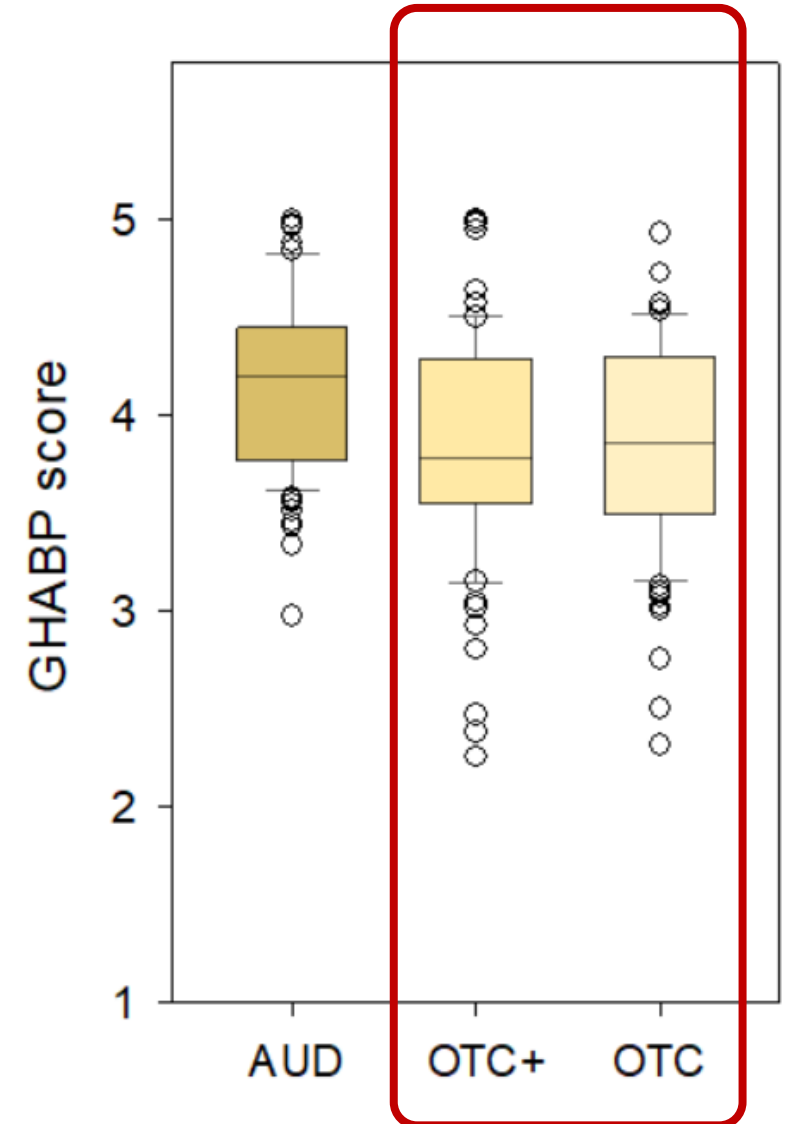
“Very satisfied”
“HA is a great help”

“Reasonably satisfied”
“HA is quite helpful”



OTC+ = OTC

- OTC+:
 - No access to fitting software
 - No probe-microphone measures
- Limited service of OTC+ did not contribute to patient outcomes.



High-end = Low-end

- Participants could not tell the difference in the real world.
 - In AUD, OTC+, and OTC
- COVID? Limited social interactions?
- GHABP: Situation-specific analysis
 - Four listening situations in the GHABP:
 - TV
 - Conversation in quiet
 - Conversation in noise
 - Group conversation

Conclusions

- OTC and OTC+ are effective, but they are not as good as AUD.
- Achieving the best outcome requires the synergy between professionals and devices.
- For the same device generation, high-end HAs and low-end HAs yield similar patient-reported outcomes in the real world.

Limitations and future research about OTC

- Limitations
 - Only one preset-based OTC device by simulation
 - Our OTC participants may not represent real-world OTC HA users.
- Future research involving real OTC patients and real OTC HAs
 - Decision-making processes (OTC vs. AUD)
 - Long-term patient outcomes of OTC
 - Post-HA behaviors following unsuccessful OTC experience

Thank you!