

Recommending OTC Hearing Aids: What do consumers need to know?

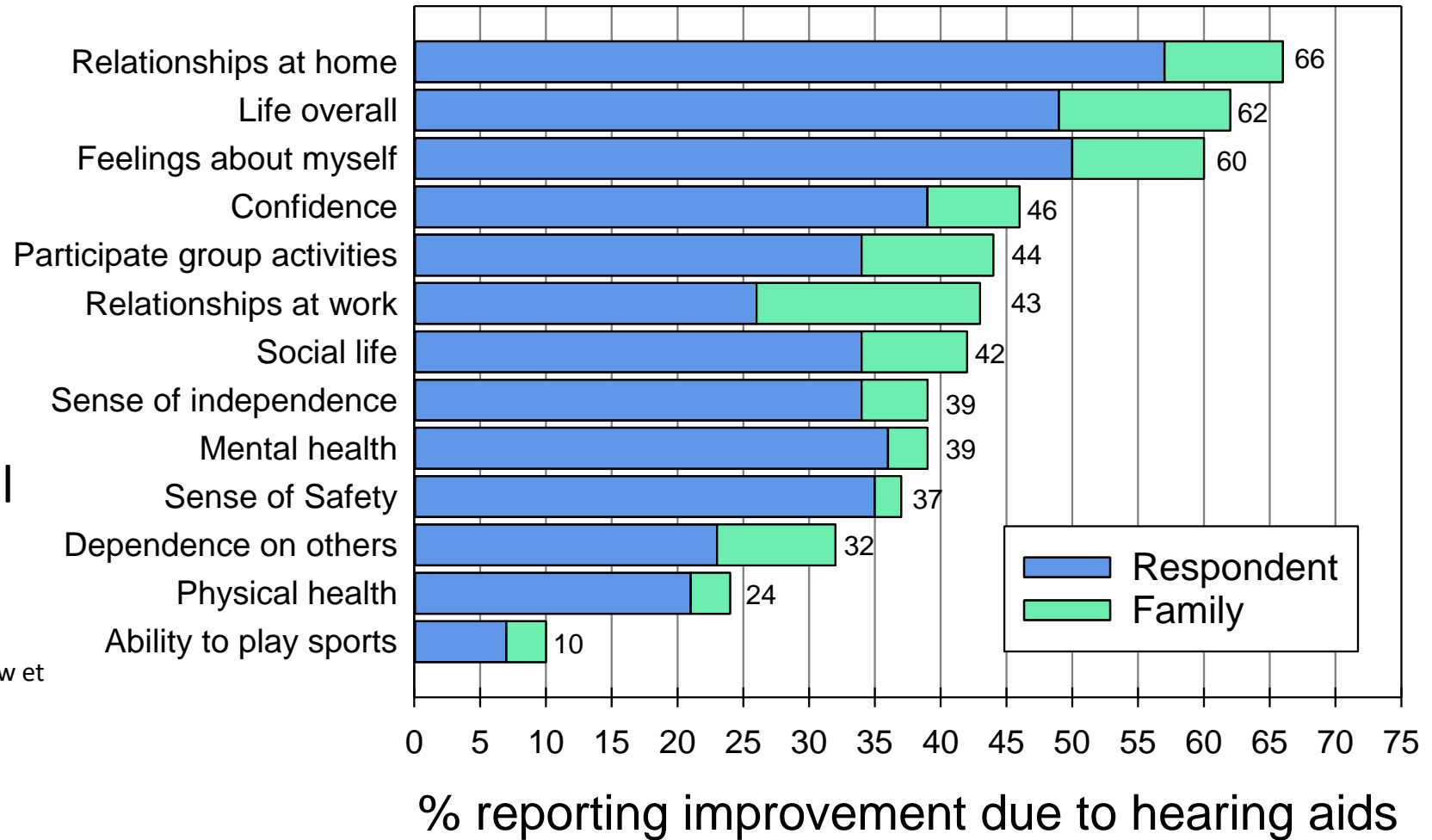
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OTCs: How did we get here?

- Benefits of hearing aids are well documented
 - Communication
 - Hearing-specific quality of life
 - Social and emotional function
 - Depression

Ferguson et al. (2017), Mueller et al., (2013), Mulrow et al. (1990)



OTCs: How did we get here?

- Estimated hearing aid adoption rate: 14-36%
- Estimated number of individuals with hearing loss in the US in 2020 was **44 million** and is expected to increase to **74 million** by 2060

Chien & Lin (2012), Gorman et al., (2017), Humes (2023) & Lin et al., (2011)

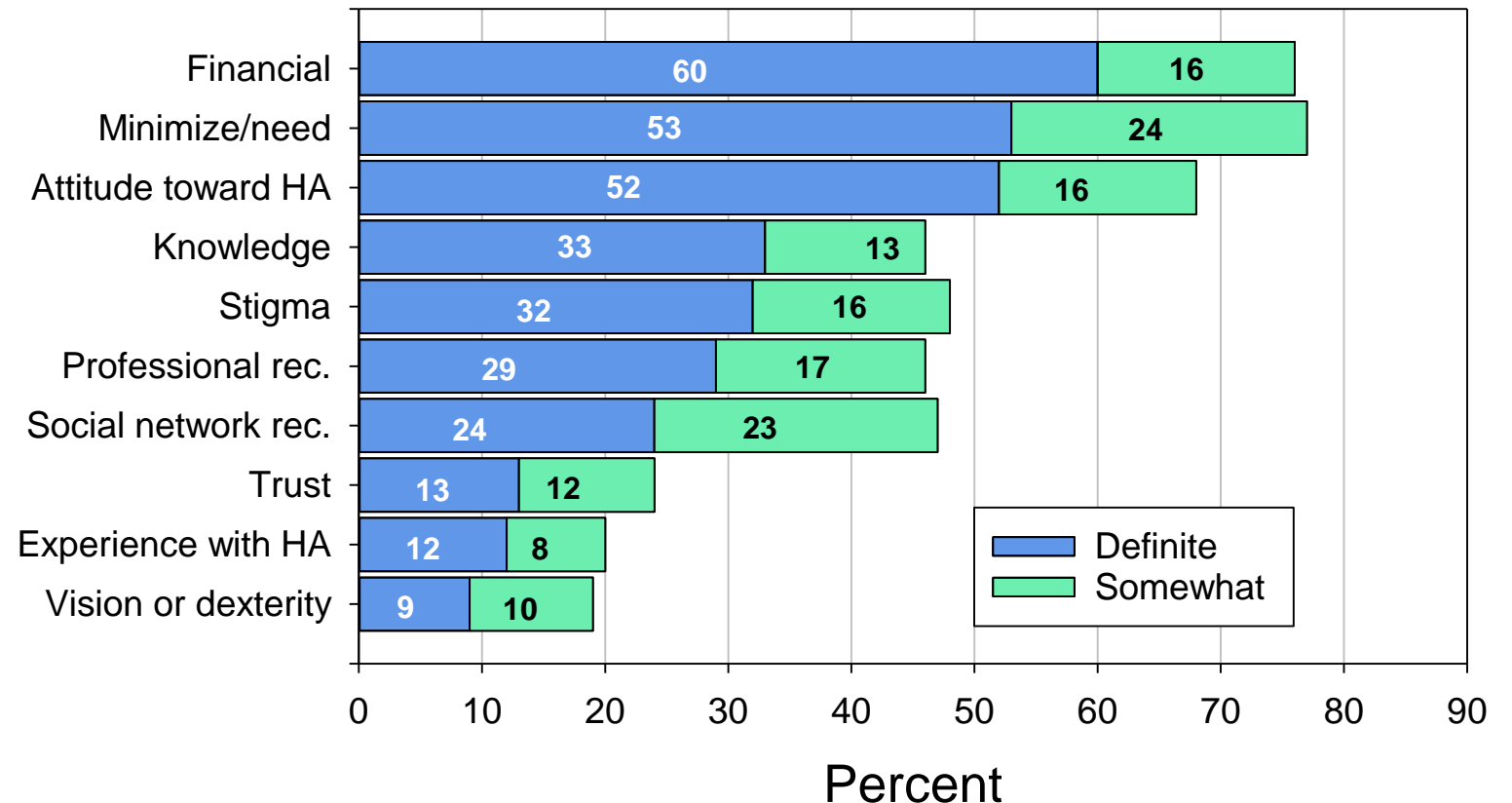
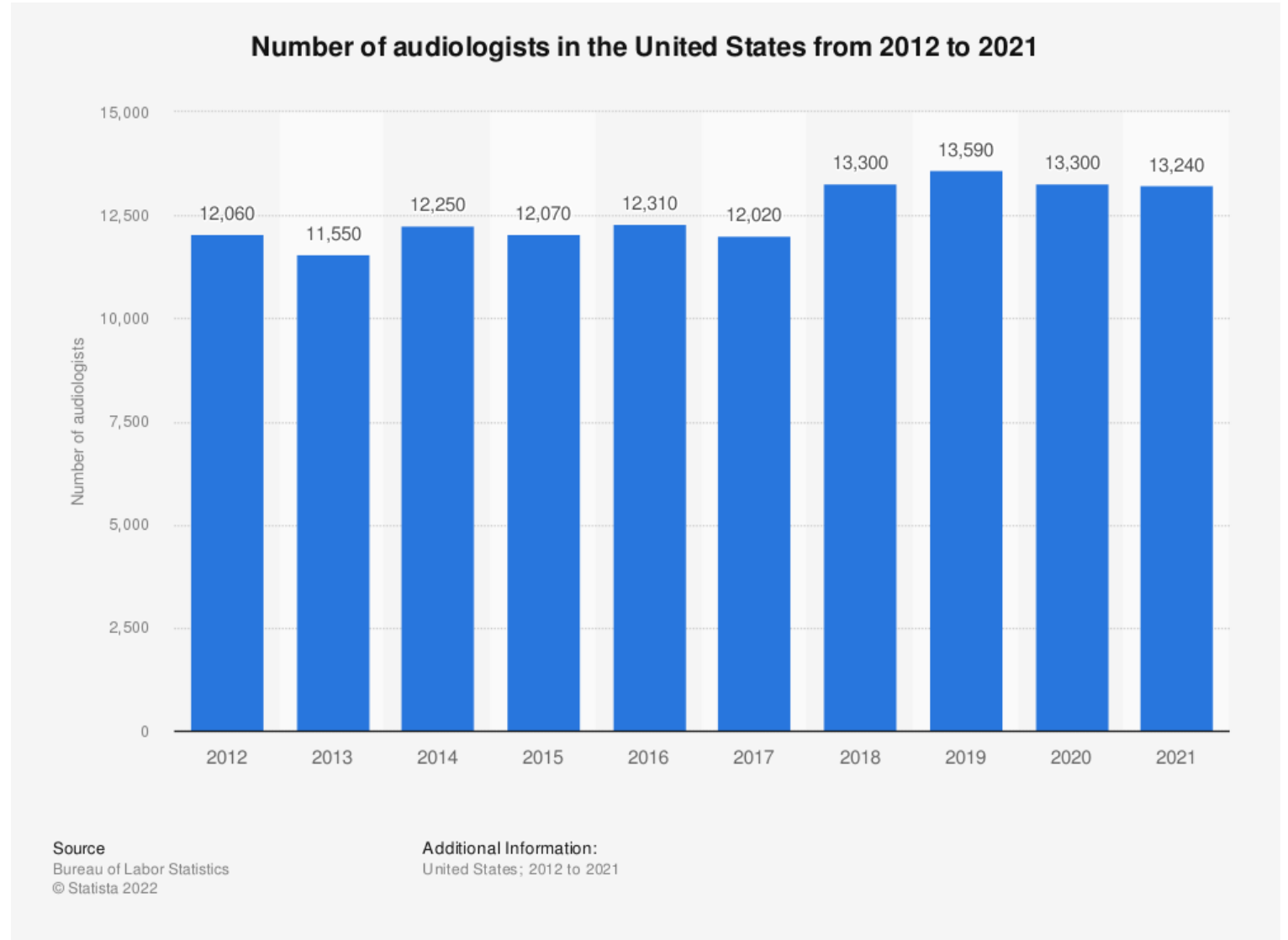


Figure 1: Leading reasons for not using hearing aids reported by individuals with hearing loss.⁷

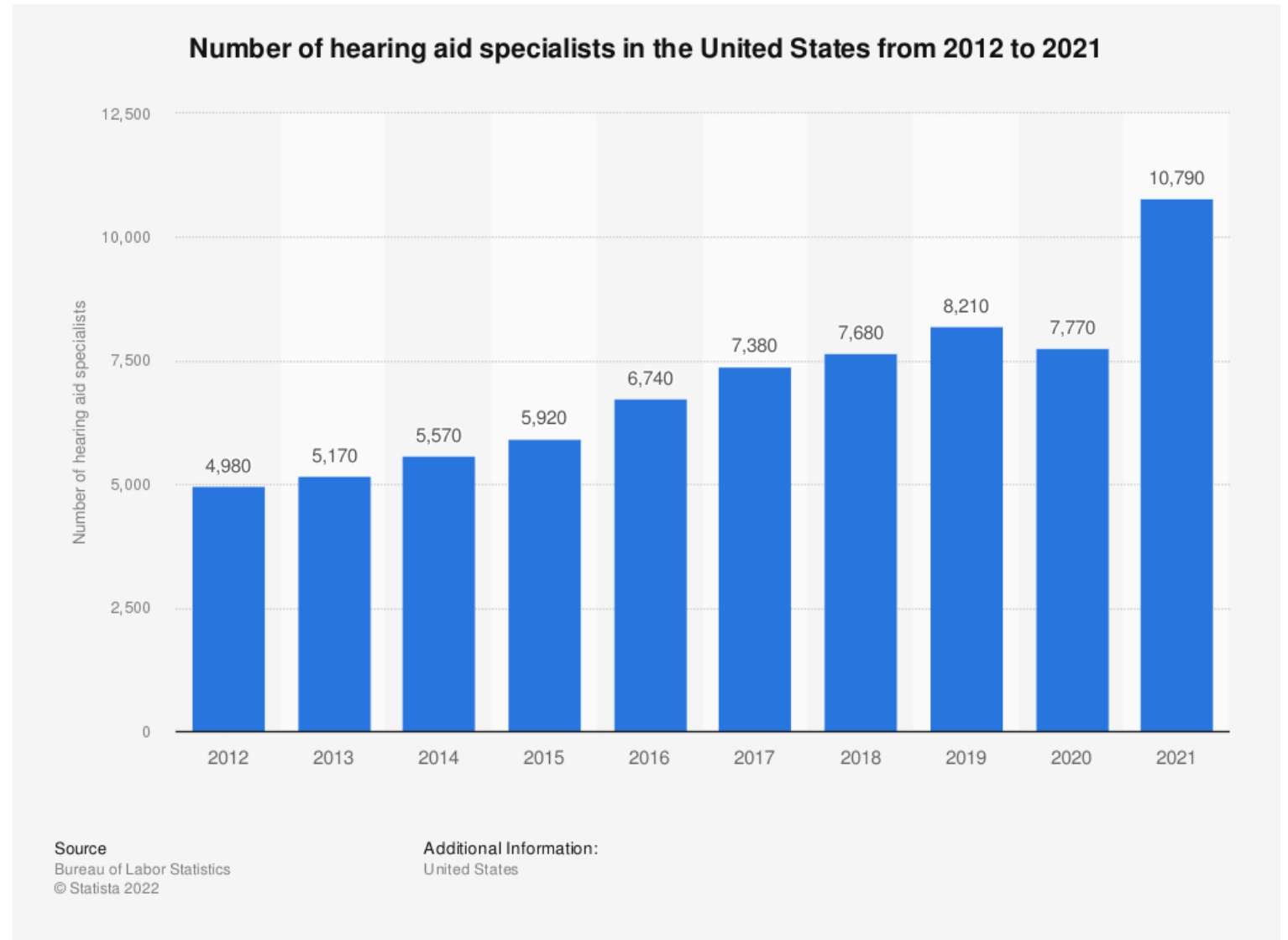
OTCs: How did we get here?

- Access to Hearing Healthcare Professionals
- Number of audiologists is not increasing as quickly as those with hearing loss
- Geographic distribution



OTCs: How did we get here?

- Access to Hearing Healthcare Professionals
- Hearing aid specialists are on a better track



OTCs: How did we get here?

- President's Council of Advisors on Science and Technology (PCAST) 2015
- National Academy of Science, Engineering and Medicine (NASEM) 2016
 - Remove requirement for physician clearance
 - Create an OTC hearing aid category
- OTC hearing aid act 2016
 - Passed and signed into law 2017

What changes were made by the FDA's Final Rule?

- Established a regulatory category for OTC HA
- Repealed conditions for sale of HA under 21 C.F.R. § 801.421
 - Medical evaluation by licensed physician
- Defined traditional hearing aids as “prescription” devices
- Updated labeling requirements
 - Not for children (3 different warnings)
 - “Red flag” conditions (2 warnings)
 - Note to ask about trial-rental or purchase-option programs
 - High output warning
 - Statement that OTC HAs are not hearing protection
 - Statement that OTC HAs should not be uncomfortable or painful
 - Statement about possibility of needing help if parts get stuck in the ear
 - Statement on expectations
 - Note on reporting adverse events to the FDA

What devices are available direct to consumer?

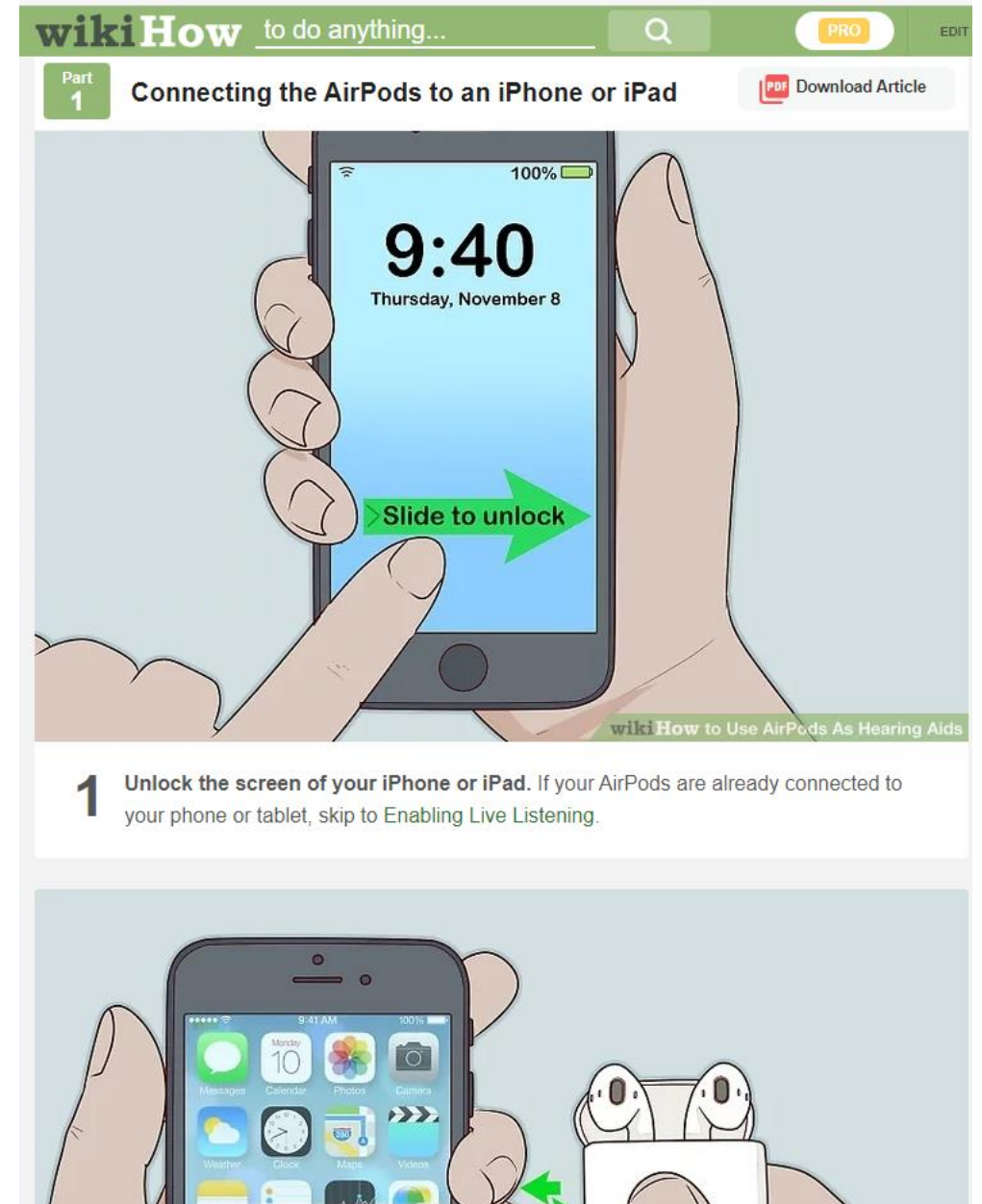
- Smartphone + Headphones/Earphones (+ App)
- Personal Sound Amplification Products (PSAPs)
- OTC Hearing aids
- DTC Hearing aids (Lively/Jabra Enhance Plus, Lexie, Audicus)

Smartphone + Ear/Headphones + App

- Apple
 - Live listen (default iPhone app)
 - Can choose between phone mic or ear level mic on AirPods Pro
 - Petralax (Subscription)
- Android
 - Petralax (Subscription)
 - Super Ear Tool (free + ads)
 - Chatable (100 minutes free per month)
 - Google Sound Amplifier (free)
- Latency may be an issue (De Sousa et al 2019)
 - iPhone generally faster than Android
 - Wired earphones are faster than wireless
- Bulkier than hearing aids (essentially a body aid)

Smartphone + True Wireless Earbuds

- Earbuds
 - Apple AirPods Pro
 - Perform similar to premium HA in the lab: Quiet and Noise(Lin et al., 2022)
 - Samsung Galaxy Buds Pro
 - Lab testing: Perform better for word in quiet than unaided, no benefit for sentences in noise (Kim et al., 2023)
 - Skullcandy Grind Fuel
 - Google Pixel Buds
- May own already!
- Situational devices, not intended for all-day use
 - Battery life, comfort of fit, occlusion



wikiHow to do anything... PRO EDIT

Part 1 Connecting the AirPods to an iPhone or iPad PDF Download Article

100% 9:40 Thursday, November 8

Slide to unlock

wikiHow to Use AirPods As Hearing Aids

1 Unlock the screen of your iPhone or iPad. If your AirPods are already connected to your phone or tablet, skip to Enabling Live Listening.

PSAPs

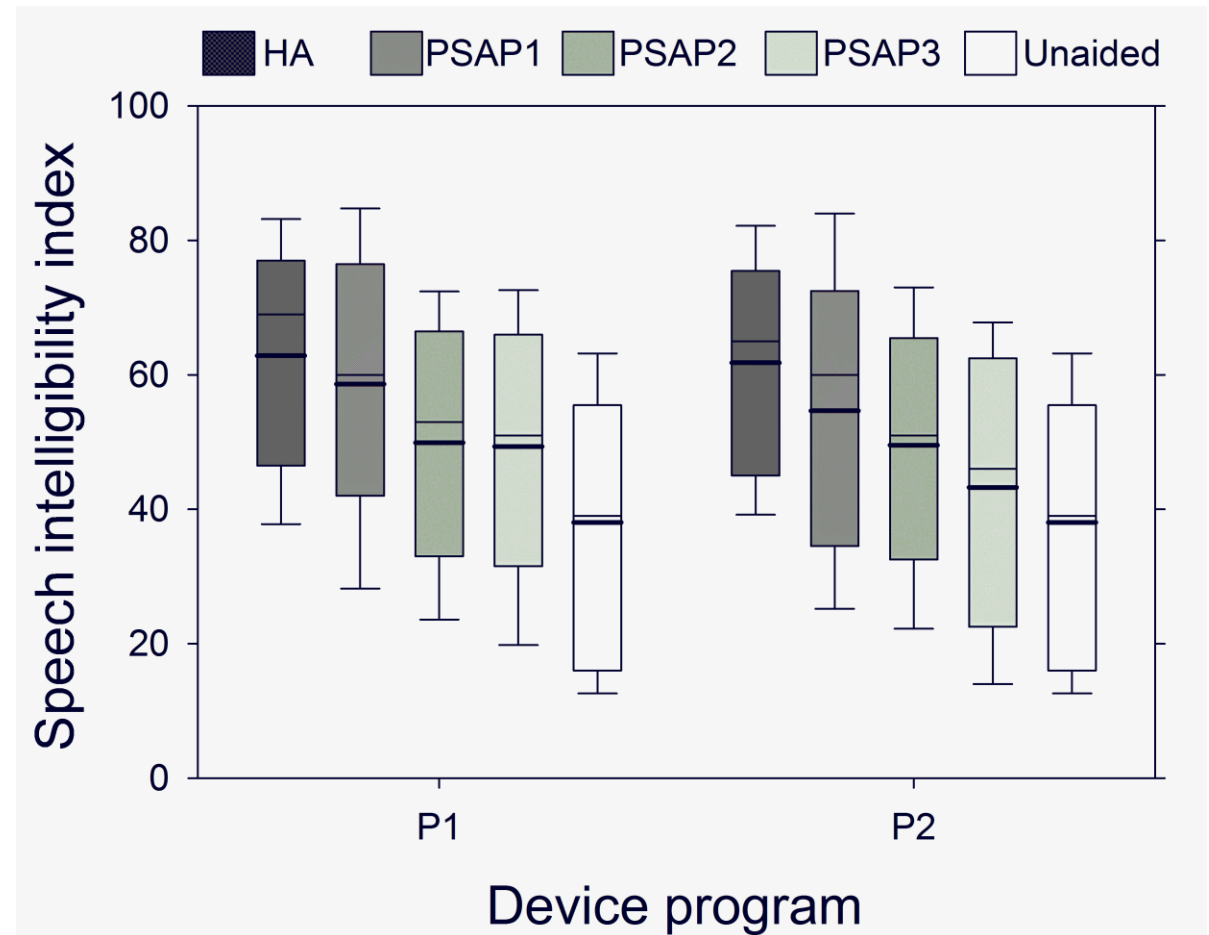
- Not FDA regulated, therefore, not intended for hearing rehabilitation
- Many PSAPs are now transitioning to OTC devices
- Much of the early “OTC” research was completed using PSAPs
 - Variable frequency response
 - Many low-end devices had the most gain in the low frequencies
 - Some higher priced devices were comparable to HAs
 - Any device below \$400 may not be worth it
- PSAP ANSI Standard: CTA 2051-2017
 - No regulating body oversees whether PSAPS meet standards
 - Transitioned to an OTC HA standard



PSAPs

- Higher end PSAPs, especially those with hearing test apps and equalizers performed similarly to mid-level hearing aids fit using probe mic measures to NAL-NL2.
- Even modestly priced PSAPs perform better than no amplification at all

(Brody et al., 2017, Reed et al., 2017)

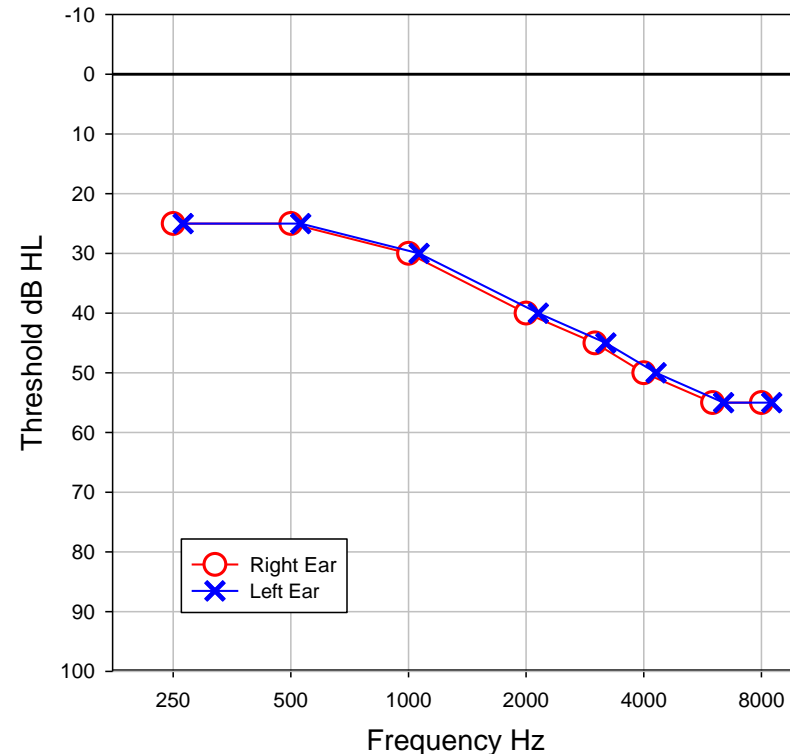


OTC Hearing Aids

WARNING: If you are younger than 18, do not use this.

You should go to a doctor, preferably an ear-nose-throat doctor (an ENT), because your condition needs specialized care. Over-the-counter hearing aids are only for users who are age 18 or older.

- OTC hearing aids are amplification devices intended to help adults with mild-to-moderate self-perceived hearing loss hear better without the aid of a licensed professional or a hearing test.
- No red flags
- As no hearing test is needed, individuals with normal hearing or severe hearing loss may easily purchase an OTC hearing aid



Preset vs. Self-fitting

- Preset: Users can choose between different frequency responses
 - Programs
 - Volume Control
- Self-fitting: Wireless air conduction hearing aids that users can customize through an app or other technology.
 - Must submit a 510(k)
 - Performance data
 - Safety and manufacturing standards
 - Clinical research data

(Powers, 2022)

Hearing Aid Categories: DTC/OTC/Prescription

Product Code	Regulation Number	OTC	Description	Example(s)
QUF	874.3300	Yes	Preset-based OTC hearing aid, air conduction	Some MD Hearing Aids, Sound World Solutions, Hearing Assist
QUG	874.3305	Yes	Preset-based OTC hearing aid, air conduction with wireless technology	Lucid, Soundwave Sontro
QDD	874.3325	No	Self-fitting hearing aid that may be sold online	Bose, Jabra Enhance Plus
QUH	874.3325	Yes	Wireless self-fitting OTC hearing aid that may be sold online and in stores, pharmacies, etc.	Nuheara
OSM	874.3305	No	Prescription wireless air conduction hearing aids	Traditional hearing aids

Adapted from <https://www.hearingtracker.com/full-list-of-otc-hearing-aids?q=otc>. Retrieved March 14 2023.

DTC Hearing aids

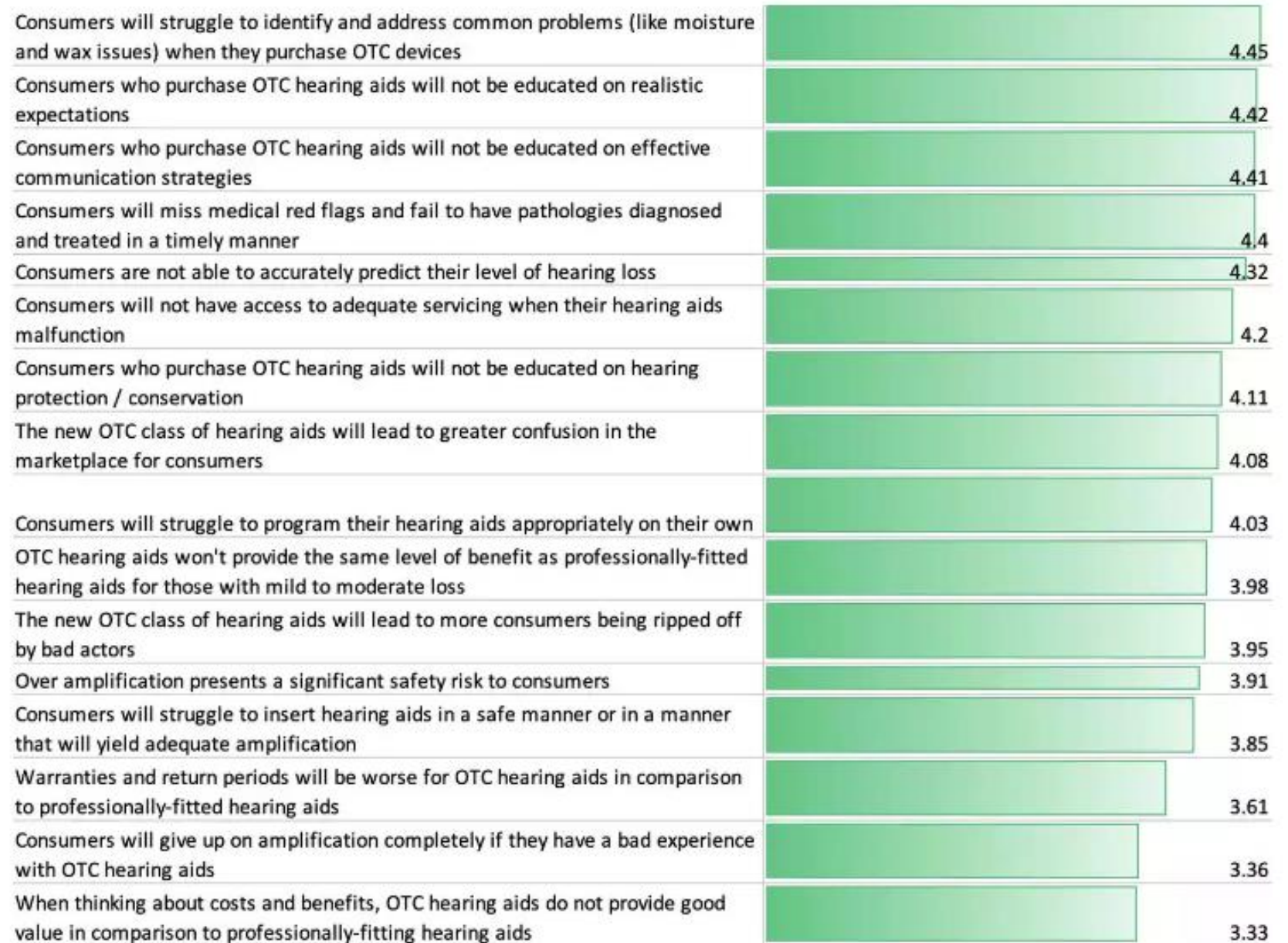
Product Code	Regulation Number	OTC	Description	Example(s)
QDD	874.3325	No	Self-fitting hearing aid that may be sold online	Bose, Jabra Enhance Plus

- Many hearing aids calling themselves “OTC” are technically not in the OTC FDA category
- Were approved before the OTC categories existed
- Many of the companies provide remote services from hearing health care professionals

Adapted from <https://www.hearingtracker.com/full-list-of-otc-hearing-aids?q=otc>. Retrieved March 14 2023.

Common objections to OTC devices

- <https://www.hearingtrackers.com/pro-news/what-do-audiologists-think-of-otc-hearing-aids>



Possible additional benefits of OTCs

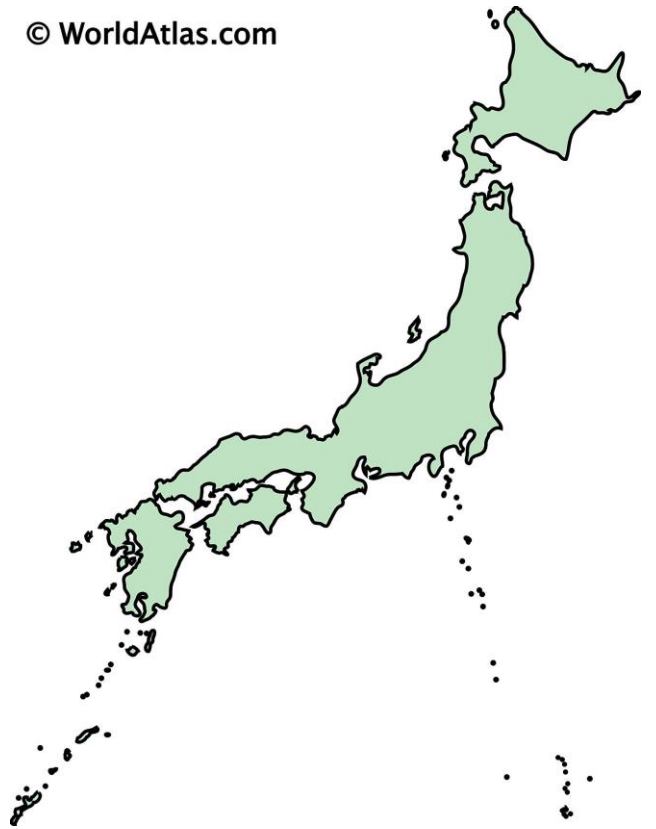
- Hearing aid “training wheels”
- Self-fitting may empower users
- New form factors may decrease stigma

What does the research say?

- True OTCs have been available for ~6 months
- Most independent, peer-reviewed research in the United States has been conducted using:
 - PSAPs
 - Prescription HA configured in the manner of preset OTC devices

JapanTrak (2018)

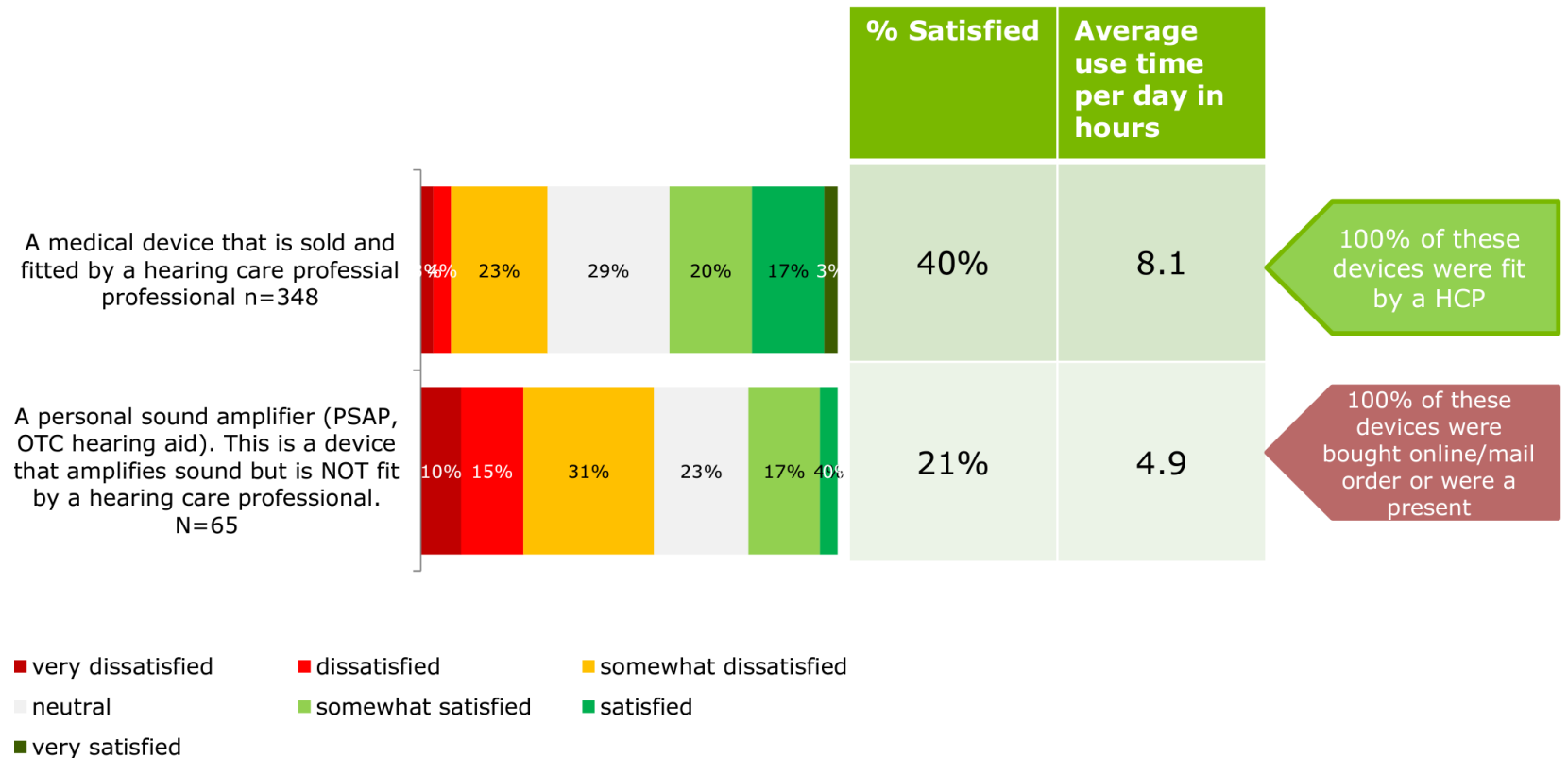
- OTC HA have been available in Japan for over 10 years.
- Perception of Device Reliability
 - Prescription devices ~80%
 - OTC ~25%
- Daily use
 - Prescription devices: 8.1 hours per day
 - OTC/PSAPs: 4.9 hours per day



JapanTrak 2018 Continued

- Owners of professionally fit devices reported much higher satisfaction than OTC/PSAP owners
 - Satisfaction with OTC/PSAPs purchased on the internet ~15%
- Satisfaction lower than Europe or US which is typically >70%

Satisfaction with medical hearing devices fitted by a hearing care professional is much higher than with PSAP's/OTC hearing aids.



MarkeTrak 2022 (Jorgensen, 2023)

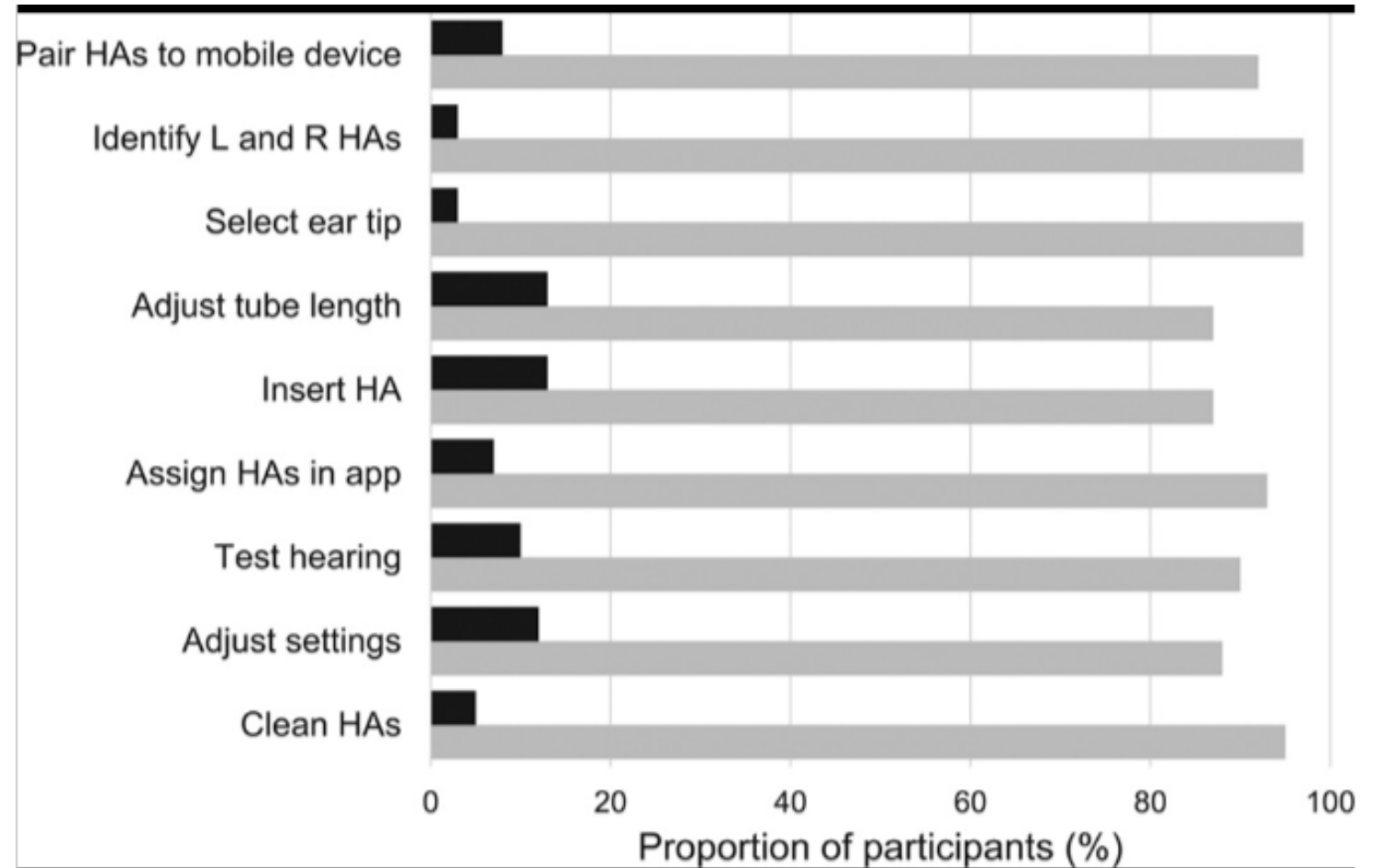
- PSAP data
- Daily Use
 - Professionally fit HA users: 63%
 - PSAP users: 46%
- Hearing Loss Severity
 - Professionally fit HA users: Moderate-to-severe HL
 - PSAP users: Mild-to-moderate HL
- Professionally fit hearing aid users are significantly more satisfied with ability to hear in background noise than PSAP users
 - Unsure whether this results from technology alone or technology + proper fitting

MarkeTrak 2022 (Jorgensen, 2023)

- PSAP users are more likely to be new users
- Current use
 - 9/10 Professionally fit hearing aid purchasers are still using their devices
 - 6/10 PSAP purchasers are still using their devices
 - May have purchased professionally-fit hearing aids
 - May not be wearing any devices at all

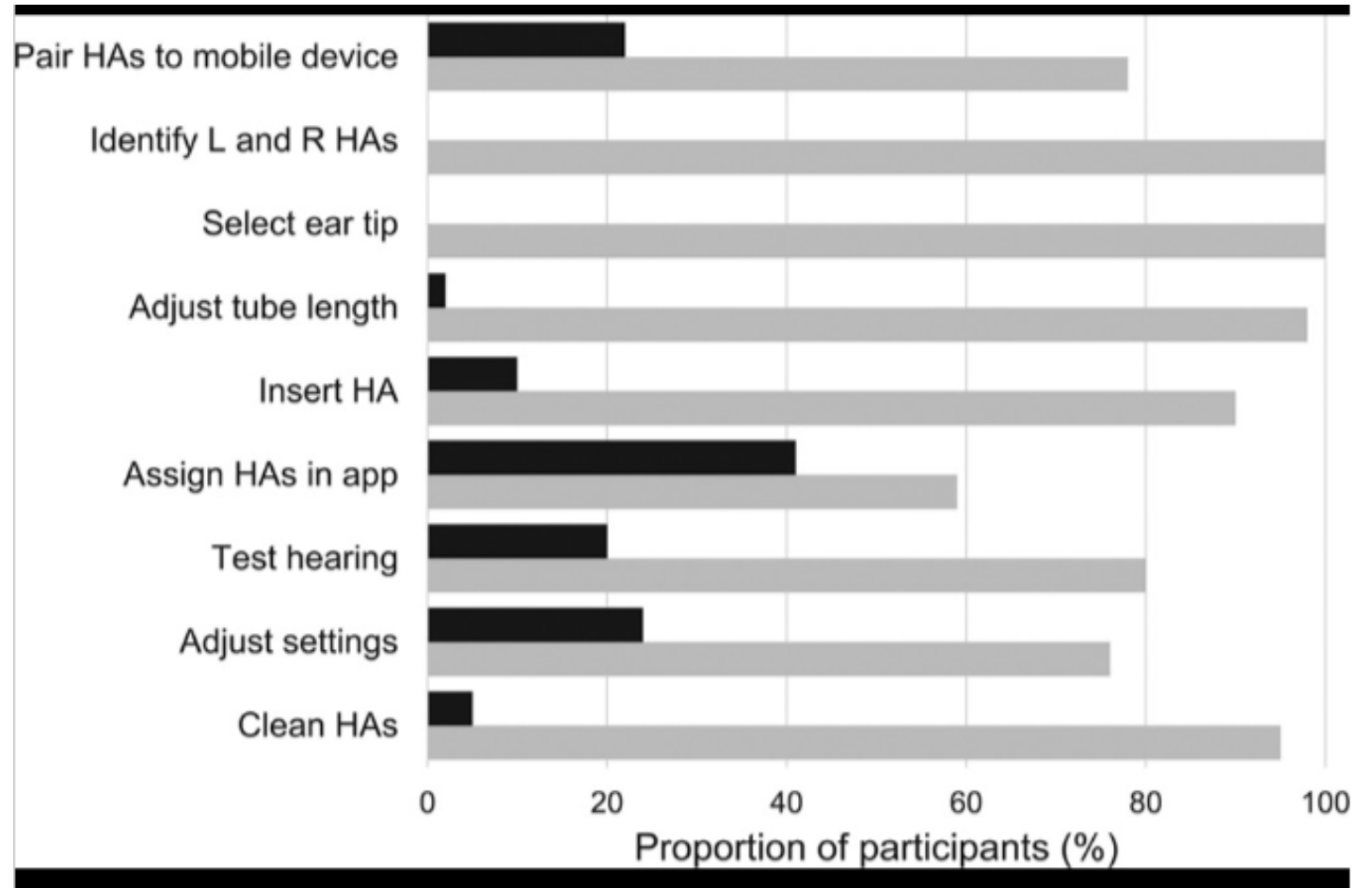
Factors Associated with Successful Setup of Self-Fitting HA (Convery et al., 2019)

- 68% (N=41) of participants were successful
 - 37% of the successful completed task completely independently (N=15)
 - 63% of the successful called for help from a “clinical assistant” on the phone (N=26)
- Graph: Completed successfully = gray; with errors = black



Factors Associated with Successful Setup of Self-Fitting HA (Convery et al., 2019)

- Participants were more likely to be successful if they:
 - Had previous HA experience
 - Own a mobile device
- Graph
 - Completed independently = gray
 - With CA support = black

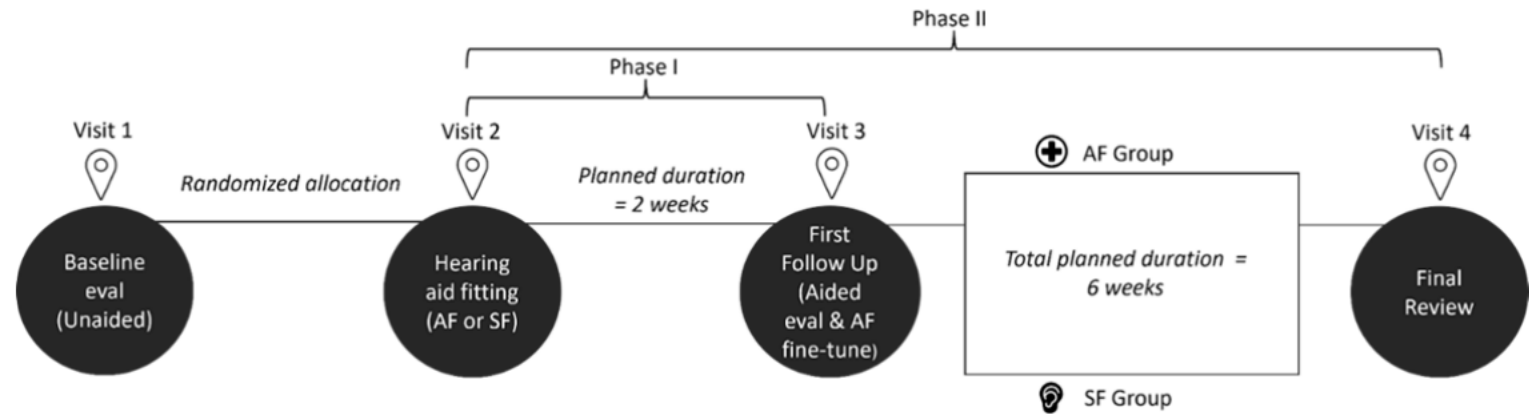


Effects of Service Delivery Model and Purchase Price (Humes et al., 2017)

- Audiology best practice and OTC models of HA delivery are efficacious when compared to Placebo
- OTC service delivery resulted in only slightly lower poorer outcomes than audiology best practices
 - Percentage of individuals who said they were likely to keep hearing aids
 - 81% of individuals in Audiologist-fit group
 - 55% of individuals in OTC group
 - 36% of individuals in Placebo group
- Purchase price did not affect outcomes
 - 85% of individuals who discontinued use paid the higher price

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

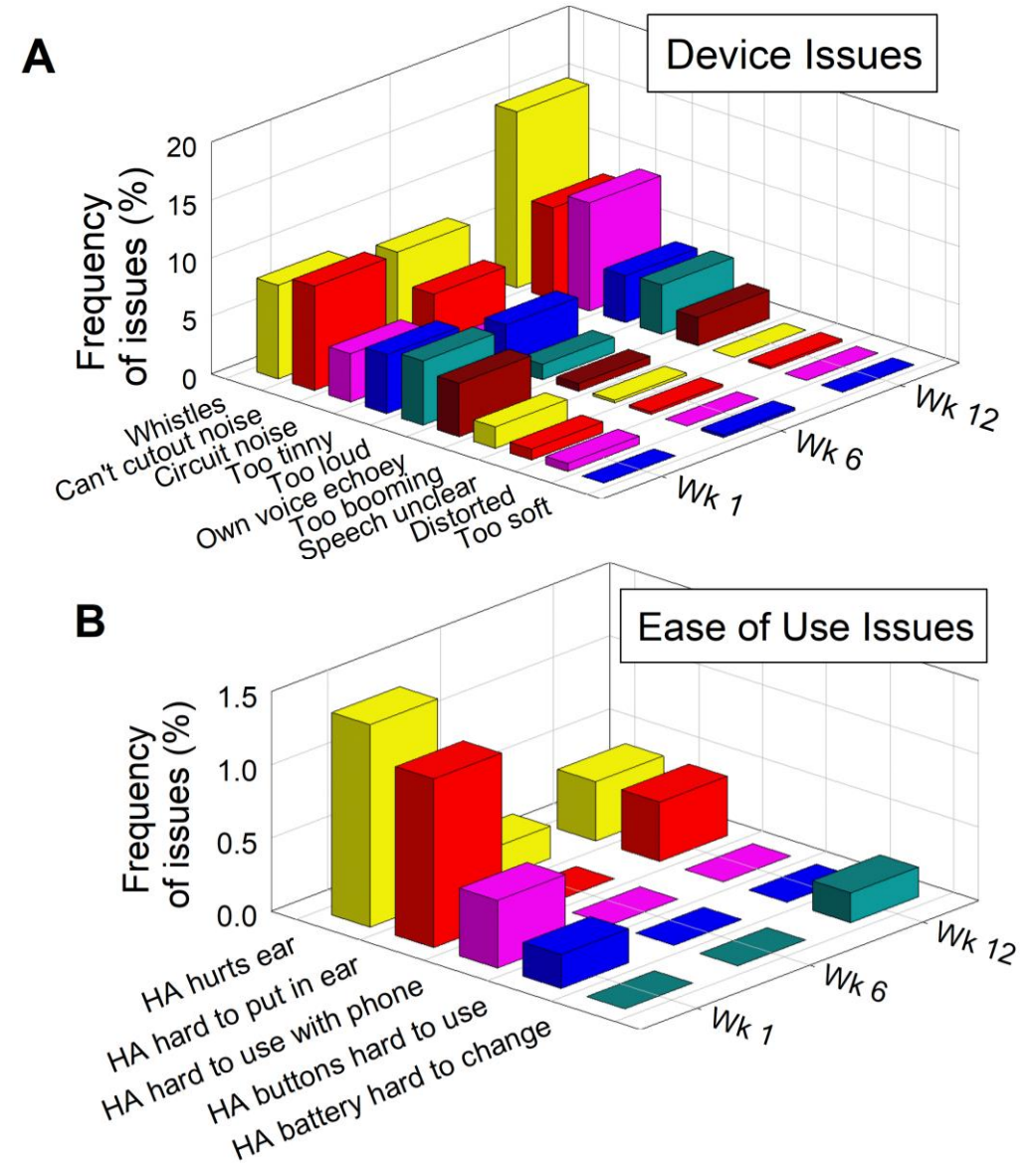
Karina C. De Sousa, PhD; Vinaya Manchaiah, PhD; David R. Moore, PhD;
Marien A. Graham, PhD; De Wet Swanepoel, PhD



- Lexi Lumen either Self-Fit or Audiologist-Fit with REM to NAL-NL2
- At 2 weeks
 - Self-report outcome measures were better for Self-Fit group
 - 65.6% and 6.3% of participants requested fine tuning in the AF and SF groups, respectively
- At 6 weeks
 - No difference in outcome measures between groups
 - Audiologist-Fit group on average performed better on QuickSIN

Unpublished Preliminary HAAR Lab Data

- Traditional low-end HA configured as “Preset OTCs”
- Ecological Momentary Assessment
 - 1 week
 - Surveys every 1.5 hours
 - 12 hours per day
- In general, fewer problems over time
 - Except for Feedback and Noise issues



Dispensing in Iowa (Email from State of Iowa, Tuesday Jan 10, 2023)

- A license is not required to sell or service OTCs in IA (21 C.F.R. § 800.30(h)(1)).
- A license **IS** required to fit OTCs.
 - Per Iowa Code §§ 154A.1(6); 147.2(1), fitting services must be performed by a licensed audiologist or hearing aid specialist.
 - “Measurement of human hearing by any means for the purpose of selections, adaptations and sales of hearing aids, the instruction and counseling pertaining to the selections, adaptations and sales of hearing aids, demonstration of techniques in the use of hearing aids and the making of earmold impressions as part of fitting hearing aids.”
- Consult with your facility and your facility’s counsel to ensure compliance with all new and augmented regulations

Helpful resources for clinicians

- Websites:
 - HearingTracker.com Full List of OTC Hearing Aids: <https://www.hearingtracker.com/full-list-of-otc-hearing-aids?q=otc+hearing+aids>
 - Hearing Health & Technology Matters: <https://hearinghealthmatters.org/>
- From Our Professional Organizations
 - AHSA Leader, Demystifying OTCs for Bewildered Customers: <https://leader.pubs.asha.org/doi/10.1044/leader.AEA.28032023.Otcs-auds-decisions.16/full/>
 - ASHA OTC Toolkit: <https://www.asha.org/aud/otc-hearing-aid-toolkit/tools-for-audiologists/>
 - AAA: <https://www.audiology.org/practice-guideline/the-audiologists-guide-to-hearing-aids-personal-sound-amplification-products-hearables-and-over-the-counter-devices/> Updated March 7,2023

Helpful resources for clinicians

- Podcasts:
 - This Week In Hearing
 - Future Ear Radio
- YouTube
 - Find an audiologist you trust who does OTC hearing aid reviews!
- Online Forums
 - Reddit, Facebook, etc.
- Email me if you want a handout with the links:
 - elizabeth-stangl@uiowa.edu

Integrating OTCs into your practice

- Add information and links to vetted OTCs on your website
 - Along with a link to a “Red flag” screener like the Consumer Ear Disease Risk Assessment: <https://cedra-project.firebaseio.com/#!/>
- Post reviews on social media
- Create OTC consultations
- Follow-up care considerations
 - Limited (if any) software adjustments
 - No replacement parts
 - May have no relationship with the manufacturer
 - AR app and website recommendations

Helpful websites for consumers

- Hearing Tracker

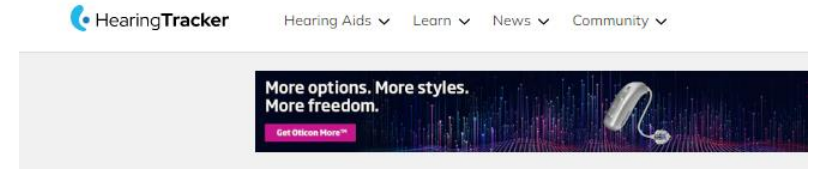
- <https://www.hearingtracker.com/over-the-counter-hearing-aids?q=otc>

- Soundly

- <https://www.soundly.com/blog/over-the-counter-hearing-aids>

- YouTube*

- Dr. Cliff:
<https://www.youtube.com/@DrCliffAuD>
- HearingTracker:
<https://www.youtube.com/@HearingTracker>



Home / Best Over-The-Counter (OTC) Hearing Aids for 2023

Best Over-The-Counter (OTC) Hearing Aids for 2023

Everything you need to know before going shopping

By [Karl Strom](#) and [David Copithorne](#) | Updated 25 January 2023

Are you turning up the TV too loud or having trouble listening without captions? Do you ask family members to repeat themselves too often? Or find yourself nodding your head when you don't really hear what they just said? It may be time for you to start shopping for a set of over-the-counter (OTC) hearing aids.



In this video, HearingTracker Audiologist Matthew Allsop provides his perspectives about OTC hearing aids. Closed captions are available on this video. If you are using a mobile phone, please enable captions clicking on the gear icon.

Here's what you need to know about the new affordable, accessible OTC hearing aids —how they can help you, what you should look for, what to avoid, price and purchase options, alternatives to consider, and more. To get you started, here are links to write-

What to consider when recommending an

OTC (Convery et al., 2019, Manchaiah et al. 2023, Klugman, 2023, & HAAR Preliminary Data)

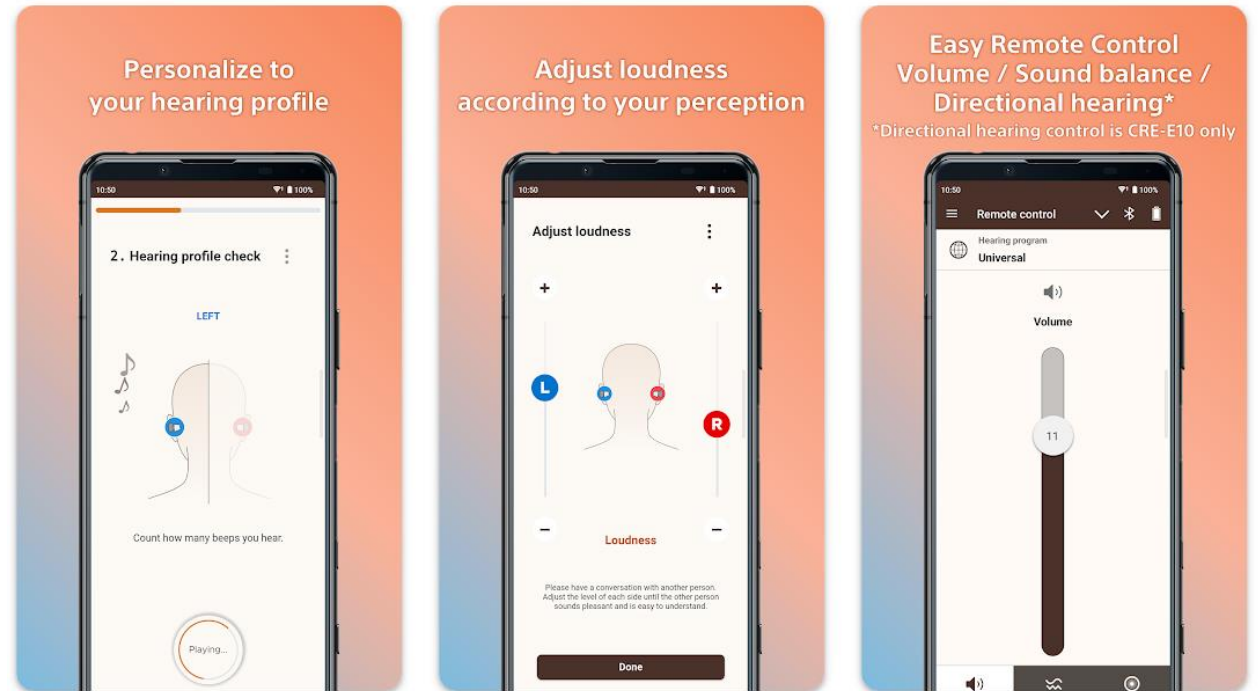
- Brand/Warranty/Return Period
- Features
- Customer Characteristics
- Customer Care/Remote Support
- Price Point
- Online Reviews

Brand/Warranty/Return Period (Manchaiah et al. 2023)

- Recommend brands with a good reputation that you believe will still be in business in a year (or as long as the warranty)
- Many major manufacturers have (or soon will have) OTC/DTC offerings
 - Some manufacturers may allow you to stock devices without activating the warranty or return period until the device is sold
- Return periods are typically 30-60 days
- Most OTC warranties last 1 year
 - Warranties and return periods are NOT required by the FDA for OTC devices
 - If there is one, it must be written and viewed by customers prior to purchase

Features (Manchaiah et al. 2023, Klugman, 2023)

- Appearance: BTE, ITE, or Earbud
- Amplification: Preset vs. Self-Fitting
- Smartphone App
- Bluetooth connectivity
- Batteries: Rechargeable vs. Disposable

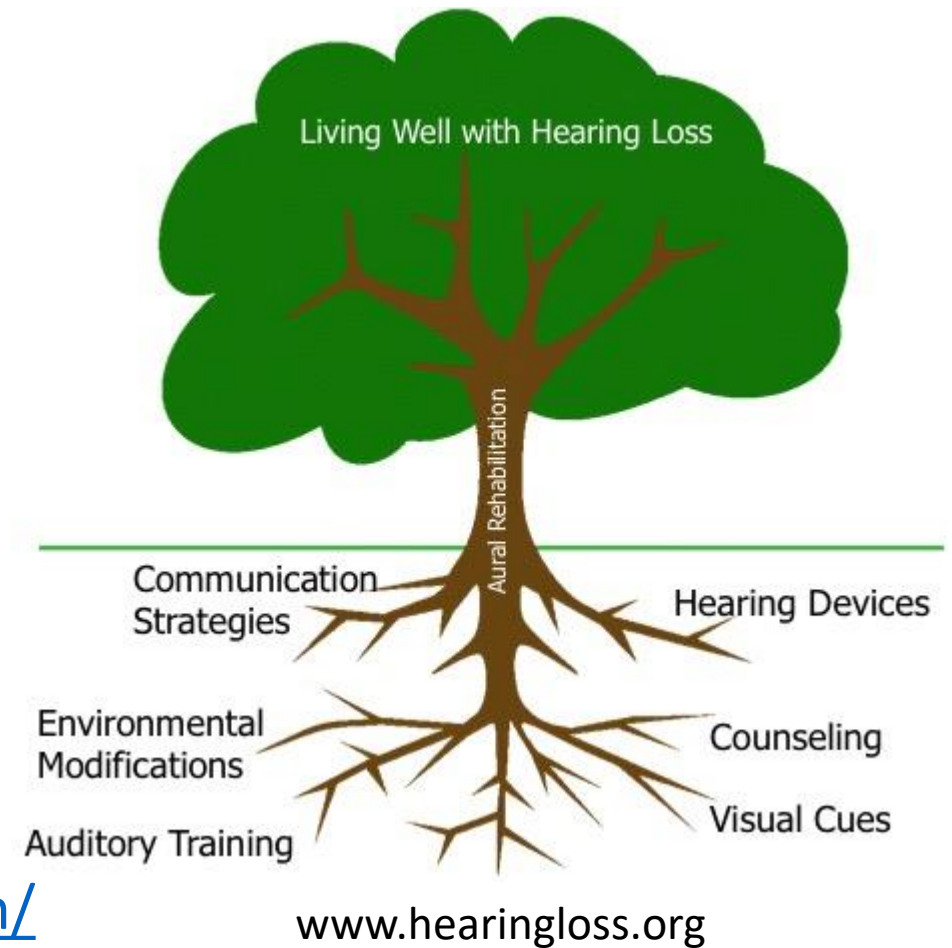


Customer Characteristics (Convery et al., 2019., Klugman, 2023, Preliminary HAAR Data)

- Cognition
 - Are they able set up the devices themselves?
- Dexterity
 - Can they manipulate the devices without coaching?
- Health Literacy
 - Are they able to process the information they read?
- Prior Mobile Device Use/Tech savviness
 - Can they successfully use technology?
- Internal Locus of Control
 - Are they self-motivated and able to manage their devices without in-person help?

Follow-up Care

- Local in-person care?
- Remote care from manufacturer
- Online resources for new users
 - www.c2hearonline.com
 - https://idainstitute.com/hearing_loss/
- Aural Rehabilitation
 - Amptify: <https://amptify.com/>
 - Hearoes: <https://www.games4hearoes.com/>



Price Point (Manchaiah et al. 2023, Klugman, 2023)

- OTCs typically range between \$200 and \$1000
 - Can be up to \$2950 (Eargo 7)
- Lower cost devices are usually preset without wireless features
- Higher cost OTCs may be similar in price to lower end traditional hearing aids

Online Reviews (Manchaiah et al. 2023)

- Device Reviews
 - List benefits and issues reported by prior users
 - Can help determine quality of device
- App Reviews
 - Can help determine ease of use
 - Can help determine flexibility of devices

Summary

- OTC hearing aids are meant to make hearing aids more affordable and accessible
- Consumers are able to self-fit devices, especially if they have some sort of customer service to ask for help
- OTCs do provide benefit relative to unaided, but not as much as professionally fit devices
- Anyone in Iowa can sell or service OTC HAs, but you must have a license to fit them
- There are many resources out there for clinicians and consumers regarding OTCs



Questions?



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