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Applications of direct-to-consumer hearing devices for adults with hearing loss

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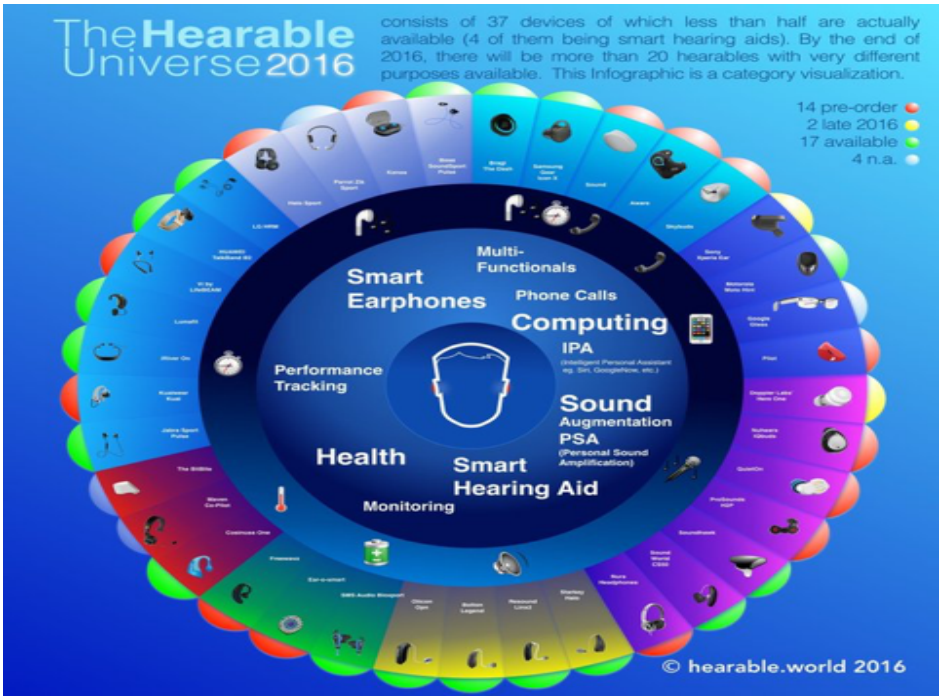
No financial and non-financial disclosures to report

Learning Outcomes

Direct-to-consumer hearing devices have become popular in recent days. This talk will present a summary of literature review on applications of direct-to-consumer hearing devices for adults with hearing loss. The summary is presented on three themes, including: (1) electroacoustic measurements; (2) consumer surveys; and (3) outcome evaluation studies.

As a result of this course, participants will be able to:

1) Define and name different types of direct-to-consumer hearing devices
2) Discuss the benefits and limitations of direct-to-consumer hearing devices
3) Discuss the practice implications of direct-to-consumer hearing devices

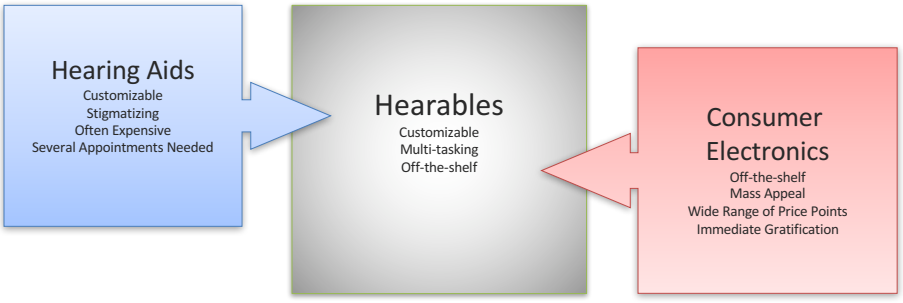


Types of Hearing-Related Technologies

- Medical Devices for Hearing Loss
  - Hearing aids
  - Over-the-counter wearable hearing devices (proposed)
- Consumer Electronics Not Intended for Hearing Loss
  - Personal Sound Amplification Systems (PSAPs)
- Hearing Assistive Devices
  - FM, infrared, loop systems
- Communication Technologies
  - Captioning, emergency information, etc.

NASEM Report (2016)

"Hearables": Morphing of Two Different Technologies

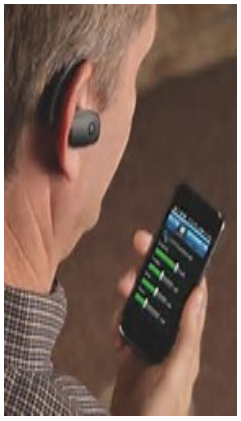


Smartphone-enabled hearing aids

Headset Amplifiers

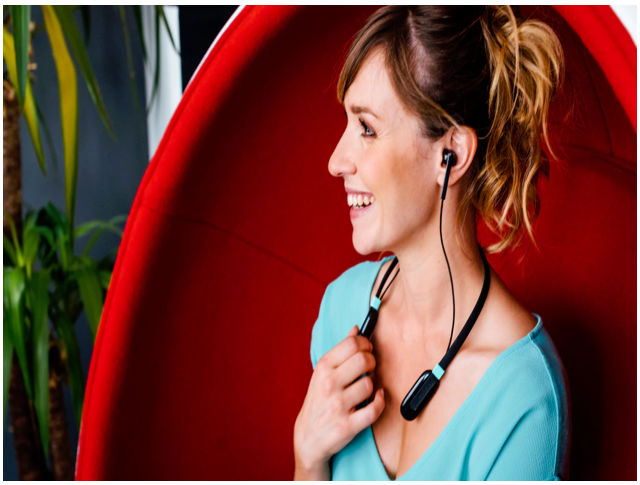
Personal Sound Amplification Products (PSAPs)

- De-featured hearing aids
- Some require app to adjust

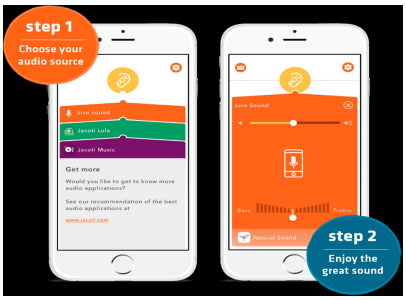


Cordless Multi-Taskers

Neck-band Multi-taskers



Smartphone Apps



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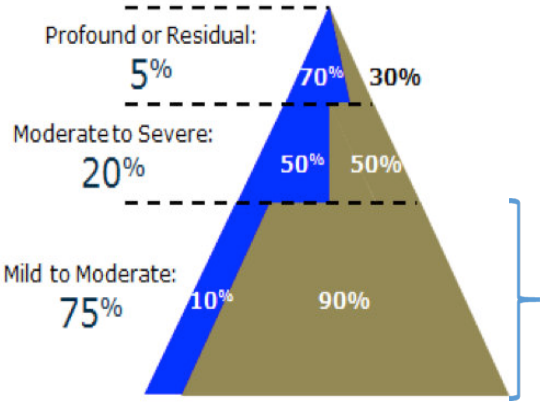
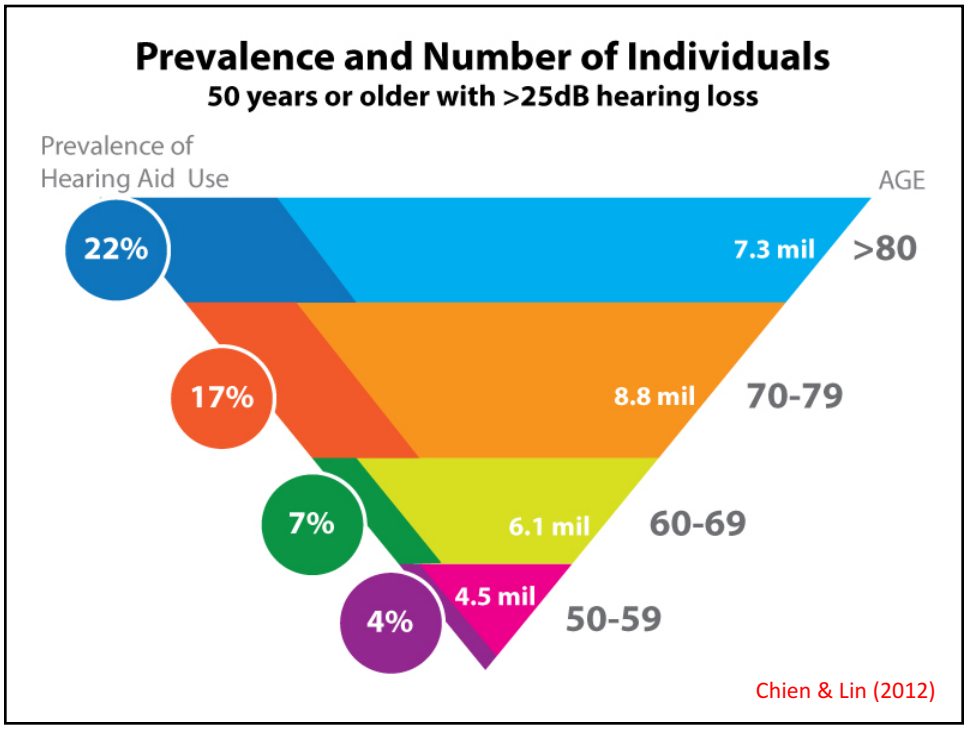
What should we call them?

Opportunities



Seeking a lifestyle enhancement through an anonymous transaction



Focus of this Talk

In this talk, we focus on three categories of direct-to-consumer hearing devices:

- Personal Sound Amplification Systems (PSAPs)
- Over-the-counter (OTC) hearing devices
- Direct-mail hearing aids

Terminologies

- Hearing aids
- Over-the-counter (OTC) hearing aids
- Over-the-counter (OTC) hearing devices
- Direct-mail hearing aids
- Personal Sound Amplification Systems (PSAPs)
- Hearable
- Smartphone based applications (Apps)

Definitions / Comparison

	Traditional Hearing aids	Over-the-Counter hearing aids (OTC) / Direct mail hearing aids	Personal Sound Amplification Products (PSAPs)	Smartphone-based Amplification Apps
Regulated under FDA	Yes	Yes	No	No
Professional Consultation Needed	Yes	No	No	No
Average Price Range per Device (in $USD)	$1000-5000	$200-500	$20-400	$0-10
Intended Target Group	PHL	PHL	PNH	PNH
Intended User	PHL	PHL	PNH	PHL & PNH
Typical Consumer Image	Stigmatizing	Stigmatizing	Stigmatizing to mass appeal	Mass appeal

Note: PHL=Person with Hearing Loss; PNH=Person with Normal Hearing

Search strategy

- A literature search was conducted during October-December 2016 through EBSCO*host*, which which including: Cumulative Index to Nursing and Allied Health (CINAHL); MEDLINE; and PsycINFO.
- Manual search of conference papers
- Two researchers conducted the search independently to ensure no existing literature in this area had been missed.
- Recent search during July 2017

Search words

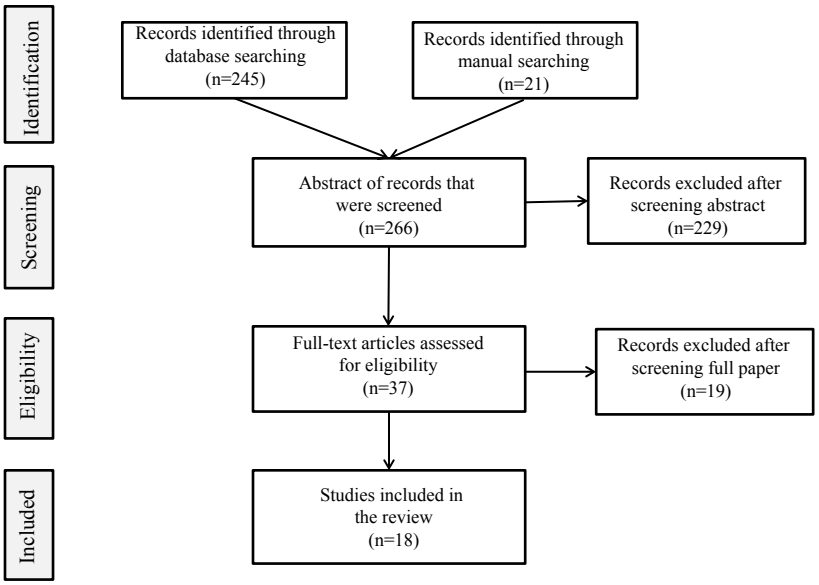
The search was conducted with the words/phrase:

- cheap hearing aids;
- personal sound amplification systems;
- personal sound amplification products (PSAPs);
- personal sound amplification devices;
- direct mail hearing aids;
- over-the-counter (OTC) hearing aids;
- direct-to-consumer hearing aids;
- direct-to-consumer hearing devices;
- hearing amplifier;
- sound amplifier;
- basic hearing aid;
- self-fitting hearing aid;
- affordable hearing aid; and
- hearable(s)

Inclusion criteria

Papers were excluded if the study did not meet the criteria below:

- Population – *adults with hearing loss*
- Condition – *electroacoustic measurements, consumer market surveys, and outcome studies*
- Context – *studies focusing on direct-to-consumer hearing devices*
- Study type – *any study design*
- Language – *studies that were published in English*
- Timescale – *no restrictions were applied*



Summary of literature: Main themes

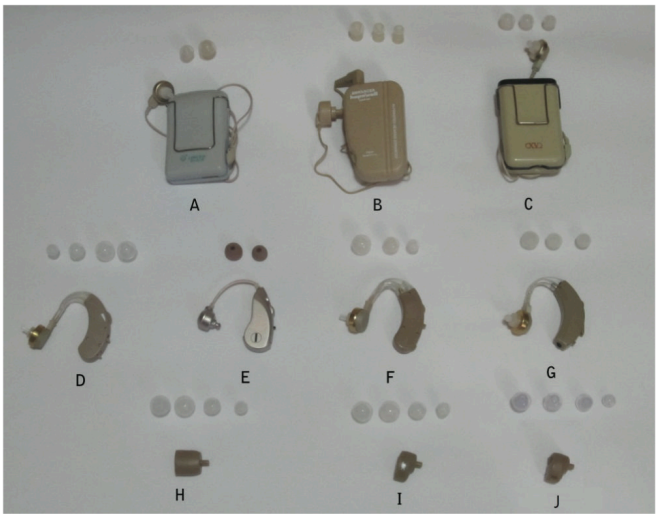
- **Electroacoustic measurements (5 studies)**
  - Cheng & McPherson (2000) – Hong Kong – Peer reviewed journal
  - Callaway & Punch (2008) – USA – Peer reviewed journal
  - Chan & McPherson (2015) – Hong Kong – Peer reviewed journal
  - Smith et al. (2016) – USA – Professional magazine
  - Reed et al. (2017) – USA – Peer reviewed journal

- **Survey of consumers (5 studies)**
  - Kochkin (2010) – USA – Professional magazine
  - Kochkin(2014) – USA – Professional magazine
  - Consumer Electronics Association (2014) – USA – Consumer organization report
  - JapanTrack (2012) – Japan – Consumer organization report
  - JapanTrack (2015) – Japan – Consumer organization report

- **Outcome evaluation (8 studies)**
  - McPherson & Wong (2005) – Hong Kong – Peer reviewed journal
  - Sacco et al. (2016) – France – Peer reviewed journal
  - Xu et al. (2015) – USA – Conference paper
  - Tedeschi & Kihm (2016) – USA – Professional magazine
  - Mamo et al. (2017) – USA – Peer reviewed journal
  - Niemal et al. (2017) – USA – Peer reviewed journal
  - Humes et al. (2017) – USA – Peer reviewed journal
  - Brody et al. (2017) – USA – Conference paper

Electroacoustic measurements

OTC devices physical appearance



Chan & McPhearson (2015)

OTC device features

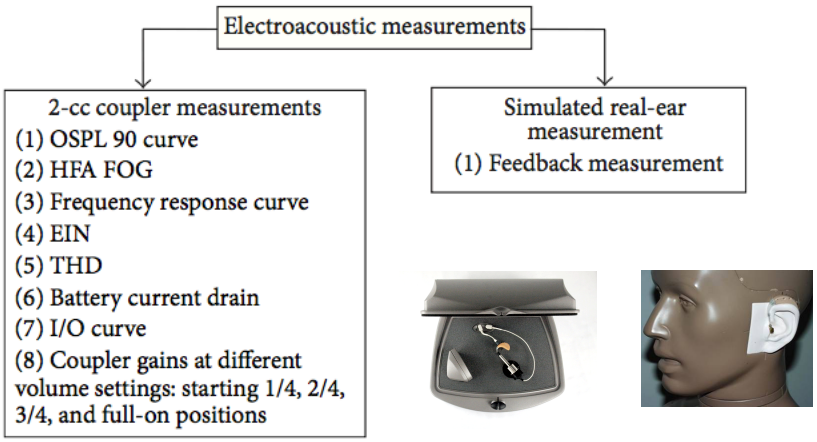
TABLE 1: Summary of the characteristics of the ten OTC hearing aids.

	Models	Style	Cost ($US)	Country of manufacturer	Volume range	Special features	Operation manual	Technical specification	Battery
A	LingYin HA 611B	BW	41	China	1–5	2 tone controls (N; H)	Yes (Chinese)	Yes	AAA
B	Hopewell HAP-40	BW	22	Unknown	No marking	—	Yes (English and Spanish)	No	AAA
C	Axwa EX-12D	BW	49	China	1–8	3 tone controls (N; H; L)	Yes (English)	Yes	AA
D	JNC-MHA-BTE130	BTE	47	Korea	1–3	—	Yes (Chinese and English)	Yes	675
E	UP-6411	BTE	52	Japan#	1–6	—	Yes (English)	Yes	675
F	ShengDe V-163	BTE	51	China	1–4	—	Yes (Chinese)	Yes	675
G	Axwa OM-188	BTE	55	China	1–4	—	Yes (English)	Yes	675
H	Powertone HAP-F883	ITE	114	Unknown	1–5	—	Yes (English)	Yes	13
I	JNC-MHA-ITE 110	ITE	47	Korea	No marking	—	Yes (Chinese and English)	Yes	312
J	Axon K-80	ITE	37	Unknown	No marking	—	Yes (English)	Yes	312

Note. #: no information of manufacturer is printed on packaging, but the salesperson claimed that it was a Japanese brand; BW: body-worn; BTE: behind-the-ear; ITE: in-the-ear; N: normal; H: high; L: low; technical specification: manufacturer's information on electroacoustic characteristics of the hearing aid.

Chan & McPhearson (2015)

Electroacoustic measurements



Chan & McPhearson (2015)

Electroacoustic characteristics

TABLE 3: Summary of the results of OTC hearing aids: 2-cc coupler measurements.

OTC	OSPL 90		HFA FOG (dB)	Frequency range (Hz)	EIN (dB)	THD (%)			Battery life (hours)
	Peak frequency (Hz)	Peak SPL (dB SPL)				500 Hz	800 Hz	1.6 kHz	
A tone N	1600	127.6	44.0	375–4000	28.4	1.9	N/A	0.4	DNT
A tone L	1600	128.5	39.7	667–4667	28.5	N/A	N/A	0.7	DNT
B	700	129.8	29.0	354–>8000	35.2	0.3	0.1	0.7	DNT
C tone N	1400	126.6	52.8	<200–3667	26.4	2.3	N/A	0.1	DNT
C tone H	1400	126.3	52.5	<200–3667	25.5	2.4	N/A	0.3	DNT
C tone L	1400	126.1	41.8	396–3667	29.7	3.3	3.1	0.1	DNT
D	1400	129.3	37.2	<200–3667	30.6	2.1	1.2	0.5	142
E	1700	118.8	19.1	<200–4667	38.1	4.2	N/A	0.1	182
F	1400	125.9	32.6	<200–3833	24.9	1.4	N/A	0.3	233
G	1600	126.8	30.6	<200–5333	33.2	2.7	N/A	0.2	235
H	800	124.4	14.2	<200–4333	45.6	6.6	1.2	10.1	307
I	2000	113.1	20.9	<200–5000	31.4	23.5	46.5	10.8	154
J	700	118.4	7.6	<200–4667	52.9	4.8	0.8	4.6	212

Note. Peak SPL: peak sound pressure level; N/A: not applicable. According to the 12 dB rule, THD does not need to be measured at that frequency when its second harmonic was amplified 12 dB more than the first harmonic in the frequency response curve (Frye, 2010 [20]).
DNT: did not test. Measurement of battery current drain was not conducted since no battery substitution pills for AA and AAA battery size were available.

Chan & McPhearson (2015)

Summary of electroacoustic characteristics

Frequency range (Hz)	<200 (low) to 8000 (high)
OSPL-90 – Peak frequency (Hz)	200 to 2000 (1400 to 2000 more often)
OSPL-90 – Peak SPL (dB SPL)	105.6 to 133
TDH (%) – 500 Hz	0 to 6.66 (outliers 15.6 & 23.5)
TDH (%) – 800 to 1000 Hz	0.02 to 9.7 (outliers 30 & 46.5)
TDH (%) – 1600 to 2000 Hz	0 to 4.6 (outliers 10.1 & 10.8)
EIN (dB)	2.4 to 52.8
Battery life (hours)	37 to 194

Manchaiah et al. (2017)

Simulation of output on KEMAR

TABLE 2: Estimated hearing thresholds of elderly people based on Stenklev and Laukli data [23].

	Frequency (Hz)					
	250	500	1000	2000	3000	4000
Estimated hearing threshold (dB HL)	23.4	23.6	27.1	38.1	51.8	55.8

Note. These values show mean hearing thresholds of elderly people aged 60 or above, including both male and female and left and right ears.

TABLE 6: Judgment of matching prescriptive targets for presbycusis with stricter criterion.

OTC	Matching the prescriptive targets for presbycusis?						Match the targets at four or more frequencies?
	0.25 Hz	0.5 Hz	1 kHz	2 kHz	3 kHz	4 kHz	
A tone N	✗	✗	✗	✗	✗	√	✗
A tone L	✗	√	√	✗	√	√	√
B	✗	✗	√	√	✗	√	✗
C tone N	✗	✗	✗	✗	√	✗	✗
C tone H	✗	✗	✗	✗	√	√	✗
C tone L	✗	✗	✗	√	√	✗	✗
D	✗	✗	✗	✗	√	✗	✗
E	√	✗	✗	✗	✗	✗	✗
F	✗	√	√	√	√	✗	√
G	√	√	√	√	√	✗	√
H	✗	√	√	✗	✗	✗	✗
I	✗	✗	✗	√	✗	✗	✗
J	√	√	✗	✗	✗	✗	✗

Note. √: OTC hearing aid matched prescriptive target.

Chan & McPhearson (2015)

Some conclusions based on electroacoustic measurements

- Most of the devices (nearly 90% based on the literature) do not meet the criteria in terms of OSPL-90, THD & EIN.
- Measurement of output on simulated hearing loss on KEMAR suggested that most devices are not suitable for high-frequency hearing loss patterns, as they had more gain in low frequencies
- Direct-to-consumer hearing devices should be chosen carefully

Survey of consumers

Survey of consumers

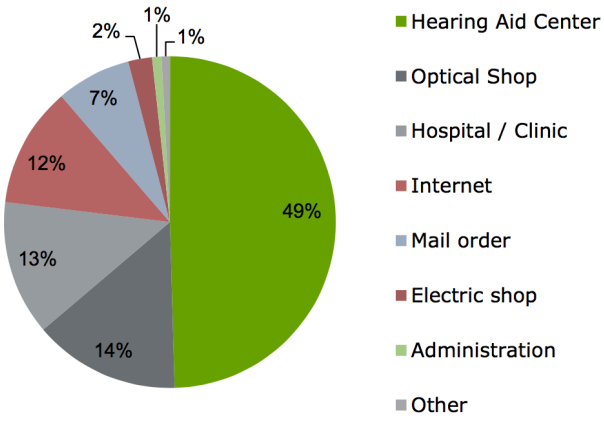
- Kochkin (2010) – USA – Professional magazine
- Kochkin(2014) – USA – Professional magazine

- Consumer Electronics Association (2014) – USA – Consumer organization report

- JapanTrack (2012) – Japan – Consumer organization report
- JapanTrack (2015) – Japan – Consumer organization report

Not peer-reviewed

Hearing aid distribution channel



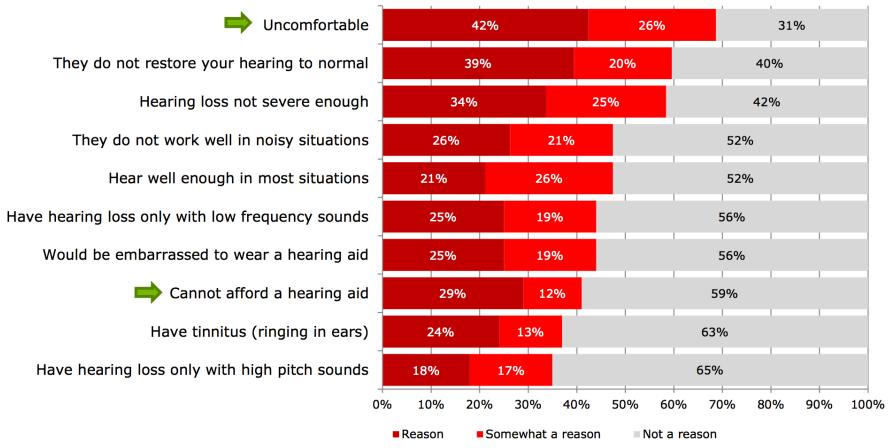
JapanTrak (2015)

Hearing aid adoption and satisfaction rates

Country	France	Germany	UK	USA	Japan
Adoption rates (%)	30.4	34	41.1	30.2	**13.5**
Overall satisfaction	84	70	77	81	**39**

MarkTrak (2014), EuroTrak (2015), JapanTrak (2015)

Top 10 reasons for not having hearing aid



JapanTrak (2015)

Some conclusions based on consumer surveys

- 5-19% of people with hearing loss purchase hearing aids through direct mail or online.
- Two thirds (i.e., nearly 75%) of direct-mail and PSAP owners were candidates for custom hearing aids, although estimates suggested that less than 18% users substitute PSAPs for custom hearing aids.
- **Direct mail hearing aids and PSAPs were associated with lower satisfaction when compared to hearing aids** that were purchased through hearing healthcare professionals.
- It is possible, however, that adults who purchase lower priced, direct-to-consumer products have lower expectations relative to individuals purchasing hearing aids through the professional channel.

Outcome evaluation

Effectiveness of an affordable hearing aid with elderly persons

- This study evaluated the effectiveness of a recently developed, low-cost OTC HA with elderly people with mild to mode mixed or SNHL.
- Two aspects were focused upon: (1) objective change in the participants' aided hearing measures; and (2) the self-reported performance and benefit obtained from the hearing aid.
- The device was rated by the majority of participants as providing benefit, with 16 of the participants (84%) using their hearing aid from at least 1 to over 8 h each day and with all participants considering the low-cost instrument 'worth the trouble' of wearing.
- **Both structured questionnaires (i.e., IOI-HA, COSI) and open- ended interviews showed positive outcomes.**
- Negative comments focused on difficulties with either acoustic feedback or background noise annoyance while wearing the hearing instrument.

McPherson & Wong (2005)

Clinical evaluation of an over-the-counter hearing aid (TEO First®) in elderly patients suffering of mild to moderate hearing loss

- Assessed the clinical value of a new OTC hearing aid device (TEO First®) in the elderly.
- There was an improvement of hearing with TEO First® in silence or in noise.
- After one month of use of the device, quality of life has improved with regards to the following parameters:
  - decrease of perceived hearing difficulties during conversation without background noise
  - decrease of perceived hearing difficulties in conversation with several people
  - decrease of negative emotions while watching TV
  - decrease of negative emotions during conversation without background noise
  - decrease of negative emotions during conversation in noisy background
  - decrease of negative emotions during conversation with several people
- The acceptability of the device was low to moderate.

Sacco et al. (2016)

Hearing Care Intervention for Persons with Dementia: A Pilot Study

- Test a novel hearing intervention for persons with dementia and family caregivers delivered in outpatient settings.
- Care-givers believed the intervention was beneficial, and most participants with dementia wore the amplification device daily.
- For the depression and neuropsychiatric outcome measures, participants with high symptom burden at baseline showed improvement at 1-month post-intervention.
- The Memory-HEARS intervention is a low-cost, low-risk, non-pharmacologic approach to addressing hearing loss and behavioral symptoms in patients with dementia.

Mamo et al. (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

- The objectives of this study were to determine efficacy of hearing aids in older adults using audiology best practices, to evaluate the efficacy of an alternative OTC intervention, and to examine the influence of purchase price on outcomes for both service-delivery models.
- A single-site, prospective, double-blind placebo-controlled randomized trial with three parallel branches: (a) audiology best practices (AB), (b) consumer decides OTC model (CD), and (c) placebo devices (P).
- **Hearing aids are efficacious in older adults for both AB and CD service-delivery models. CD model of OTC service delivery yielded only slightly poorer outcomes than the AB model.**
- Purchase price had no effect on outcomes

Humes et al. (2017)

Article Design Summaries			
Author, Year, Location	**Study Design**	**Population**	**Study Length**
Humes et al (2017) USA	Prospective, Quantitative, Randomized, double-blind, Placebo-controlled trial with three categories	n=154; Mean age 69.1 yrs (across all 3 groups).	6-weeks; with additional 4-weeks
Sacco et al (2016) France	Prospective, Quantitative, Single Focus	n=31; Mean age 78.3 yrs.	One month
Nieman et al (2016) USA	Pilot study, Prospective, Quantitative, Randomized, Control group	n=15 dyads; Participants mean age 70.1 yrs. CP at least 18 yrs old.	Three month; with 3 & 6 month follow-up
Mamo et al (2017) USA	Pilot Study, Prospective, Quantitative, and Qualitative	n=20 dyads; Participants mean age 76.9 yrs, mild cognitive impairment - Dementia. Caregivers mean age 64.3 yrs.	One month; with a one month follow-up
McPherson & Wong (2005) China	Prospective, Quantitative, Qualitative	n=19; mean age 73 yrs.	Four months; with measures taken throughout

Tran et al. (2017, Manuscript in preparation)

Devices Product Information				
Source	**Device Used**	**Cost**	**Device Type**	**Device Features**
Humes et al (2017)	ReSound Alera 9 Mini-BTE	$100 ea	FDA approved hearing aid	Advanced Signal Processing: Multi-channel compression; Feedback cancellation; Noise reduction; Directional microphones; Four programs.
Sacco et al (2016)	TEO First®	$250 ea	OTC developed in France	Amplification Range 0-22 dB; Digital Signal Processing; Multiband dynamic compression; Two programs (calm & noisy); Volume control; Rechargeable battery.
Nieman et al (2016)	Sound World Solutions CS-50; Williams Sound Pocketalker Ultra Duo Pack	$350 (CS-50); $120 (Pocketalker)	CS-50: PSAP; Pocketalker: Assistive Listening Device	CS-50: Monaural device, Bluetooth, paired & programmed with smartphone, rechargeable batteries; Pocketalker: remote microphone, headphones, volume control, AAA batteries, non-programmable.
Mamo et al (2017)	Sound World Solutions CS-50; Williams Sound Pocketalker Ultra Duo Pack	$100 - $300	CS-50: PSAP; Pocketalker: Assistive Listening Device	CS-50: Monaural device, Bluetooth, paired & programmed with smartphone, rechargeable batteries; Pocketalker: remote microphone, headphones, volume control, AAA batteries, non-programmable.
McPherson & Wong (2005)	ReSound Avance HE4	$125 ea	OCT hearing aid	Max gain of 31 dB SPL; Semi-open-canal fit; Size 10 batteries; Sound compression and volume trimmer.

Tran et al. (2017, Manuscript in preparation)

Device Specific Uses				
Source	**Verification of Device Fit**	**Prescriptive Fitting Type**	**Average Daily Use**	**Fitting Sides**
Humes et al (2017)	Yes, Verifit	AB: Custom fit NAL-NL2; CD: Pre-fit to common HL	6.3 hrs	Binaural
Sacco et al (2016)	No	Pre-fit to common HL	1 hour	Binaural
Nieman et al (2016)	No	PSAP: Fit according to cell phone program response; ALD: Volume Control only	1-4 hrs	PSAP: Monaural; ALD: Binaural
Mamo et al (2017)	No	PSAP: Fit according to cell phone program response; ALD: Volume Control only	1 hour	PSAP: Monaural; ALD: Binaural
McPherson & Wong (2005)	Yes, Real-ear	NAL-R	1- 8 hrs	Monaural

Tran et al. (2017, Manuscript in preparation)

Delivery and Support Variations		
Source	**Service Delivery Method**	**Provision of Additional Support**
Humes et al (2017)	AB: Audiology Best Practice method CD: OTC self-select P: AuD best Practice, but H.A. programmed to 0 dB gain.	AB & P: Device Orientation, Communication Strategies Training CD: OTC method - No additional clinician support
Sacco et al (2016)	Audiological evaluation, pre-selected device with pre-fitted hearing loss configurations; most similar to OTC delivery method	Device Orientation, OTC: No additional clinician support
Nieman et al (2016)	HEARS Program. Community Based, single-session delivery method with clinician. Selection between PSAP or ALD. Device orientation. Incorporation of CP. Communication strategies AR session.	Device Orientation, Communication Strategies Training, Incorporation of CP
Mamo et al (2017)	HEARS Program. Community Based, single-session delivery method with clinician. Selection between PSAP or ALD. Device orientation. Incorporation of CP. Communication strategies AR session.	Device Orientation, Communication Strategies Training, Incorporation of CP
McPherson & Wong (2005)	Audiological evaluation, single device option, pre-fit to common hearing loss configuration to simulate OTC delivery model.	OTC: No additional clinician support

Tran et al. (2017, Manuscript in preparation)

Some conclusions based on outcome evaluation studies

- Studies on outcome evaluation suggest a positive outcome (improved hearing in quiet and in noisy situations, improved communication, and improved activities of daily living) of OTC devices in adults with hearing loss.
- A laboratory study suggested PSAPs performed as well as hearing aids for listening in noisy situations and for listening to music, but not as well for listening to speech.
- According to a single study, the outcome of direct-to-consumer hearing devices seems to be better when hearing healthcare professionals supports users.

Quality analysis

Look at study findings in relation to its design & method

- Due to limited studies both peer-reviewed and non-peer reviewed work was included
- The studies on electroacoustic measurements have used conventional study designs with test box measures and simulated real-ear measures in the KEMAR.
- The consumer surveys generally used **convenience sampling**, which may have resulted in sampling bias.
- Studies on patient outcomes with these devices **used open-trial design without control group** and **blinding**. This may have resulted in some bias as hearing aid research has a documented placebo effect.
- Study design of existing literature in this area was found to be generally poor

Quality analysis of outcome studies

Quality Assessment											
Source	RCT	Double-Blind RCT	Control Group	Incl/ Excl	Baseline	Verify H.A. Fit	Analysis Bias	Effect Size	Power Analysis	Drop-out	Level of Evidence
Humes et al (2017)	2	2	2	2	2	2	2	2	2	2	20: High
Sacco et al (2016)	0	0	0	2	2	1*	1**	0	0	2	8: Low
Nieman et al (2016)	2	0	2	2	2	0	0	2	0	0	10: Low
Mamo et al (2017)	0	0	0	2	2	0	0	0	0	2	6: Low
McPherson & Wong (2005)	0	0	0	0	2	2	0	0	0	2	6: Low

*Unspecified type of verification
**Independent study, but funded by the OTC company.

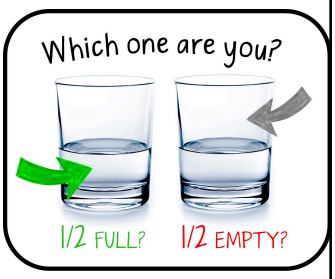
Tran et al. (2017, Manuscript in preparation)

Some conclusions based on outcome evaluation studies with study design considerations

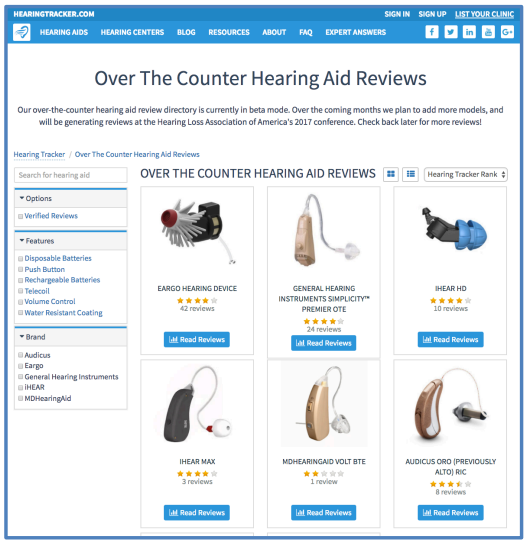
- Poor study design / Except on a study by Humes et al. (2017)
- Limited (or inadequate) sample size
- Short-term outcomes (4 weeks to 6 months)
- **Hearing healthcare professionals chose the device – *How much do we know about the direct-to-consumer model?***

Overall conclusion

Although ***some devices have the capability to cause harm due to high output sound levels***, the existing literature suggests a ***few direct-to-consumer products perform electroacoustically similar to hearing aids, have shown positive outcomes and have the potential to benefit people with hearing loss***.

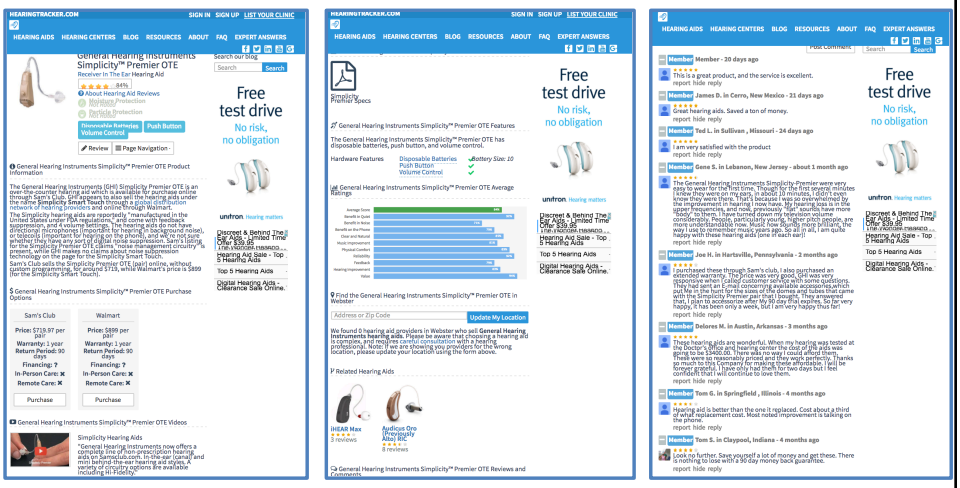


HearingTracker



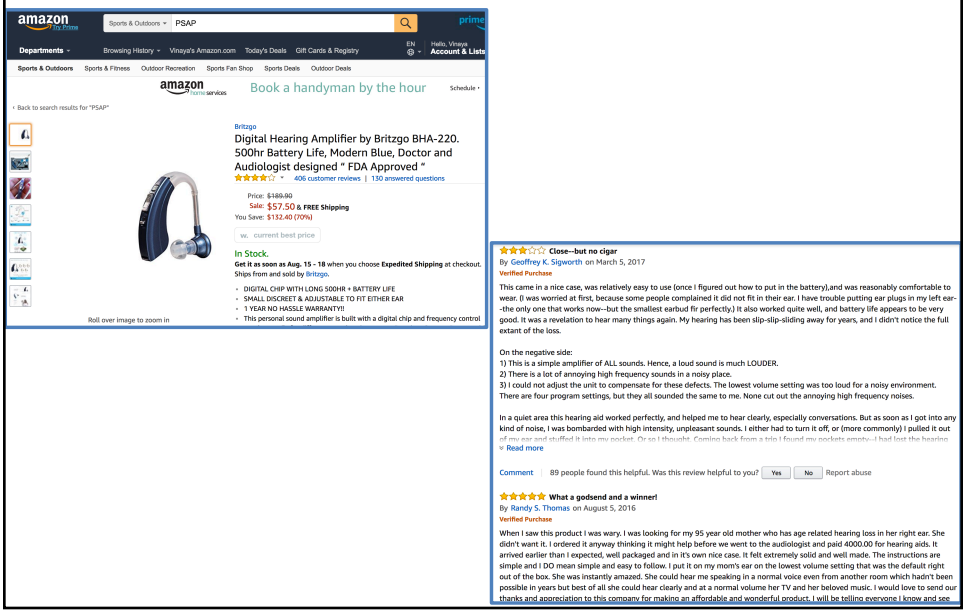
https://www.hearingtracker.com/over-the-counter-hearing-aids

HearingTracker



https://www.hearingtracker.com/over-the-counter-hearing-aids

User reviews



Future directions

Domain	Specific area
Selection and candidacy	▪ Define a specific group of individuals ▪ Define the context of use
Expectations	▪ Does lower costs correlate to lower expectation ▪ Differences between traditional and direct-to-consumer products
Acoustic physical fact finding (i.e., electroacoustic measures)	▪ Test box and coupler measurements ▪ Simulated real-ear measures using a KEMAR
Verification	▪ Real ear measures ▪ Functional gain
User experience and perception	▪ Fitting comfort ▪ Image perception ▪ Decision making process of consumers ▪ Use and maintenance of the device
Outcome evaluation dimensions	▪ Perceived hearing disability ▪ Speech perception in quiet ▪ Speech perception in noise ▪ Communication ability ▪ Activities and participation ▪ Health related quality of life ▪ Tinnitus distress
Factors that may influence the outcome	▪ Socio-economic status ▪ Cost of the device ▪ Health literacy ▪ Guidance and support from hearing healthcare professional ▪ Aural rehabilitation
Economic evaluation	▪ Cost analysis ▪ Cost-benefit analysis ▪ Cost-effectiveness analysis ▪ Cost-utility analysis

Questions

Reference

Clinical Interventions in Aging

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REVIEW

Applications of direct-to-consumer hearing devices for adults with hearing loss: a review

This article was published in the following Dove Press journal:
Clinical Interventions in Aging
18 May 2017
Number of times this article has been viewed

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Background: This systematic literature review is aimed at investigating applications of direct-to-consumer hearing devices for adults with hearing loss. This review discusses three categories of direct-to-consumer hearing devices: 1) personal sound amplification products (PSAPs), 2) direct-mail hearing aids, and 3) over-the-counter (OTC) hearing aids.

Method: A literature review was conducted using EBSCOhost and included the databases CINAHL, MEDLINE, and PsycINFO. After applying prior agreed inclusion and exclusion criteria, 13 reports were included in the review.

Results: Included studies fell into three domains: 1) electroacoustic characteristics, 2) consumer surveys, and 3) outcome evaluations. Electroacoustic characteristics of these devices vary significantly with some meeting the stringent acoustic criteria used for hearing aids, while others producing dangerous output levels (ie, over 120-dB sound pressure level). Low-end (or low-cost) devices were typically poor in acoustic quality and did not meet gain levels necessary for most adult and elderly hearing loss patterns (eg, presbycusis), especially in high frequencies. Despite direct-mail hearing aids and PSAPs being associated with lower satisfaction when compared to hearing aids purchased through hearing health care professionals, consumer surveys suggest that 5%–19% of people with hearing loss purchase hearing aids through direct-mail or online. Studies on outcome evaluation suggest positive outcomes of OTC devices in the elderly population. Of note, OTC outcomes appear better when a hearing health care professional supports these users.

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