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# Efficacy and Effectiveness of Direct to Consumer Devices and Interventions

Nicholas S. Reed, AuD, Instructor, Johns Hopkins University School of Medicine Jonathan J. Suen, AuD, Research Fellow, Johns Hopkins University School of Medicine

Moderated by: Fawn Carson, MS, OTR/L, ATP

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# Efficacy and Effectiveness of Direct to Consumer Devices and Interventions

Nicholas S. Reed, AuD, Instructor, Johns Hopkins University School of Medicine

Jonathan J. Suen, AuD, Research Fellow, Johns Hopkins University School of Medicine

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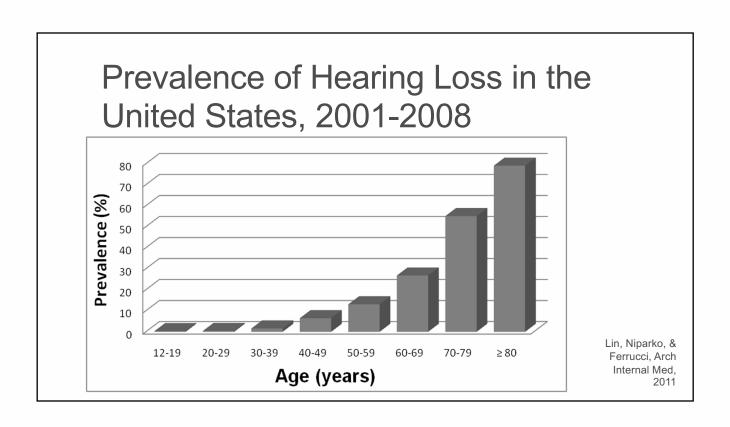
# **Learning Objectives**

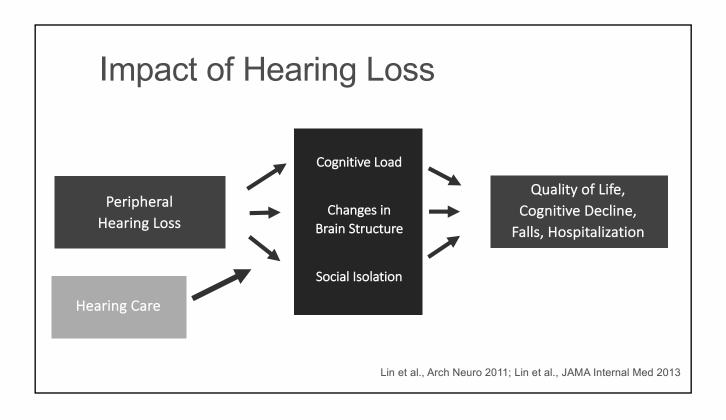
- Introduce background information on direct to consumer hearing care
- Present efficacy studies of direct to consumer technology
- Apply efficacy knowledge to real-world decision making

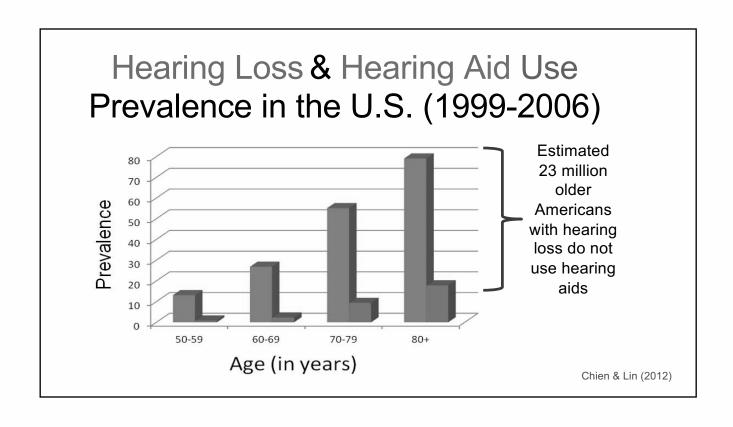
# **Learning Objectives**

- Apply established knowledge of health disparities and barriers to hearing care for older adults
- Integrate established public health research approaches to the evolving field of community-delivered hearing care
- Discuss a first-in-kind, community-delivered hearing care intervention tailored for older adults

# Efficacy of Direct to Consumer Devices







# **Amplification**

- ≤ 20% of persons with hearing loss own hearing aid(s) in the United States
- Barriers: financial cost, time commitment, access to a licensed audiologist/HA dispenser, and stigma
- Possible changes on the horizon:

Presidents Council of Advisors on Science & Technology National Academies of Sciences, Engineering, & Medicine Over-the-counter Hearing Aid Legislation

Source: Adapted from Amanda Allen (2015)

NASEM, 2016; Reed et al., JAMA, 2017; Reed et al., Otology & Neurotology, 2017

# **Amplification**

#### **Hearing Aids:**

Regulated by the FDA

\$800 to \$3000 per device

Minimal insurance benefit (no Medicare benefit)

Accepted gold standard of care

Minimal Internet Sales

#### **Personal Sound Amplification Products:**

Unregulated by the FDA

Cost \$30-300 per device

E-commerce

Tremendous recent advances

NASEM, 2016; Reed et al., JAMA, 2017; Reed et al., Otology & Neurotology, 2017

# PSAPs/OTC: Literature Review

Low cost devices tend to produce high EIN, THD, and limit amplification to low frequencies (Chan & Mcpherson, 2000, 2015)

Some devices in the mid-price range performed similar to hearing aids (Callaway & Punch, 2008)

Comparison of PSAPs and Hearing aids shows high end devices provided appropriate levels of amplification and directional benefit for mild to moderate hearing loss (Smith et al., 2016)

Callaway & Punch, 2008 AJA; Chan & Mcpherson, 2015 BioMed Res Intl; Smith et al., 2016, Hearing Review

## PSAPs/OTC: Literature Review

No preference for environmental and music sounds between PSAP and hearing aid – though hearing aid was preferred for speech (Breitbart et al, 2014)

Evidence that cost does not necessarily drive outcomes (Cox et al. 2014)

Efficacious consumer selection OTC approach (Humes et al., 2017)

~1.5 million w/ hearing loss own PSAP or OTC device and of them, ~18% would have purchased traditional hearing aid without PSAP option and ~75% used PSAP for hearing loss (Kochkin, 2010)

Breitbart et al., 2014 Poster; Cox et al., 2014 Gerontology; Humes et al., 2017 AJA; Kochkin 2010, Hearing Journal

# Electroacoustic Analysis

**Electroacoustic exploration of PSAPs and OTC HAs** 

10 Devices: 9 in \$150-400 range, 1 was \$30

6 Devices: appropriate frequency range (200-6000+ Hz),

Relatively Low EIN (<24), Low THD (<1%)

6 Devices: able to approx. NAL targets within 10 dB at 6+ targets

3 Devices: able to approx. NAL targets within 5 dB at 6+ targets

Reed et al., Otology & Neurotology, 2017

# Study 1 Objective

Comparative analysis of PSAPs and a hearing aid on speech-in-noise performance among adults with mild-to-moderate hearing loss

# Methods: Study Population

#### **Inclusion:**

Mild-to-moderate sensorineural hearing loss (PTA .5-4k 21-55 dB in the better ear)

Adult on set hearing loss

60-85 years of age

No cognitive impairment (MMSE ≥ 24)

#### **Exclusion:**

Unilateral/asymmetric hearing loss

Conductive hearing loss

Hearing loss secondary to medical conditions

Prior hearing aid usage

Powered to N=42 for non-inferiority trial with type I error rate of 0.05 and 80% power (Williams Design)

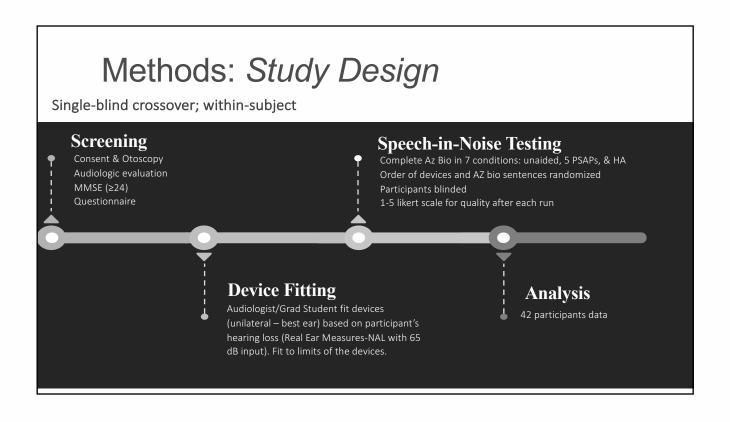
Reed et al., JAMA, 2017

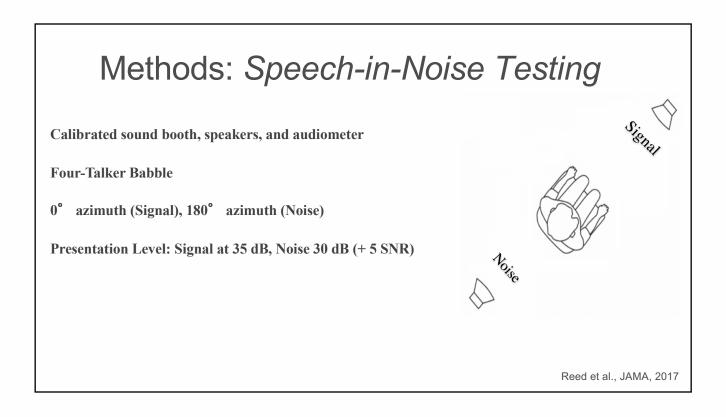
# Methods: Device Selection

One mid-level technology hearing aid (\$1910 wholesale cost)

Four electroacoustically acceptable PSAPs from in-house analysis: SoundHawk, SoundWorld Solutions CS-50+, Etymotic Bean, Tweak Amplifier

One electroacoustically unacceptable PSAP from in-house analysis: MSA-30x





# **Outcomes**

#### **Primary:**

Change in % correct from baseline unaided speech-in-noise scores to that in aided conditions

Reed et al., JAMA, 2017

# Results: Demographics

Number of Participants	N=42 (14 Male, 28 Female)
Mean Age	71.6 years (SD 6.0) (61-83 years)
Mean Perceived Duration of Hearing Loss	4.9 years (0-55 years)
Mean MMSE	28.8 (25-30)
Mean PTA (.5-4k) Right	34.7 dB (21.25-52.5 dB)
Mean PTA (.5-4k) Left	36.1 dB (22.25-51.25 dB)
Percent Reported Noise Exposure Hx.	33.3% (14/42)
Percent Reported Perceived Tinnitus	52.4% (22/42)
Percent Reported Perceived Hearing Loss	88.0% (37/42)

# Results: Primary Outcome

Table. Accuracy in Speech Understanding in Noise From Unaided to Aided With PSAPs and a Hearing Aid Among 42 Older Adults With Mild to Moderate Hearing Loss<sup>a</sup>

	Cost, US \$b	Mean Accuracy, % (95% CI)		Change From Unaided Hearing, Percentage Points (95% CI)	Difference Between PSAP and Hearing Aid Change, Percentage Points (95% CI)
Unaided hearing		76.5 (72.7 to 80.3)	П		NA
Oticon Nera 2 hearing aid <sup>c</sup>	1910.00	88.4 (84.5 to 92.4)	П	11.9 (9.8 to 14.0)	
PSAP			П		
Sound World Solutions CS50+	349.99	87.4 (83.5 to 91.4)	П	11.0 (8.8 to 13.1)	-1.0 (-2.7 to 0.8)
Soundhawk	349.99	86.7 (82.7 to 90.6)	П	10.2 (8.0 to 12.3)	-1.8 (-3.5 to 0)
Etymotic BEAN	299.99	84.1 (80.2 to 88.1)	П	7.7 (5.5 to 9.8)	-4.3 (-6.1 to -2.5)
Tweak Focus	269.99	81.4 (77.4 to 85.3)	П	4.9 (2.8 to 7.0)	-7.0 (-8.8 to -5.3)
MSA 30X Sound Amplifier	29.99	65.3 (60.1 to 70.4)		-11.2 (-15.2 to -7.3)	-23.1 (-26.9 to -19.4)

Abbreviations: NA, not applicable; PSAP, personal sound amplification products.

 $^{\rm a}$  The pure-tone average was 500-4000 Hz; the mean dB HL was 34.7 in the right ear and 36.1 in the left ear.

<sup>b</sup> The cost of the hearing aid was the wholesale price paid by the Johns Hopkins University Audiology Clinic. PSAPs were purchased online (Sound World Solutions CS50+, Soundhawk, Etymotic BEAN, Tweak Focus) and storefront retail (MSA 30X Sound Amplifier). All devices were purchased between January 2016 and April 2016.

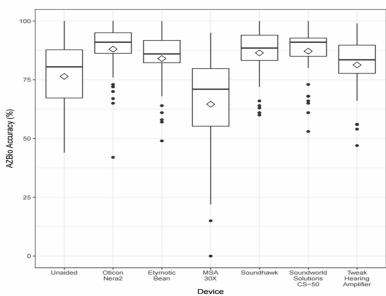
<sup>c</sup> Oticon Nera 2 is a US Food and Drug Administration-regulated hearing aid, whereas all other devices are PSAPs.

jama.com

JAMA July 4, 2017 Volume 318, Number 1

Reed et al., JAMA, 2017

# Results: Primary Outcome



# Study 2: *User Fittings?*

Objective is to examine the impact of user fittings

Greene-Oliver, 2017, Towson U.

# Study 2: Methods

Same criteria and same speech-in-noise outcome

**Out-of-Box Fit**No device manipulation

V. User free to manipulate with instructions and full access to internet

Audiologist Fit
V-Gold-standard fitting with realear measures

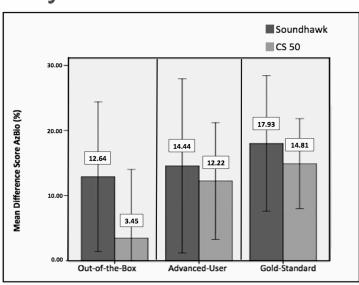
Greene-Oliver, 2017, Towson U.

# Study 2: Results

		PSAPs						
		SOUNDHAWK			CS 50+			
Participant	Unaided	Out-of-the-Box	Advanced User	Gold Standard	Out-of-the-Box	Advanced User	Gold Standard	
001	63	75	87	77	62	82	85	
002	55	54	75	84	54	61	59	
003	62	80	81	84	74	86	82	
004	64	72	69	80	72	69	74	
005	55	70	77	68	60	71	75	
006	64	67	51	64	67	63	67	
007	72	62	60	70	44	66	78	
800	28	58	56	68	48	51	52	
009	52	90	87	81	66	77	77	
Mean	57.16	69.80	71.60	75.09	60.61	69.38	71.97	
SD	12.58	11.12	13.51	7.66	10.42	10.73	10.83	

Greene-Oliver, 2017, Towson U.

# Study 2: Results



Greene-Oliver, 2017, Towson U.

# Discussion

Analysis suggests in ideal conditions two higher-end PSAPs are not significantly different from a hearing aid in speech-in-noise sentence testing while less advanced products may actually degrade speech-in-noise results

Early data suggests user fitting is slightly less impactful than audiologist fitting

OTC hearing care devices may represent a transitory step in hearing healthcare that addresses situation specific needs, reduce amplification gap, reduce time to hearing aid adoption, and increase technologic innovation

Reed et al., JAMA, 2017

# Discussion

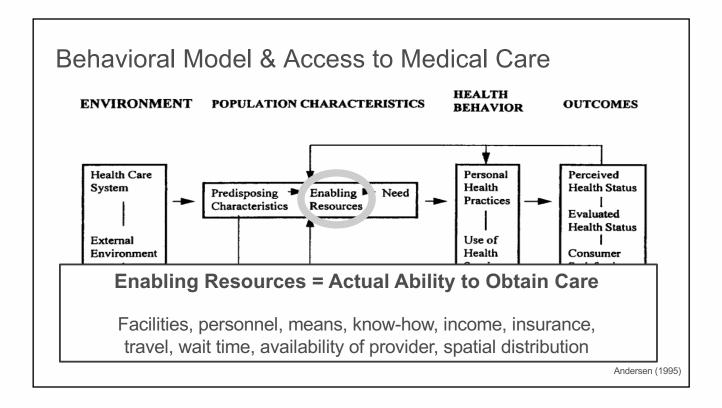
Study limitations include: One-time snapshot, Unilateral fitting, Ideal conditions (clinical setting, clear signal, audiologist fit device), Advantage to directionally capable devices, may not be representative population, analysis of other factors not included

We don't know the impact of real-world factors

Other methods of assessment are important! Quality of Life improvement, subjective perception, etc.

More research needed – efficacy and effectiveness trials!

Effectiveness of Community-Delivered Care: The HEARS Intervention



# Hearing Care Journey

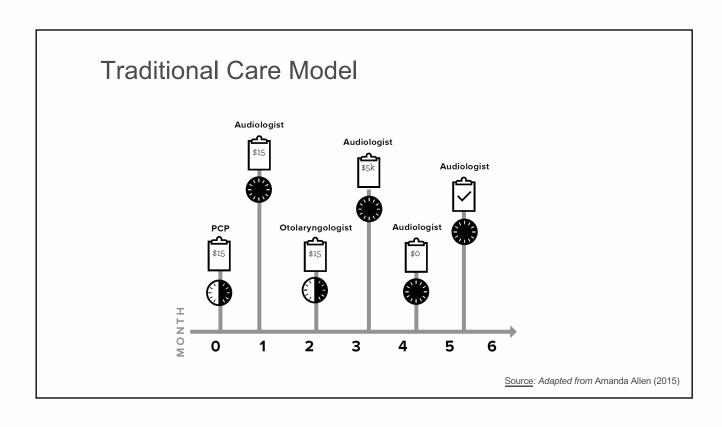


## Our Older Adults

- Independent, subsidized housing community
- Primary residents:
  - Age 62+
  - Age < 62, with disability</li>
- 16-24% live below poverty

- 50% live alone
- About 20% completed education before receiving high school diploma, or equivalent

Centers for Disease Control and Prevention (2008-2012)
City of Baltimore Department of Finance (2015)
US Census Bureau Small Area Income and Poverty Estimates (2011-2015)
Weinberg Senior Living Communities (2017)





# Lack of Minority Older Adult Representation in Population Studies of Hearing Loss = Limitation



# Hearing Aid Use among Adults with Hearing Loss in the U.S., by Income

	60-69 years (n = 291) <sup>b</sup>		70-79 years (n = 571) <sup>b</sup>		80 and older $(n = 523)^b$		m . 1	
	Prevalence	Population Estimates	Prevalence	Population Estimates	Prevalence	Population Estimates	Total Population Estimates	
Total Household Income						F.		
< \$20,000	0.84 (0.74,0.95)	2,132,000	0.83 (0.78,0.88)	1,904,000	0.74 (0.67, 0.81)	1,919,000	5,955,000	
\$20,000-44,999	0.91 (0.83,1.00)	2,853,000	0.77 (0.69,0.85)	2,686,000	0.67 (0.60,0.74)	2,118,000	7,030,000	
> \$45,000	0.75 (0.61,0.88)	2,413,000	0.70 (0.64, 0.77)	1,959,000	0.66 (0.57, 0.75)	1,436,000	5,808,000	
TOTAL UNTREATED <sup>c</sup>		7,397,000		6,549,000		5,473,000	19,419,000 <sup>d</sup>	
Poverty-Income Ratio		ſ		ſ		F	1	
★ 0-1.30	0.88 (0.79,0.96)	1,651,000	0.84 (0.79,0.90)	1,594,000	0.70 (0.61,0.78)	1,312,000	4,557,000	
> 1.30-3.50	0.88 (0.80,0.96)	2,909,000	0.75 (0.68,0.83)	3,413,000	0.70 (0.65,0.76)	2,839,000	9,101,000	
> 3.50	0.73 (0.61,0.85)	2,755,000	0.72 (0.65,0.79)	1,988,000	0.66 (0.57,0.76)	1,822,000	6,564,000	
TOTAL UNTREATED:		7,315,000		6,994,000		5,973,000	$20,283,000^{d}$	

\*Hearing loss defined as speech-frequency pure tone average (PTA) >25 dB HL in the better hearing ear – 500, 1000, 2000, 4000 Hz used to calculate PTA.

\*Sample n's show the number of people in the sample with hearing loss. \*FIPR < 1.3 = corresponds to poverty level where government

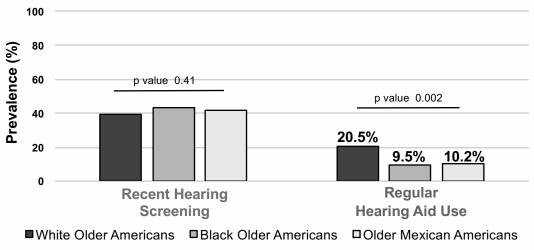
Numbers do not sum to group total because of rounding.

"Numbers differ due to some missing data in the total household income variable."

"Medicaid"

Mamo et al. (2016)





Nieman et al. (2015)

Culturally-adapted & -sensitive health promotion programs aimed at engaging ethnic minorities are effective.

Resnicow et al. (1999); Barrera et al. (2013)



A Community-Delivered, Affordable, Accessible Hearing Care Intervention for Older Adults









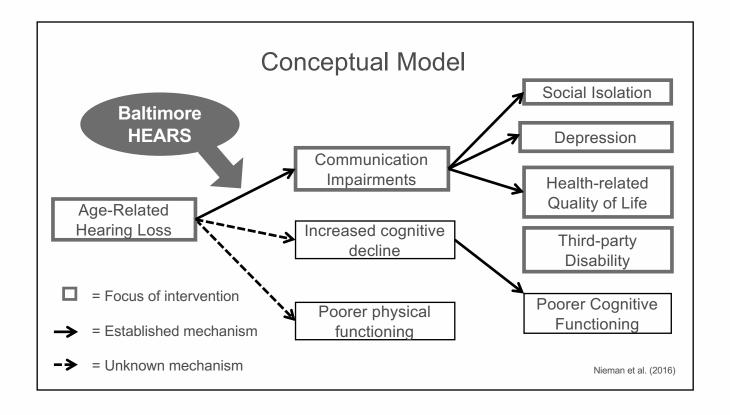




Nieman et al. (2016)



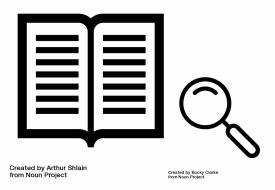
ACCESS to HEALTHY AGING through HEARING.



# The Need

Many hearing aid user guides were rated "not suitable" for older adults in areas of:

- Scope
- Vocabulary & reading grade level
- Layout & typography
- Learning stimulation & motivation

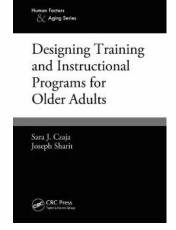


Caposecco et al. (2014)

## Principles of Design

- Text (font & size)
- Colors (hues & high contrast)
- Icons & graphics
- Reading level

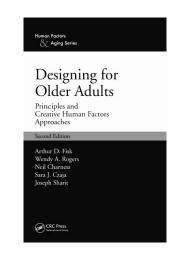




Czaja & Sharit (2013); Fisk et al. (2009)

## Principles of Instruction

- Engage in solving meaningful problems
- Activate relevant previous experience
- Demonstration
- Use new skill to solve problems
- Integrate new skill into daily life



Designing Training and Instructional Programs for Older Adults

Sara J. Czaja Joseph Sharit

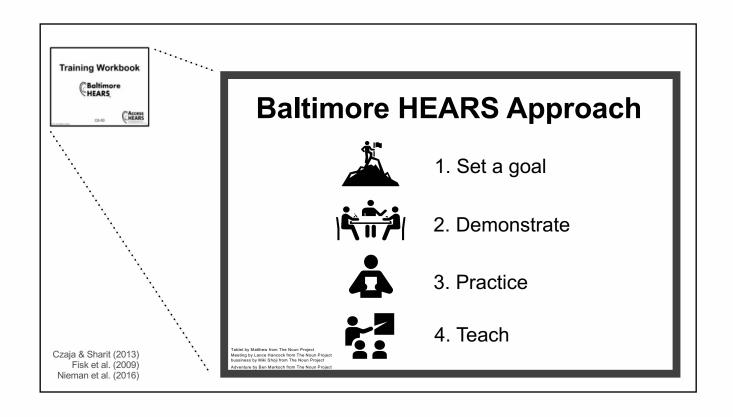
Czaja & Sharit (2013); Fisk et al. (2009)

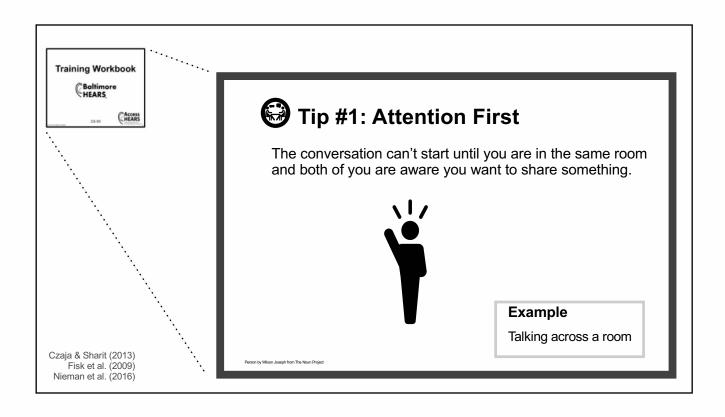
# Principles of Design

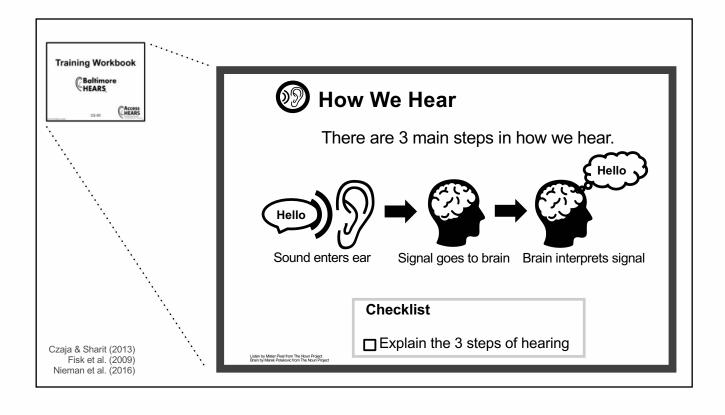
- Text (font & size)
- Colors (hues & high contrast)
- Icons & graphics
- Reading level

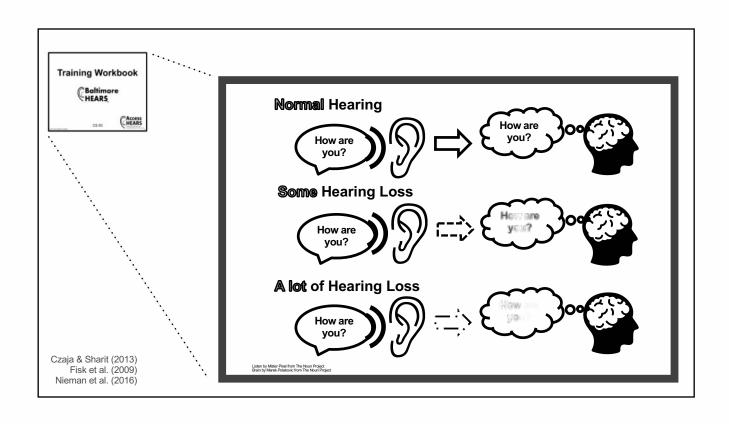


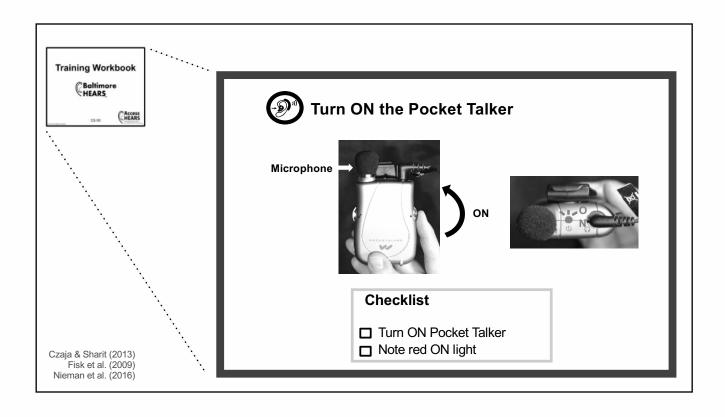
Fisk et al. (2009); Nieman et al. (2016)

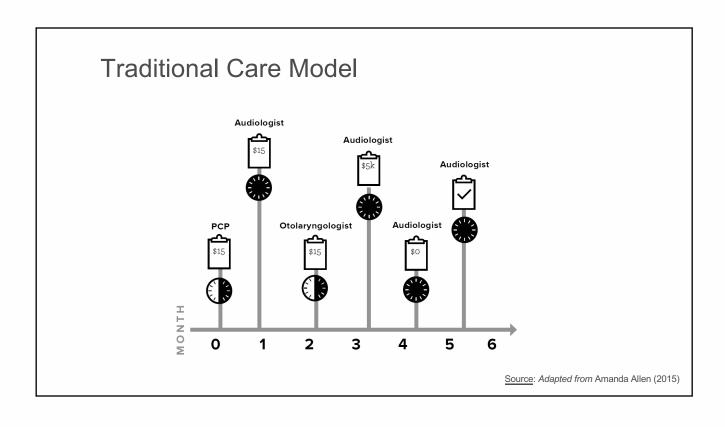


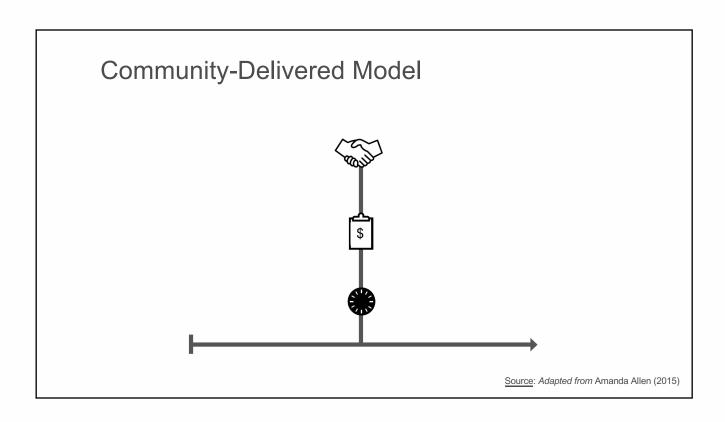












# Study Goals & Methodology

Is a community-delivered, affordable, accessible hearing care intervention....

feasible?

acceptable?

demonstrate preliminary effectiveness?

## Design:

Prospective, randomized control pilot with 3-month delayed treatment group as a waitlist control

Nieman et al. (2016)

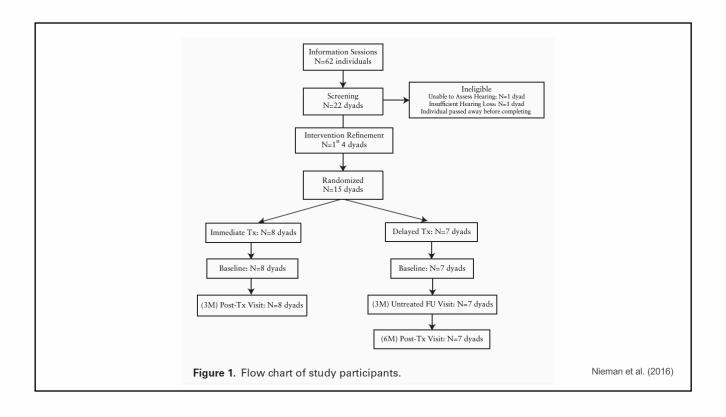
## Our Participant Demographic (N=15)

- 70.1 years old (median)
- 60% minority
- 80% live alone
- 53.4% HS education or less
- \$1,100 monthly household income (median)
- 93.3% mild to moderate hearing loss

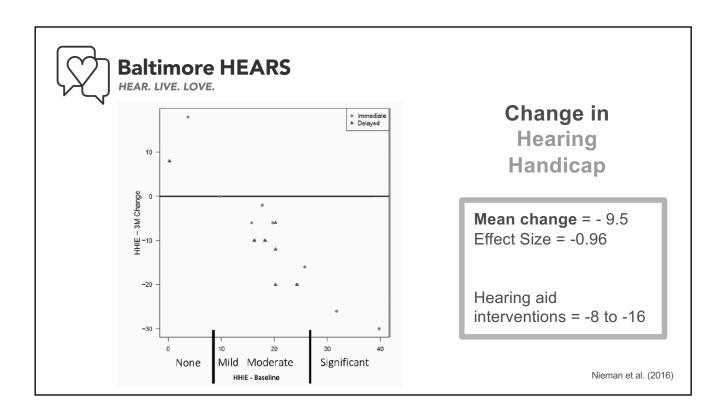


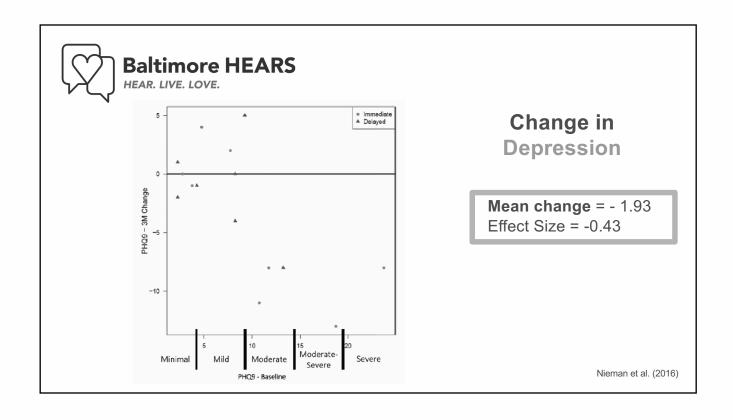
HEAR. LIVE. LOVE.

Nieman et al. (2016)



Outcome Measur	es	
DOMAIN	INSTRUMENT	_
<b>Communication Function</b>	Hearing Handicap Inventory for the Elderly – Screening (HHIE-S)	
	Revised Quantified Denver Scale of Communication (RQDS)	
Social-Emotional Function	UCLA Loneliness Index – Revised	
	Patient Health Questionnaire (PHQ-9)	
<b>Health-related Quality of Life</b>	Short Form – 36 (SF36)	
Acceptability & Satisfaction	International Outcome Inventory – Alternative Interventions (IOI-AI)	
	Focus group	







## **Baltimore HEARS**

HEAR. LIVE. LOVE.

#### Our participants reported:

 87% Would <u>not</u> be able to use his/her device as well <u>without</u> the program

• 93% Benefited from the program

80% Felt more connected with others

100% Would recommend the program

67% Interested in helping train others

• \$87.50 Median amount willing to pay for program

Post-HEARS
Program
Evaluation

Nieman et al. (2016)

## **HEARS Adaptations**



Baltimore HEARS

HEAR. LIVE. LOVE.

Korean-American Community



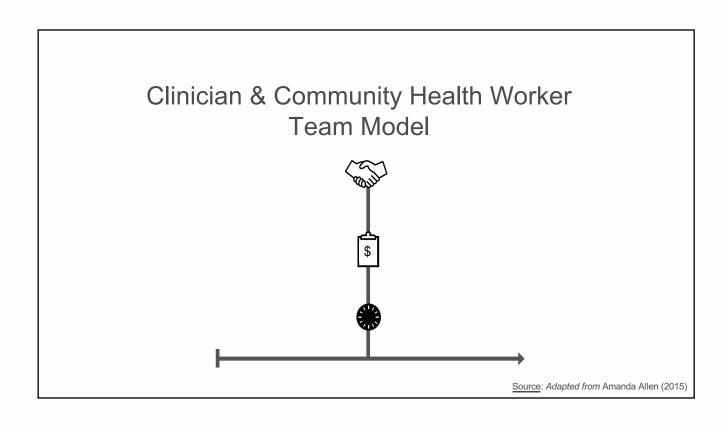
Janet S. Choi

Memory Clinic HEARS



Sara K. Mamo

Choi et al. (2016) Mamo et al. (2017)



## Community Health Worker (CHW)

"A frontline public health worker who is a trusted member of and/or has an unusually close understanding of the community served. This trusting relationship enables the worker to serve as a liaison between health/social services and the community to facilitate access to services and improve the quality and cultural competence of service delivery.

A CHW also builds individual and community capacity by increasing health knowledge and self-sufficiency through a range of activities such as outreach, community education, informal counseling, social support and advocacy."



AMERICAN PUBLIC HEALTH ASSOCIATION For science. For action. For health.

> Community Health Workers (2017) Retrieved from APHA.org

### **Current Status**

- Pilot study of intervention effectiveness with audiologist-community health worker (CHW) team currently ongoing:
  - Two (2) trained CHW interventionists currently operating under audiology supervision
  - Ten (10) residents received audiologist-CHW team delivered intervention as of August 2017
- Plans to expand to broader randomized controlled trial across multiple community residences throughout Baltimore City



HEAR. LIVE. LOVE.

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