



Efficacy and Effectiveness of Direct to Consumer Devices and Interventions

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Learning Objectives

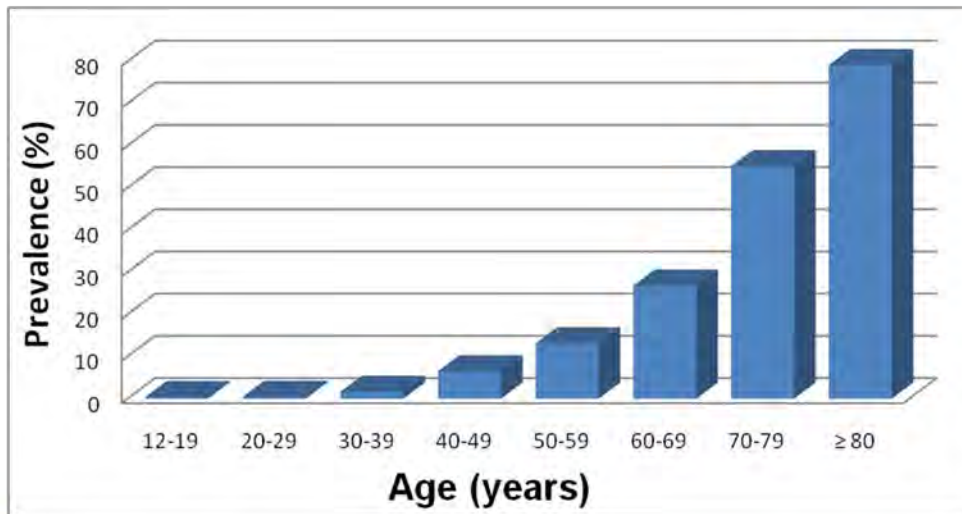
- Introduce background information on direct to consumer hearing care
- Present efficacy studies of direct to consumer technology
- Apply efficacy knowledge to real-world decision making

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

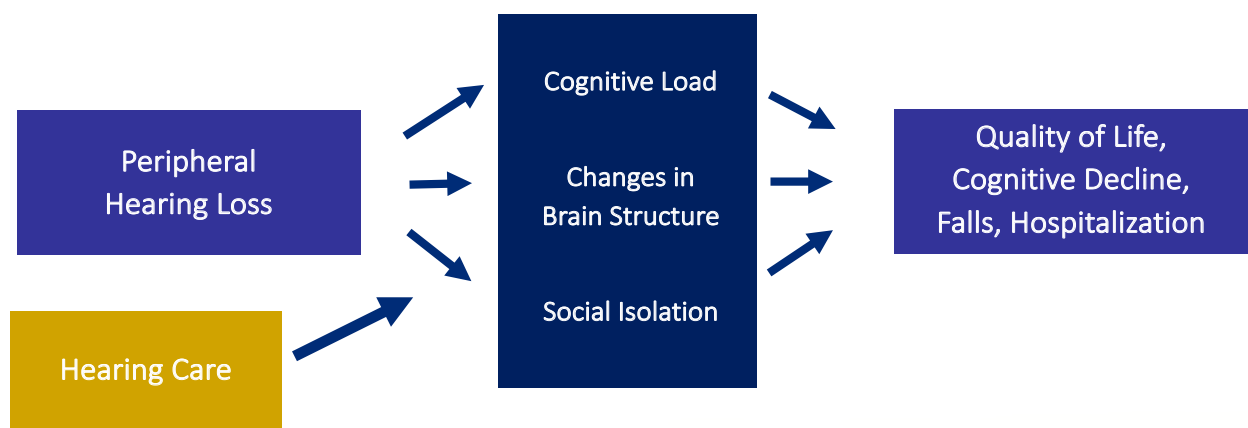
Efficacy of Direct to Consumer Devices

Prevalence of Hearing Loss in the United States, 2001-2008



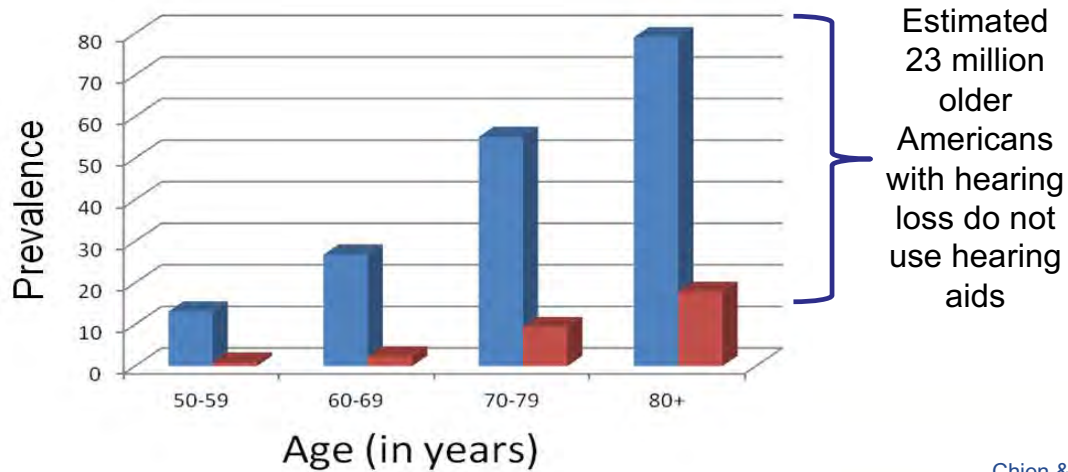
Lin, Niparko, &
Ferrucci, Arch
Internal Med,
2011

Impact of Hearing Loss



Lin et al., Arch Neuro 2011; Lin et al., JAMA Internal Med 2013

Hearing Loss & Hearing Aid Use Prevalence in the U.S. (1999-2006)

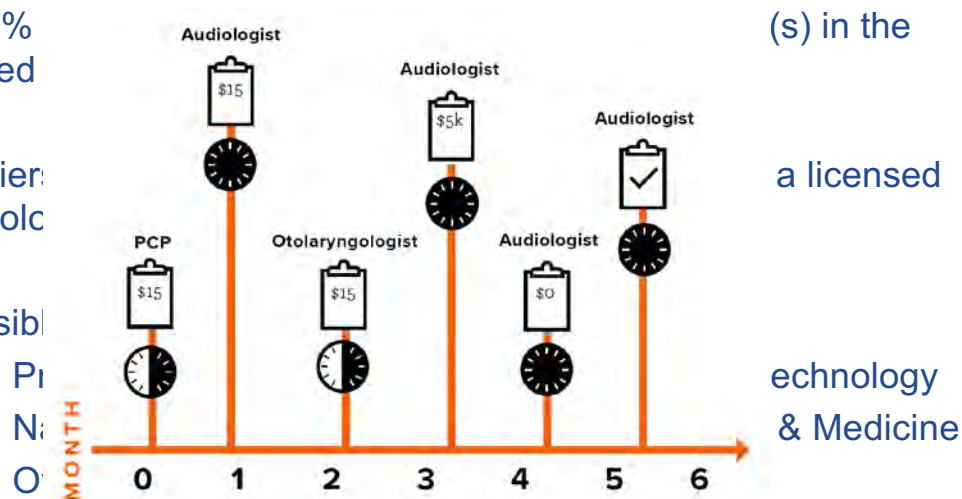


Amplification

- $\leq 20\%$ United

- Barrier: audiologic

- Possible



Source: Adapted from Amanda Allen (2015)

NASEM, 2016; Reed et al., JAMA, 2017; Reed et al., Otolaryngology, 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

Reed et al., JAMA, 2017

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)

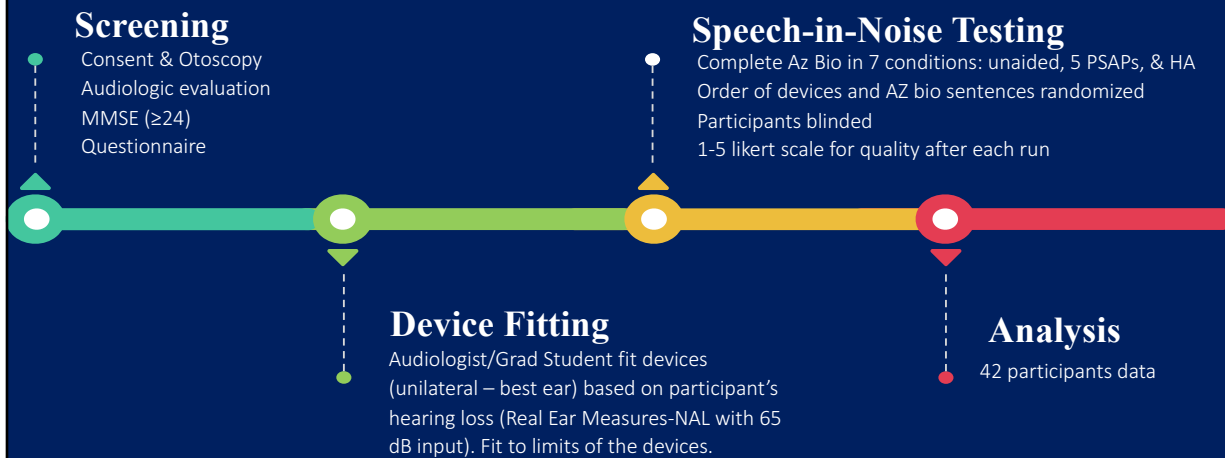
Four electroacoustically acceptable PSAPs from in-house analysis: SoundHawk, SoundWorld Solutions CS-50+, Etymotic Bean, Tweak Amplifier

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

Reed et al., JAMA, 2017

Methods: *Study Design*

Single-blind crossover; within-subject



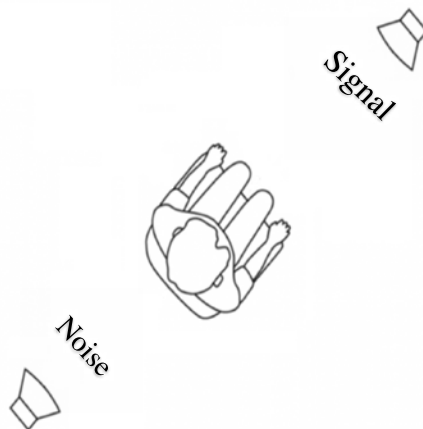
Methods: *Speech-in-Noise Testing*

Calibrated sound booth, speakers, and audiometer

Four-Talker Babble

0° azimuth (Signal), 180° azimuth (Noise)

Presentation Level: Signal at 35 dB, Noise 30 dB (+ 5 SNR)



Reed et al., JAMA, 2017

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)

Reed et al., JAMA, 2017

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^a

	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)		NA
Oticon Nera 2 hearing aid ^c	1910.00	88.4 (84.5 to 92.4)	11.9 (9.8 to 14.0)	
PSAP				
Sound World Solutions CS50+	349.99	87.4 (83.5 to 91.4)	11.0 (8.8 to 13.1)	-1.0 (-2.7 to 0.8)
Soundhawk	349.99	86.7 (82.7 to 90.6)	10.2 (8.0 to 12.3)	-1.8 (-3.5 to 0)
Etymotic BEAN	299.99	84.1 (80.2 to 88.1)	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)	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.

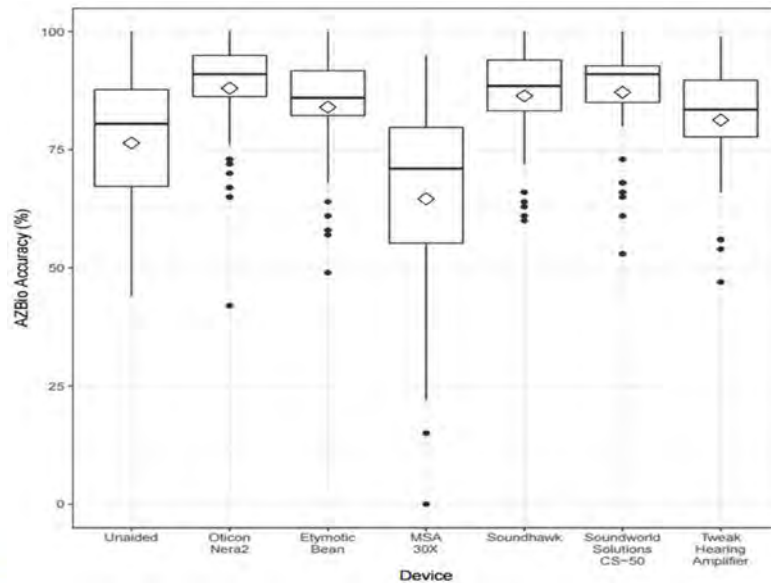
^a The pure-tone average was 500-4000 Hz; the mean dB HL was 34.7 in the right ear and 36.1 in the left ear.

^b 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.

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

Results: *Primary Outcome*



Reed et al., JAMA, 2017

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. Advanced Fit
User free to manipulate with instructions and full access to internet

V. Audiologist Fit
Gold-standard fitting with real-ear measures

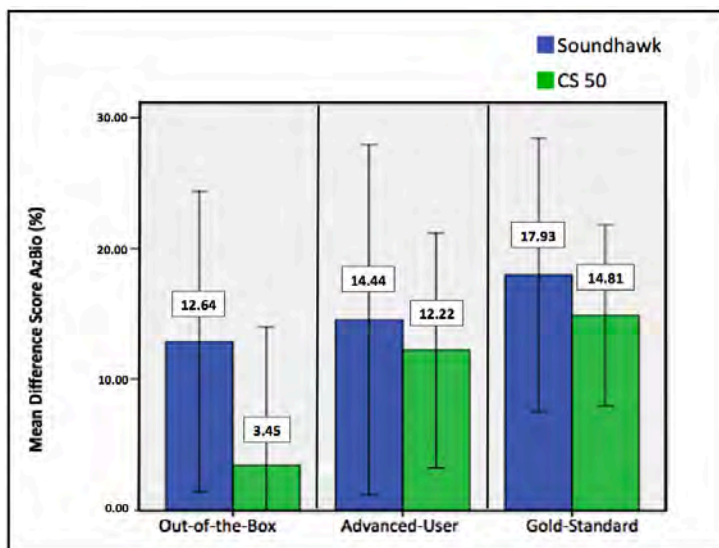
Greene-Oliver, 2017, Towson U.

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
008	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

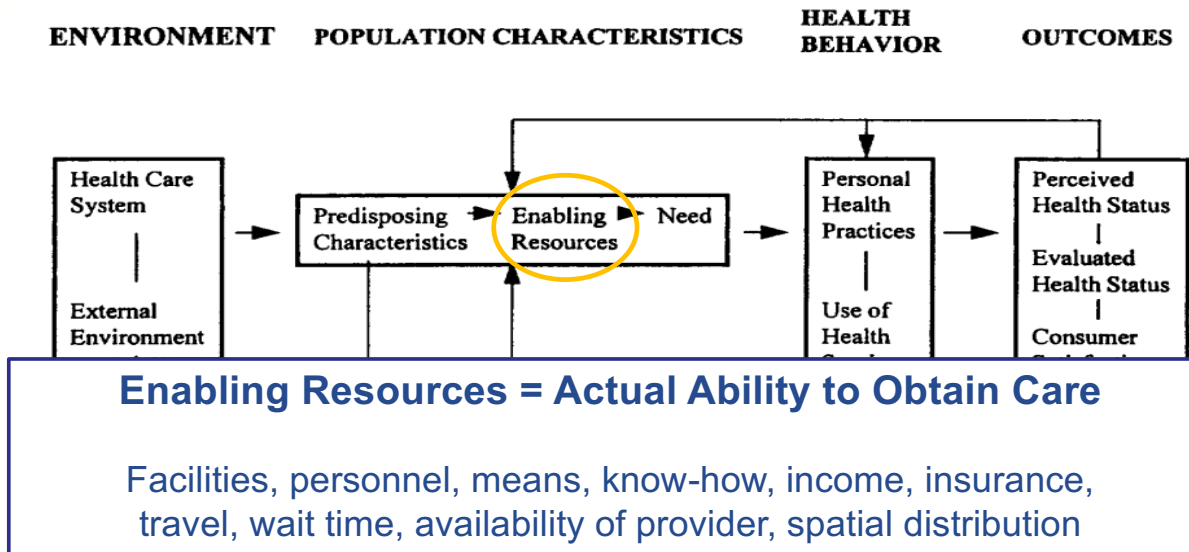
We don't know the impact of real-world factors

More research needed – efficacy and effectiveness trials!

Reed et al., JAMA, 2017

Effectiveness of Community-Delivered Care: The HEARS Intervention

Behavioral Model & Access to Medical Care



Andersen (1995)

Hearing Care Journey

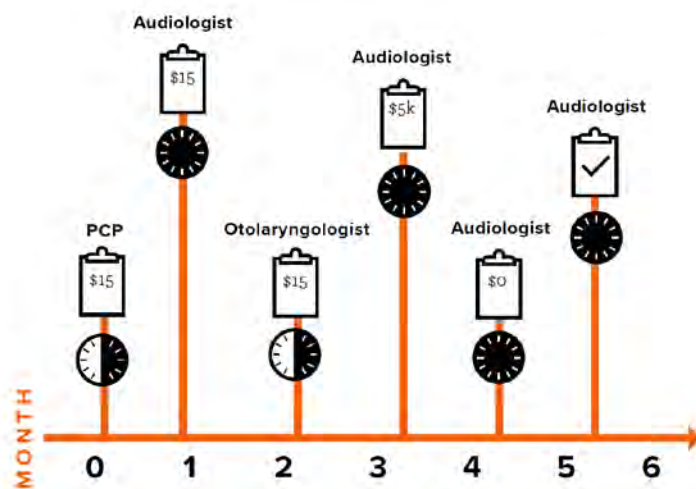


Our Older Adults

- Independent, subsidized housing community
- Primary residents:
 - Age 62+
 - Age < 62, with disability
- 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)

Traditional Care Model



Source: Adapted from Amanda Allen (2015)

Behavioral Techniques in Audiology and Otology

Hearing in the Elderly: The Framingham Cohort, 1983–1985

Part I. Basic Audiometric Test Results



George A. Gates, MD, J. C. Cooper, Jr, PhD;
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Boston, MA; Department of Epidemiology, Harvard School of Public Health, Boston, MA;
School of Medicine, Boston University, Boston, MA; and
School of Medicine, Boston University, Boston, MA

more problem that is becoming more prevalent due to the increasing number of elderly people in our society. These groups of putative etiologic factors are generally recognized: (1) intrinsic, age-related degeneration; (2) noise damage in its two general forms, wear and tear effects from the everyday sounds of our noisy society (noise-induced) and the classic noise-induced hearing loss from recreational and occupational noise overexposure; and (3) the biologic effects of diseases and ototoxic agents (ototoxic) and that superimposed upon a genetic substrate. We use the term, presbycusis—literally, old hearing—to encompass all possible etiologies of



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Prevalence of Hearing Loss in Older Adults in Beaver Dam, Wisconsin The Epidemiology of Hearing Loss Study

Karen J. Cruickshanks,¹ Terry L. Wiley,² Theodore S. Tweed,^{1,2} Barbara E. K. Klein,¹ Ronald Klein,¹
Julie A. Mares-Perlman,¹ and David M. Nondahl¹

ORIGINAL ARTICLE

ONLINE FIRST

The Prevalence of Hearing Impairment and Associated Risk Factors

The Beaver Dam Offspring Study

Scott D. Nash, MS; Karen J. Cruickshanks, PhD; Ronald Klein, MD, MPH; Barbara E. K. Klein, MD, MPH;
F. Javier Nieto, MD, PhD; Guan H. Huang, PhD; James S. Pankow, PhD, MPH; Theodore S. Tweed, MS

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) ^b		70–79 years (n = 571) ^b		80 and older (n = 523) ^b		Total Population Estimates
	Prevalence	Population Estimates	Prevalence	Population Estimates	Prevalence	Population Estimates	
Total Household Income							
< \$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	7,596,000
> \$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^c		7,397,000		6,549,000		5,473,000	19,419,000^d
Poverty-Income Ratio							
* 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	9,161,000
> 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^c		7,315,000		6,994,000		5,973,000	20,283,000^d

^aHearing 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.

^bSample n's show the number of people in the sample with hearing loss.

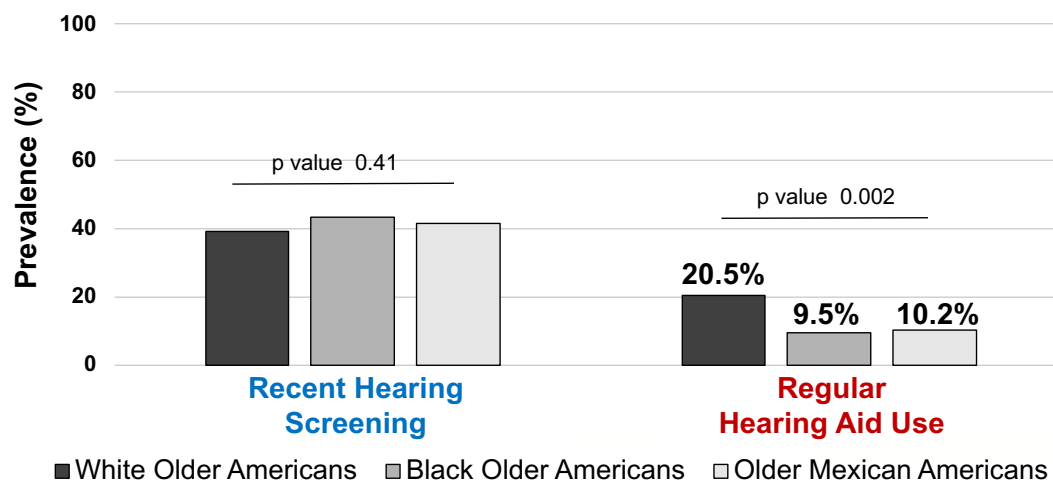
^cNumbers do not sum to group total because of rounding.

^dNumbers differ due to some missing data in the total household income variable.

*FIPR ≤ 1.3 = corresponds to poverty level where government agencies provide services (e.g., supplemental nutrition assistance & Medicaid)

Mamo et al. (2016)

Hearing Screening & Hearing Aid Use Prevalence in the U.S., by Race/ethnicity



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)



Baltimore HEARS
HEAR. LIVE. LOVE.

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

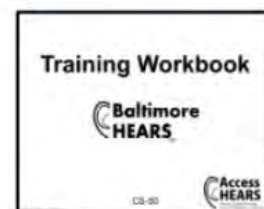
1 Hearing
Screening



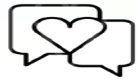
2 Device Fitting &
Orientation



3 Education &
Counseling



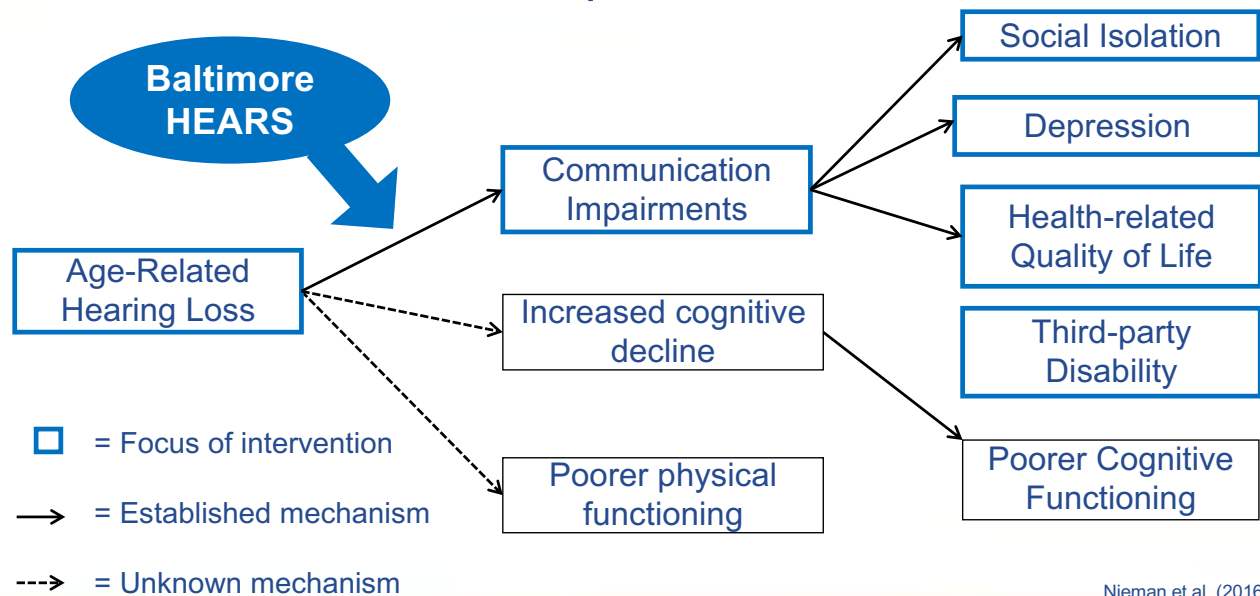
Nieman et al. (2016)



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ACCESS to HEALTHY AGING through HEARING.

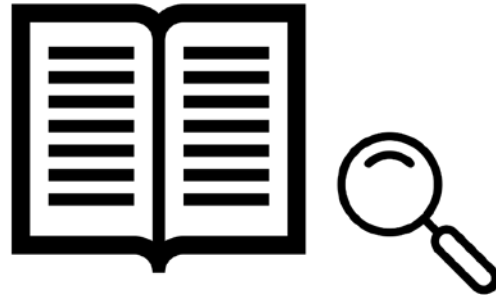
Conceptual Model



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



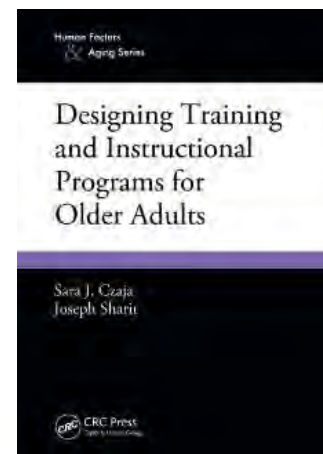
Created by Arthur Shlain
from Noun Project

Created by Ducky Clarke
from Noun Project

Caposecco et al. (2014)

Principles of Design

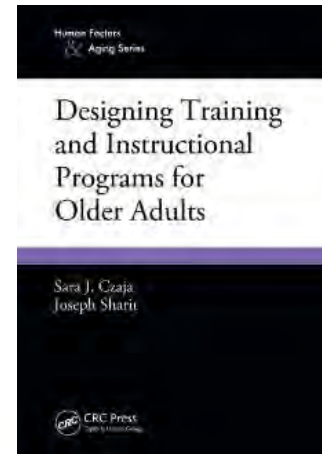
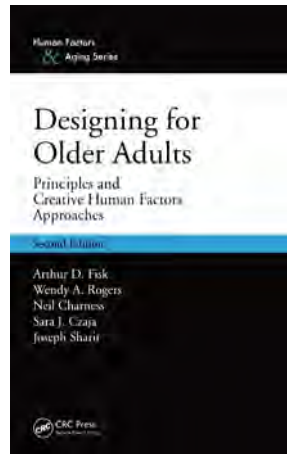
- Text (font & size)
- Colors (hues & high contrast)
- Icons & graphics
- Reading level



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



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)

Training Workbook

Baltimore
HEARS

Access
HEARS

Baltimore HEARS Approach

1. Set a goal

2. Demonstrate

3. Practice

4. Teach

Tablet by Matthew from The Noun Project
Meeting by Lance Hancock from The Noun Project
business by Miki Shoji from The Noun Project
Adventure by Ben Markoch from The Noun Project

Czaja & Sharit (2013)
Fisk et al. (2009)
Nieman et al. (2016)

Training Workbook

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HEARS

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HEARS

Tip #1: Attention First

The conversation can't start until you are in the same room and both of you are aware you want to share something.

Example

Talking across a room

Person by Wilson Joseph from The Noun Project

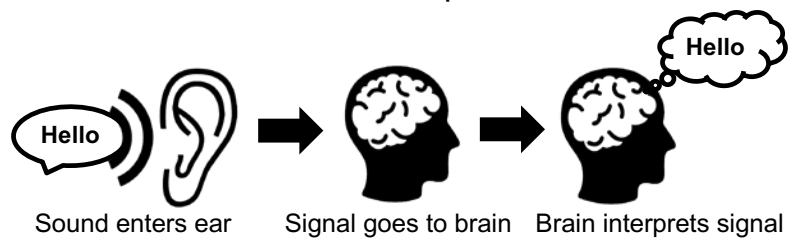
Czaja & Sharit (2013)
Fisk et al. (2009)
Nieman et al. (2016)

Training Workbook

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How We Hear

There are 3 main steps in how we hear.



Checklist

- ☐ Explain the 3 steps of hearing

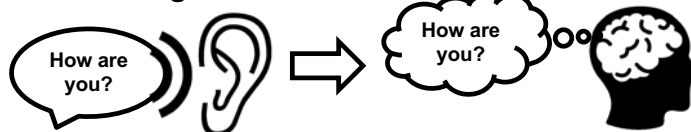
Czaja & Sharit (2013)
Fisk et al. (2009)
Nieman et al. (2016)

Listen by Mister Pixel from The Noun Project
Brain by Marek Polakovic from The Noun Project

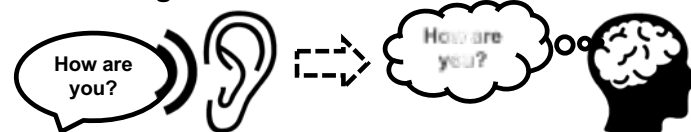
Training Workbook

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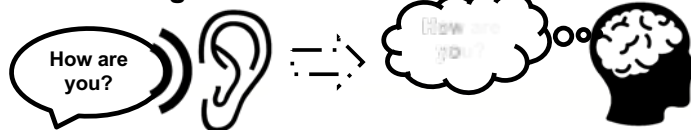
Normal Hearing



Some Hearing Loss



A lot of Hearing Loss



Czaja & Sharit (2013)
Fisk et al. (2009)
Nieman et al. (2016)

Listen by Mister Pixel from The Noun Project
Brain by Marek Polakovic from The Noun Project

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Turn ON the Pocket Talker

Microphone

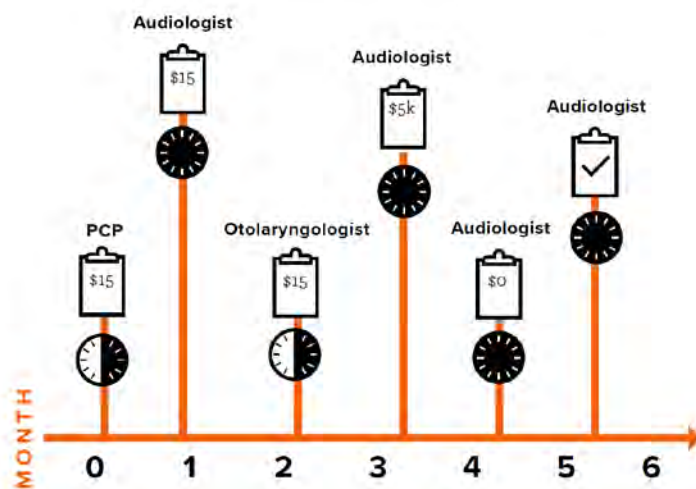
ON

Checklist

- ☐ Turn ON Pocket Talker
- ☐ Note red ON light

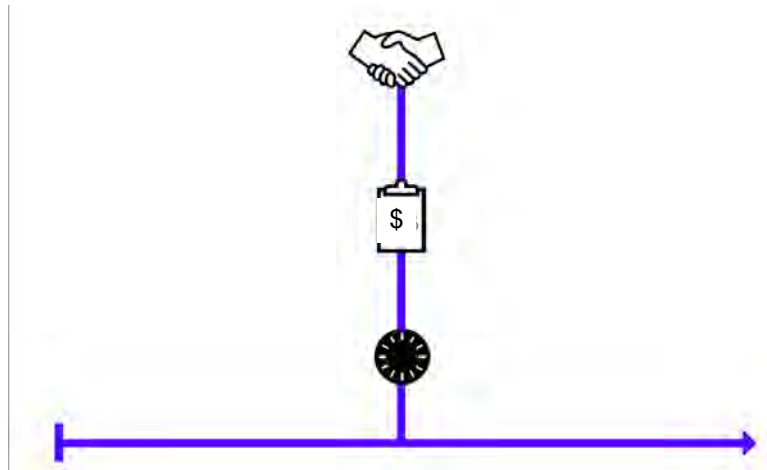
Czaja & Sharit (2013)
Fisk et al. (2009)
Nieman et al. (2016)

Traditional Care Model



Source: Adapted from Amanda Allen (2015)

Community-Delivered Model



Source: Adapted from Amanda Allen (2015)

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



Nieman et al. (2016)

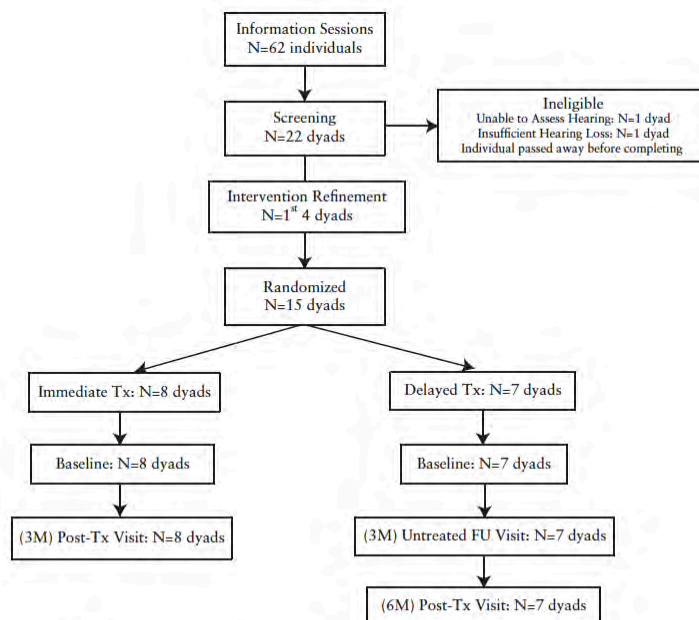


Figure 1. Flow chart of study participants.

Nieman et al. (2016)

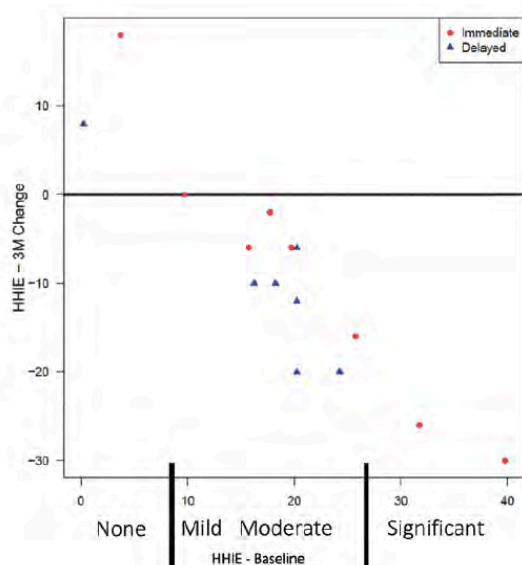
Outcome Measures

DOMAIN	INSTRUMENT
Communication Function	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)
Health-related Quality of Life	Short Form – 36 (SF36)
Acceptability & Satisfaction	International Outcome Inventory – Alternative Interventions (IOI-AI)
	Focus group

Nieman et al. (2016)



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Change in Hearing Handicap

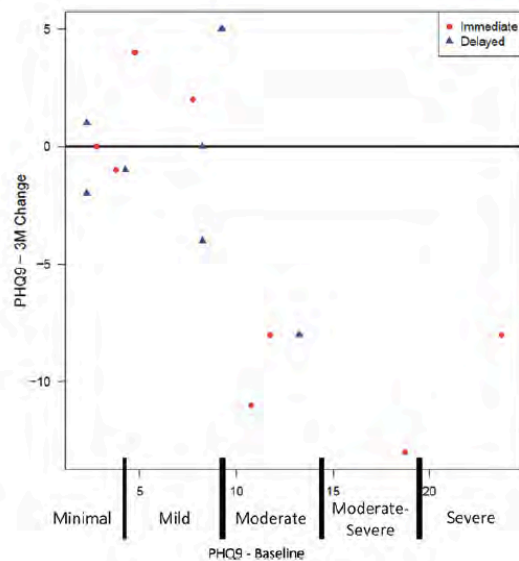
Mean change = - 9.5
Effect Size = -0.96

Hearing aid
interventions = -8 to -16

Nieman et al. (2016)



Baltimore HEARS
HEAR. LIVE. LOVE.



Change in Depression

Mean change = - 1.93
Effect Size = -0.43

Nieman et al. (2016)



Baltimore HEARS
HEAR. LIVE. LOVE.

Our participants reported:

- 87% Would **not** be able to use his/her device as well **without** 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

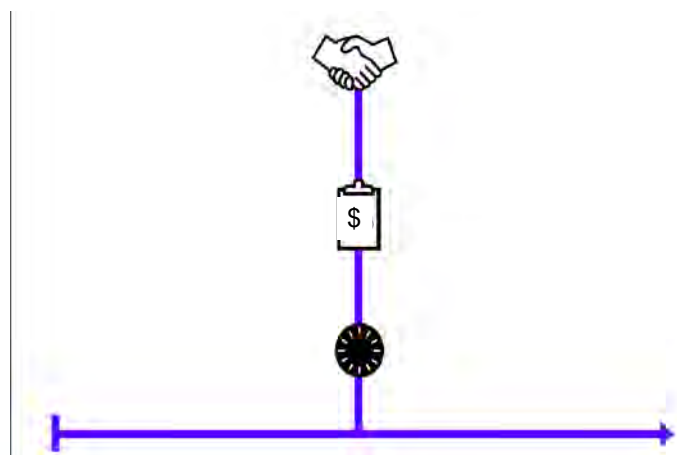
Memory Clinic
HEARS



Sara K. Mamo

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

Clinician & Community Health Worker Team Model



Source: Adapted from Amanda Allen (2015)

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.”



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



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