The Baltimore HEARS Study: Hearing Equity Through Accessible Research & Solutions

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JHM IRB - eForm A – Protocol

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1. Abstract

a. Provide no more than a one page research abstract briefly stating the problem, the research hypothesis, and the importance of the research.

Hearing loss is the third most prevalent chronic condition among older adults in the United States, but the impact of hearing loss on the social, cognitive, and physical functioning of older adults is often underestimated. Hearing loss is independently associated with poorer cognitive functioning, accelerated cognitive decline, incident dementia, social isolation, and poorer physical functioning. Large studies on the epidemiology of hearing loss and rates of hearing health care, such as data from NHANES, demonstrate that the prevalence of hearing loss increases with age, ranging from greater than 45% among those aged 70-74 years to greater than 80% for adults 85 years and older with less than 20% of adults with hearing loss utilizing hearing aids (Lin et al., 2012). The NIDCD has called for new approaches to improve the affordability and accessibility of hearing health care, and we are investigating new models of care to address the gap between the number of people with age-related hearing loss and the number of people who use hearing aids.

Baltimore HEARS (Hearing Health Equity through Accessible Research & Solutions) is a hearing care intervention that has been culturally tailored for a minority, low-income population. Previous related projects from our research group investigated the use of hearing health care among minority older adults with low-income backgrounds, developed the HEARS intervention to provide affordable, accessible hearing care to older adults (IRB# 00088278), and investigated the feasibility of delivering the intervention through a community health worker (CHW)-delivery model (IRB#00079481). The objective of this proposal is to conduct a randomized controlled trial of the HEARS intervention as delivered by an audiology-CHW care team. The trial will be conducted in partnership with several Baltimore area residences for older adults.

We will evaluate outcomes at 3-months post-intervention by comparing an immediate treatment group versus a 3-month waitlist control group. The primary outcome is communication function as measured by the Hearing Handicap Inventory for the Elderly-Screening (HHIE-S). Secondary outcomes include measures related to social and emotional function, such as quality of life, depression, and loneliness. Although the primary outcome will be collected at 3-month post-intervention, participants will be followed for 12 months post-intervention in order to obtain data on reflective of longer-term outcomes related to the intervention.

A prior feasibility study of the HEARS intervention (IRB# NA_00088278) demonstrated the feasibility, acceptability, and preliminary efficacy of a community-delivered hearing program in reducing communication impairment and depressive symptoms (Nieman et al, 2017). Preliminary observations in an ongoing pilot study (IRB# 00079481), suggest similar findings with the intervention delivered by trained CHW's. This randomized controlled trial is a first-in-kind study designed to investigate the effects of a community-based hearing care intervention targeting a vulnerable urban population.

2. Objectives (include all primary and secondary objectives)

The primary objective of this study is to conduct a randomized controlled trial studying the efficacy of the HEARS intervention in reducing self-reported hearing handicap as delivered by trained community health

workers (CHW). The primary endpoint is change in score on the HHIE-S from baseline to 3-month post-randomization in the immediate vs. waitlist control group. The project aims to recruit and enroll eligible community-dwelling older adult residents from independent, affordable housing to receive the intervention. After 3 months of follow-up post-randomization, participants in the waitlist control group will also be offered the HEARS hearing intervention. All participants (also referred to as "clients" in the HEARS intervention materials) will then be followed observationally for up to 12 months post-intervention. Participant outcomes will be collected through phone calls and in-person visits. Long-term follow-up will provide an understanding of both short- and long-term effects of a community-based hearing care program on participants' communication, social, and emotional function. Outcome measures will assess various domains such as communication function, depression, loneliness, and social connectedness, with the primary outcome being communication function as measured using the Hearing Handicap Inventory for the Elderly-Screening (HHIE-S).

3. Background (briefly describe pre-clinical and clinical data, current experience with procedures, drug or device, and any other relevant information to justify the research)

Hearing aids, along with adequate counseling and education, form the foundation of a comprehensive approach to hearing health care. Hearing aids can improve audibility, communication, and may help promote better general health and social engagement in older adults (Boi et al., 2012). While an important component of hearing health care, hearing aids are underutilized. Only 15% of older adults undergo hearing screening and less than 20% of older adults with demonstrated hearing loss use hearing aids (Kochkin, 2009; Popelka et al., 1998; Gates et al., 1990). This demonstrates a gap in care that the NIDCD, Healthy People 2020, and the National Academies of Science, Engineering, and Medicine (NASEM) have identified and, subsequently, called for the development of additional models of affordable and accessible hearing health care (Donahue et al., 2010; NASEM, 2016).

One NHANES study found that 8.3% of Blacks and 12.9% of Mexican or Hispanic elderly participants as compared to 19.9% of Whites utilized hearing aids on a regular basis and only 12.5% of those with < $20,000 household income report hearing aid use as compared to 22.9% with household income of ≥ $45,000 (Lin et al.,2011). This study uses the Baltimore HEARS intervention that was developed to aid in NIDCD's charge to deliver hearing health care for all. Baltimore HEARS is an intervention that provides affordable and accessible hearing care to minority and low-income older adults. In previous pilot studies (IRB# NA_00088278 and IRB#00079481), we used a community-engaged research approach to develop a culturally-tailored, community-delivered hearing care intervention that included hearing screening, education on age-related hearing loss, communication strategies, and provision of a low-cost over-the-counter amplification device. The initial pilot study was delivered by a medical expert (i.e., an ENT resident) and demonstrated the feasibility and acceptability of the novel accessible and affordable approach to hearing care intervention for low-income, minority older adults. The follow-up pilot study tested the feasibility of delivering the hearing loss intervention (HEARS program) in the community through trained CHWs.

The current study aim is to conduct a RCT of the HEARS intervention delivered by an audiologist-CHW care team utilizing an immediate treatment and 3-month delayed treatment group of low-income and primarily minority older adults living independently in Baltimore. Lessons and insights acquired through direct encounters with pilot participants and advisory board meetings informed the design and procedure of the proposed study. Active engagement with community representatives through a Community Advisory Board will be ongoing.

4. Study Procedures

a. Study design, including the sequence and timing of study procedures (distinguish research procedures from those that are part of routine care).

PARTICIPANTS

The study cohort will consist of older adults (≥ 60 years old) with age-related hearing loss who are not currently utilizing a hearing aid or amplification device. Participants will be encouraged to involve a self-identified communication partner willing to complete the program alongside them. Communication partners are any individuals with whom the participant engages in daily spoken communication.

A total of 175 participants will be recruited in partnership with Weinberg Senior Living and Catholic Charities, local nonprofit agencies that provide and oversee independent, subsidized housing buildings for low-to-moderate income older adults in Baltimore and local community sites. Weinberg Senior Living, which comprises ~ 1500 units of senior housing in 13+ buildings in the Baltimore area, has been our community partner in previous studies (IRB# NA_00088278 and IRB# 00079481) and the current study (IRB#00152093).

Ms. Tiffany Nicolette, Director of Resident Services for Weinberg Senior Living, will assist the study team in communicating with building service coordinators and participant recruitment efforts. We will also work with Catholic Charities, which has 20+ building for senior living in the Baltimore metropolitan area. Mr. Arnold Eppel, Division Director for Senior Services of Catholic Charities, and his staff will assist the research team in recruiting participants and providing space for intervention delivery. Participants will also be recruited from other community sites (such as Baltimore City senior centers and social clubs) and independent senior living buildings in Baltimore City.

COMMUNITY PARTNERS & ADVISORY BOARDS

The Hearing and Speech Agency (HASA), a nonprofit audiology clinic in Baltimore, is a study partner providing meeting space and audiological expertise to support the research team in conducting study-related activities. HASA's Executive Director (Erin Stauder) is a member of the study's Community Advisory Committee and has been in regular communication with the research staff regarding the objectives and logistics of the project. HASA was identified as a study partner given that it is a facility staffed with audiologists and maintains community-based initiatives throughout Baltimore.

A Community Advisory Board was previously established to guide the development of the Baltimore HEARS intervention. Members of the Community Advisory Board reflect key stakeholders and primary users within the community. Stakeholders include partners such as local, nonprofit hearing agencies, representatives from area agencies on aging, and service coordinators from partner agencies providing care to older adults. Users within the community include low-income and minority older adults with hearing loss and their communication partners. The Community Advisory Board reflects the diversity of our community partners in terms of race/ethnicity, age, educational level, and hearing loss status. The study staff meets with the Community Advisory Board on a quarterly basis.

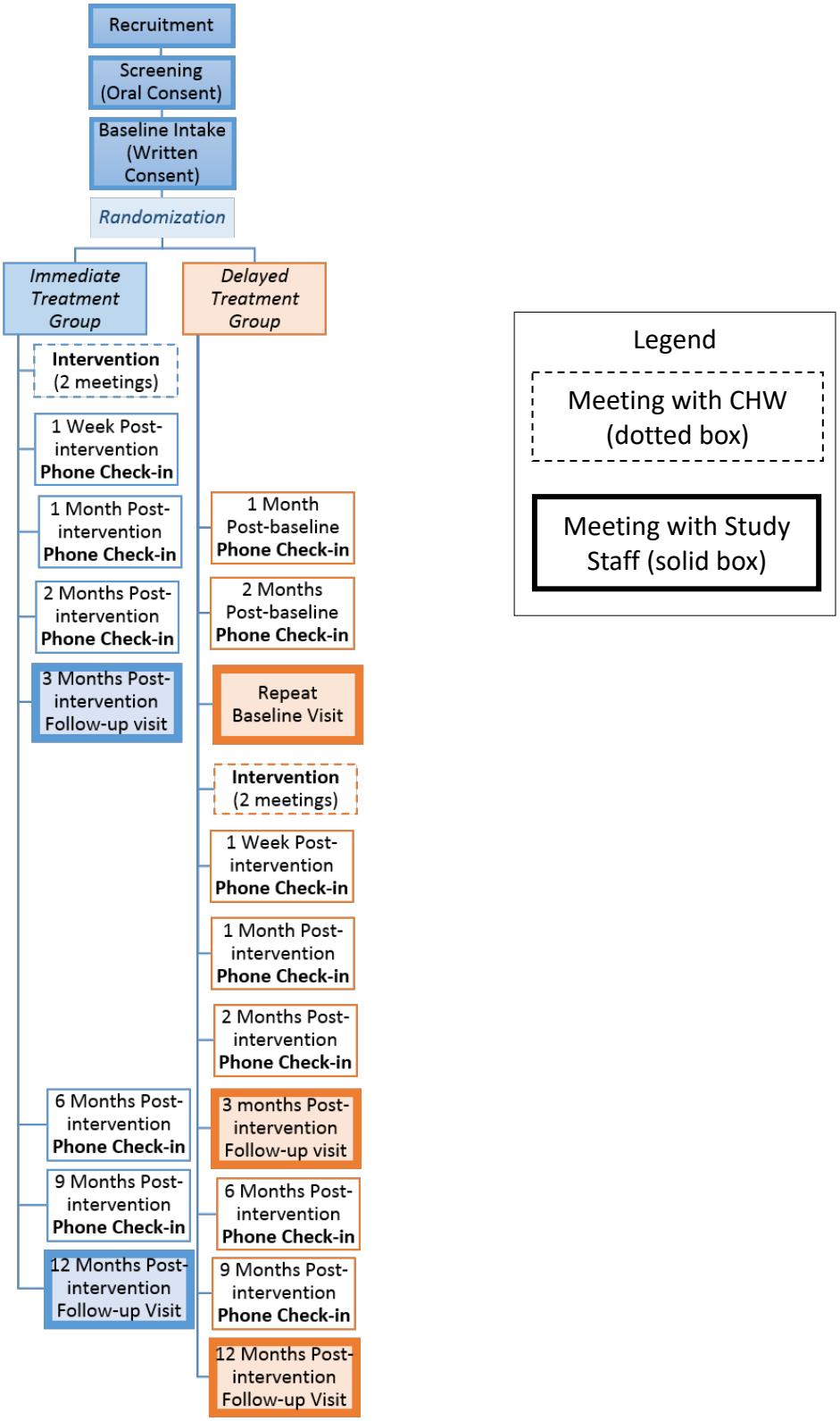
A Scientific Advisory Board was also previously established to guide the scientific development of the Baltimore HEARS study. This committee is comprised of study investigators with expertise in gerontology, audiology, otology/otolaryngology, behavioral intervention research, community-based participatory research (CBPR), training of CHW's, and social design. The study staff meets with the Scientific Advisory Board on a quarterly basis.

STUDY DESIGN

Initially, the study will be based in several buildings from Weinberg Senior Living and Catholic Charities in Baltimore. Additional buildings from either of the two organizations or community sites may be added in order to reach recruitment goals. These community sites will be identified through referrals from our CAB members. These include sites such as senior centers and other community sites (such as the Zeta and Waxter Senior Centers run by Baltimore City, Rhome and Co-op by Civic Works).where we coordinate directly with the directors and leadership of these centers. The study may also recruit participants and build partnerships through recruitment opportunities at community events. See Figure 1 for the overall study design.

Recruitment efforts will include posters, flyers, mailings, brochures, and information sessions at each site that will be led jointly by trained CHWs and the study team targeting residents who may be eligible as study participants and their communication partners. Following the information sessions, interested potential participants will undergo screening by the study staff after providing oral consent. Given the minimal risk involved with hearing screening, oral consent will be given to reduce the time burden on a potential participant in the screening process. Screening involves questions regarding demographics, self-reported perceived hearing handicap, and pure-tone audiometric threshold testing. Hearing screening will be conducted using a portable, remote audiometer specifically designed for field-testing without a soundproof booth. When interacting with potential participants, study staff will utilize an amplification device (such as the SuperEar or Pocketalker) to ensure individuals are able to hear the study staff. Potential participants who are eligible and interested in participating in the study will be asked to provide their contact information.

Figure 1: Overall Study Design



Once deemed eligible based on review of study criteria, the study team will review the full written consent form and study details prior to the start of any study activities with both the study participants and their communication partners (if one is available and interested). The written consent form will cover details including the study objectives, benefits for participating, steps the study team will take to minimize breach of confidentiality, and opt-in/opt-out section for audio-recording. The purpose of collecting audio-recordings will be for study monitoring and quality assurance. Following written consent, the study staff will obtain baseline measures from surveys such as those detailed in Table 1. Following collection of baseline measures, the participants will be randomized into one of two groups: 1) immediate treatment group and 2) 3-month delayed treatment group, which will function as a control group. Communication partners will be asked to attend meetings with their study participants to complete baseline and follow-up self-report questionnaires that assess domains such as third-party disability and program evaluation. Examples of outcome measures for communication partners are detailed in Table 2.

Table 1: Participant baseline surveys

Domain	Tests	Number of Items	Time Required (min)
Hearing & Communication	Hearing Handicap Inventory for the Elderly-Screening (HHIE-S)	10	2
Quality of Life	Adapted Quality of Life – AD	12	5
Social Isolation & Loneliness	UCLA-Loneliness Index-Revised	20	5
	Cohen Social Network Index	12	5
Depression	Patient Health Questionnaire (PHQ9)	9	2
Health-related Quality of Life	Short Form-12 (SF12)	12	5
Cognitive Function	Montreal Cognitive Assessment (MoCA)	11	10
Health Literacy	Rapid Estimate of Adult Literacy in Medicine – Short Form (REALM-SF)	7	2
Computer Self-Efficacy	Modified Computer Self-Efficacy Scale	10	5
Technology Self-Efficacy	Adapted Attitudes Towards Computers Questionnaire	10	5
Total		113	46

Table 2: Communication partner baseline surveys

Domain	Tests	Number of Items	Time Required (min)
Third-Party Disability	Significant Other Scale for Hearing Disability (SOS-HEAR)	27	10
	Hearing Impairment Impact – Significant Other Profile	20	5
Program Evaluation	International Outcome Inventory – Alternative Interventions, Significant Others (IOI-AI-SO)	14	10
Total		61	25

The immediate treatment group will receive the intervention from a trained CHW in their community. Intervention details are further described below. Following completion of the intervention with the CHW, the study staff will follow-up with the participant at 1 week, 1-month, 2-months, 6-months, and 9-months post-intervention via phone calls. At 3-months and 12-months post-intervention, the study staff will schedule to meet with the participant in-person to collect primary and secondary outcome measures as well as program evaluation. The overall flow for the immediate treatment group is shown in Figure 2.

Participants randomized to the delayed treatment group will receive a call from study staff 1- and 2-months after their baseline measures to verify contact information and remind them of their study involvement. They will be scheduled for a visit by study staff 3-months after their baseline visit to collect repeat baseline measures. After this visit, participants will be scheduled to receive the intervention from a trained CHW. Once study staff is notified by the CHW of intervention completion, the study staff will follow-up with the intervention recipient at 1-week, 1-month, 2-months, 6-months, and 9-months post-intervention via phone calls. At 3-months and 12-months post-intervention, the study staff will schedule to meet with the participant to collect primary and secondary outcome measures and program evaluation. CHWs will not be involved in any aspect of data collection from study participants and will not have access to collected data. The overall flow for the delayed treatment intervention group is shown in Figure 3.

Following all intervention deliveries and follow-up measures (detailed in Table 1 and 2), a post-intervention focus groups and/or semi-structured interview will be scheduled. Participants and their communication partners are invited to attend sessions designed with gather additional insight into how the intervention was perceived and can be improved. The session will focus on topics, such as the following: hearing loss (i.e., What do you think about hearing now? Do you think of it differently? What does your hearing mean to you now? How does your hearing loss factor into daily life now? What does hearing loss mean in communities like yours? What would you tell your friend or family member about hearing loss?), treatment of hearing loss (i.e., What do you think about treating hearing loss? Does it work? What would you tell your friend or family member about treating hearing loss?), the Sidekick device (i.e., What did you think about the hearing device? How much did you use the hearing device? What would have made it better? Something you would use more often? Do you plan to use the hearing device in the future? What would you say about the hearing device to your friend or family member?), and about learning technology (i.e., What do you think about how you learned how to use the hearing device? What could make it easier? Better? How did the study make it difficult? How did the study make it easier? How would you teach your friend or family member to use the hearing device?).

In addition the phone calls between in-person visits with participants, the study team may be in touch with participants to maintain updated contact information and participant engagement. For intervention fidelity monitoring, the study team will review audio-recordings of randomly selected HEARS interventions between CHW and participant. This procedure allows the study team to assure the quality and accuracy of the intervention. All participants will have previously indicated their consent to being audio-recorded during the written consent process. The study team will be the sole managers of the audio-recording devices and securely store the audio files in an encrypted and password-protected database.

Figure 2: Immediate Intervention Group Participant Flow

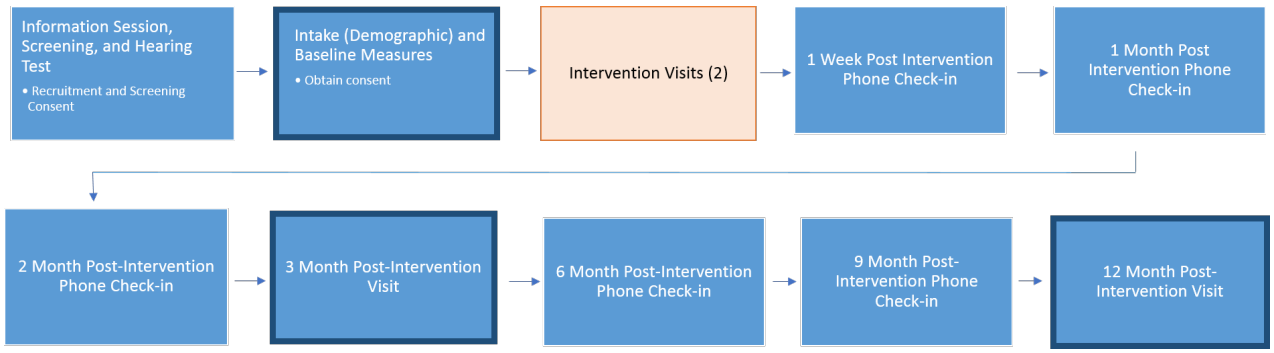
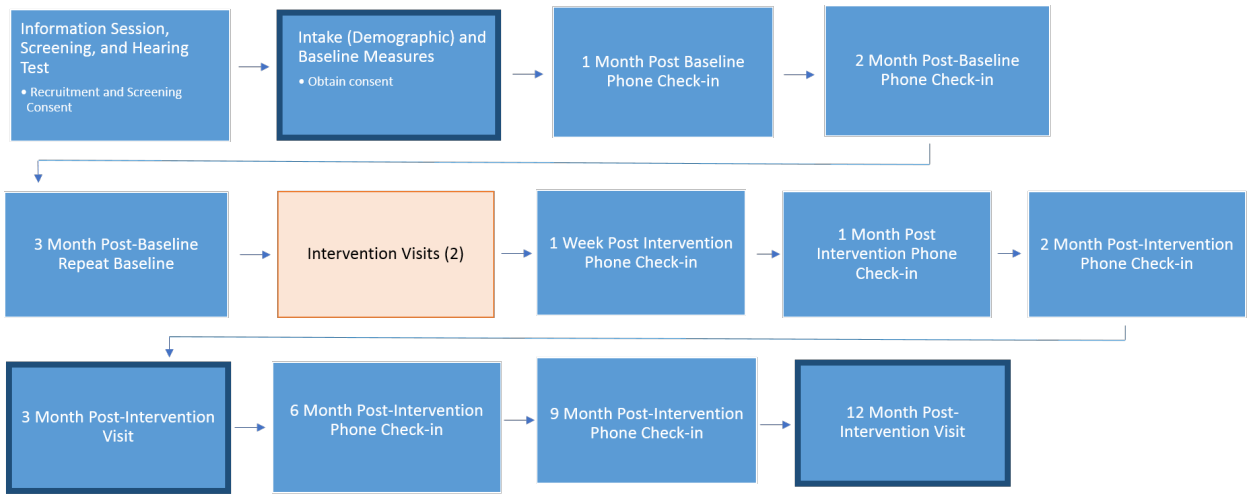


Figure 3: Delayed Intervention Group Participant Flow



INTERVENTION DESCRIPTION

The HEARS intervention is a community-delivered hearing care intervention that provides education on hearing loss, communication strategies, and provision of an over-the-counter amplification device. The program is designed for older adults and has been previously piloted locally in partnership with Weinberg Senior Living. The intervention involves two one-hour meetings between the participant and his/her CHW. CHW's will be trained to deliver the HEARS intervention to participants through a separate ongoing study (IRB#00152093).

During the first meeting, the CHW will introduce the HEARS program and review communication strategies and basics of age-related hearing loss, as well as options for amplification including the differences between over-the-counter amplifiers used in the program versus conventional hearing aids typically acquired through audiologists. The second meeting will consist of a step-by-step fitting and orientation to the participant's amplifier of choice. Based on the needs of the participant and the discretion of the CHW, additional meetings may occur to ensure the participant is comfortable using his/her amplifier independently. .

The device options used in this current study are similar to devices used in previous studies (IRB #NA_00088278). All of the devices are currently available over-the-counter and represent low-cost, self-fit amplifiers. One of the devices, called the Sidekick, was developed by Sound World Solutions (SWS) and relies on in-situ fitting and programming. The device was developed by Stavros Basseas, former chief audiological engineer for GNResound, one of the major hearing aid manufacturers, and David Green, a MacArthur Fellow and social entrepreneur known for developing disruptive public health-related technologies. Dr. Lin (PI) collaborates with David Green, and SWS had previously expressed their willingness to work with us on this study. Although the device is limited compared to the gold standard of custom-fitted hearing aids provided conventionally by an audiologist, it provides an affordable, accessible, and audiologically sound option that is potentially scalable to others with limited resources. The SWS device, as an amplification device, has undergone testing by SWS and is currently available on the market. The FDA, consistent with all personal hearing devices, does not regulate the device. Additional amplification devices (e.g., Sonic Technology Products' SuperEar SE9000) that will be offered in the study represent other models of affordable sound amplifying and listening devices that are available on the market and directly available to consumers. Similar to the SWS device, all devices are considered personal sound amplifier products (PSAPs) and are not regulated by the FDA.

INTERVENTION TIMING AND ADHERENCE

All analyses will be conducted according to the intention to treat (ITT) principle: participants will be analyzed as they were randomized, irrespective of the receipt of treatment. Individuals would be considered as not adhering to treatment if they do not complete the two-session intervention (i.e., did not attend all scheduled intervention meetings) or do not use the amplification device 1 or more hours per day at 3-months post-intervention.

Please see Statistical Analysis Plan (SAP) in Supplemental Documents for more information.

PRIMARY OUTCOME DATA COLLECTION MODE AND WINDOW

Primary outcome survey collection will be allowed up to 6 months post intervention visit (for immediate group) or 6 months post-baseline visit (for delayed group). If a participant is unable to meet in person to provide their answers, phone substitution will be allowed after 3 attempts to meet with the participant in person.

If any of the 10 questions are not answered, the primary outcome will be invalid. The ideal mode of collection will be in person, but if this is not possible, phone substitution is allowed.

Please see Statistical Analysis Plan (SAP) in Supplemental Documents for more information.

COVID-19 Protocol

Starting Friday, 3/13/2020, all in-person meetings (including meeting between HEARS Staff and Clients and meetings between Teachers and Clients) have been paused due to COVID-19.

Teachers have been counseled to do all of their troubleshooting over the phone and to postpone all in-person visits until the end of COVID-19 stay-at-home order is lifted. If any Client needs a device replacement, a staff member will arrange a no-contact drop off with the client and a Teacher can help the client set up the device if they have any questions. The HEARS Trainer is also available to help with phone troubleshooting if needed.

In-person data collection will not permitted and all check-ins will be done via phone. All clients will outstanding primary outcome visits will be prioritized for HHIE collected via phone. HEARS staff will call clients for phone check-ins at their scheduled time to check in on the client and see if they are having any trouble with their device. For clients scheduled for a phone-check in, HEARS staff will attempt to get in touch 3 times through the client's primary number and then use all secondary contact methods (email, second number, emergency contact) at least once to reach the client. For clients who are due for their in-person visit, all contact attempts are the same as phone check-in attempts with the additional attempt to contact their service coordinator to assist with delivering a memo (if they are willing).

If a client brings up any concerns about COVID-19 or wants to know more resources, a "COVID-19 Resource guide" is available for study staff to reference some reminders and numbers that could be helpful to HEARS Clients.

For clients due for an in-person survey visit, staff will first collect a phone HHIE and then discuss options for collecting the rest of their answers to the HEARS Surveys (Following the COVID-19 Screening script). The screening script will address common limitations including limited cell phone minutes, internet connection, and comfort level with using technology. These methods are listed in order of study investigator preference for fidelity of data collection:

1. Zoom (with screen-share)
2. Skype (with screen-share)
3. Facetime or other video program (Hangouts, Duo, Facebook, etc)
4. Phone call with survey printout (printout mailed or delivered to them contact-free)
5. Phone call without survey printout

If a client is willing and able to complete additional surveys, a time will be scheduled where a HEARS Staff member will ask and collect their answers virtually.

Virtual surveys will be conducted in the order listed in Section 3 (same as in-person visits) other than if a client indicates they are not interested in completing the entire set of surveys.

Surveys will be prioritized in this order and as many as they are willing to complete will be completed (including offering to split up the meetings):

1. HHIE
2. UCLA
3. PHQ9
4. IOI-AI
5. Device Use
6. Program Evaluation
7. SF-12
8. SNI
9. VOL
10. Tech-SE
11. HEARS Basic Assessment
12. LSEQ

b. Study duration and number of study visits required of research participants.

The study will take place over approximately 18 months. Details are summarized in Figure 4.

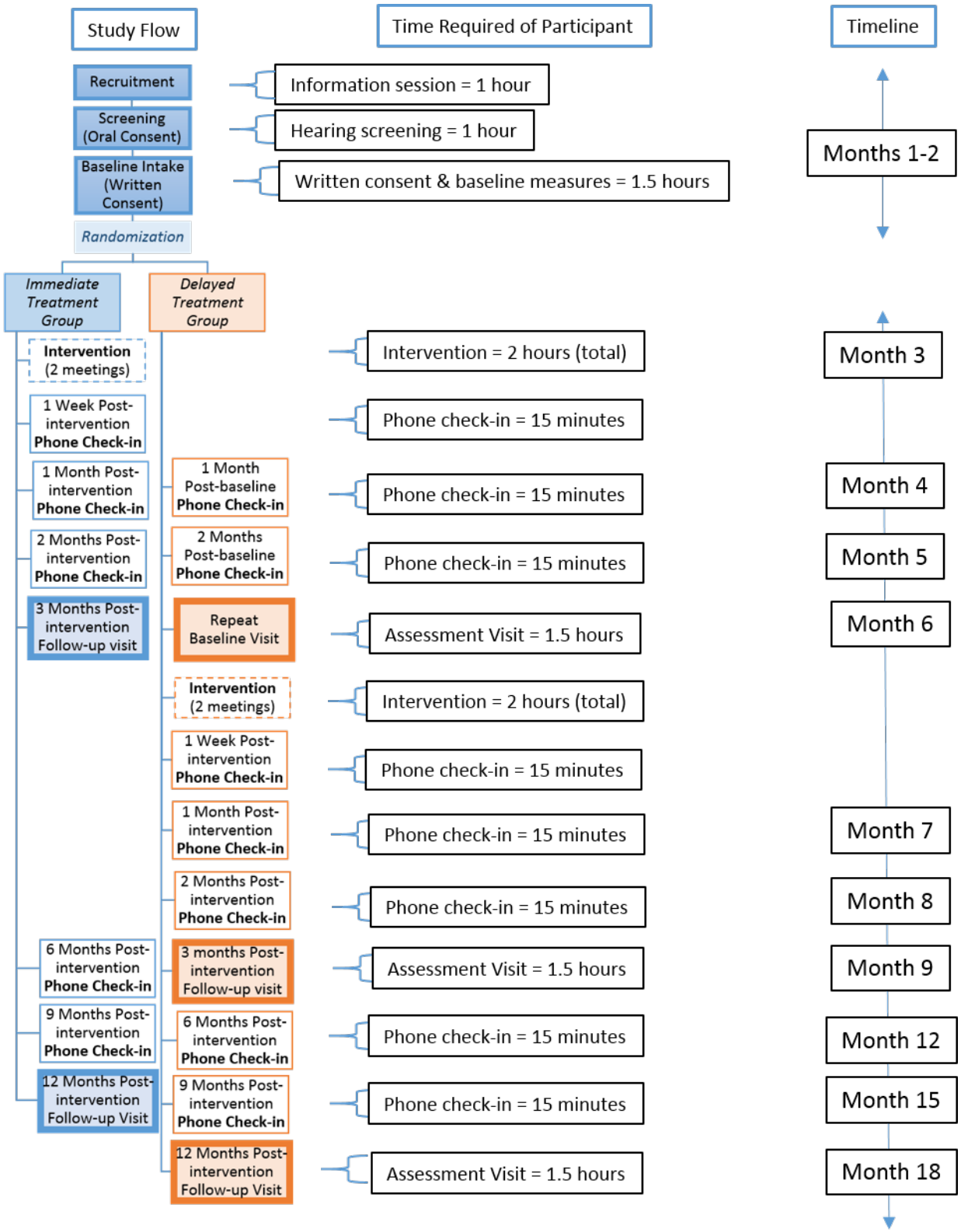


Figure 4: Overall Study Design and Timeline

An information session with a follow-up hearing screening will require an estimated total of 90 minutes. The meeting will introduce the study and HEARS program to interested participants, and screen consenting participants for study eligibility. Information sessions will be delivered by trained CHW's and the study staff.

Following attendance at an information session, study staff will meet with interested residents to obtain oral screening consent to undergo hearing screening and to gather other screening measures related to eligibility criteria. The participant will be advised about his/her eligibility. If eligible participants are interested in proceeding, the study staff will review the study, the associated written consent form, and obtain written consent. Participants will then complete baseline measurements and be randomized into either the immediate or delayed treatment groups. The baseline questionnaires will take approximately 45-50 minutes to complete.

Participants assigned to the immediate treatment group will be assigned a CHW. Once assigned to a CHW, the participant will meet with his/her assigned CHW to complete the intervention. The intervention will take place over two sessions and will take a total of approximately 120-150 minutes across two separate meetings. Follow-up evaluations at 1-week, 1-month, 2-months, 6-months, and 9-months post-intervention will be conducted via phone and will take approximately 10-15 minutes. Follow-up evaluations at 3-months and 12-months post-intervention will be conducted in-person by study staff with the participants and will take approximately 90 minutes per visit. In total, participants in the immediate treatment group will have contact with Baltimore HEARS study staff and CHW a minimum of 10 times. (see Figure 4 for overall study flow)

Participants assigned to the delayed treatment group will receive a call from study staff 1- and 2-months following their baseline visit. They will then be scheduled for a 3-month repeat baseline visit with study staff that will take approximately 90 minutes. Following this visit, participants will be assigned a CHW and receive the intervention as outlined above. Follow-up evaluations at 1-week, 1-month, 2-months, 6-months, and 9-months post-intervention will be conducted via phone and will take approximately 10-15 minutes. 3-month and 12-month post-intervention visits will be conducted in-person by study staff with the participants and will take approximately 90 minutes. In total, participants in the delayed treatment group will have contact with Baltimore HEARS study staff and CHW a minimum of 13 times (see Figure 4 for overall study flow). Of note, all participant visits, from the information session to follow-up visits, will be conducted at the participant's building.

c. Blinding, including justification for blinding or not blinding the trial, if applicable.

Study participants and data collectors will be unblinded as to randomization status. Participants will know which intervention group they are assigned to. Study staff collecting data will also be aware of group assignment depending on whether the participant is using the hearing device that is provided with the HEARS intervention. Study stuff analyzing trial data for the primary endpoint will be blinded to treatment group status.

d. Justification of why participants will not receive routine care or will have current therapy stopped.

Not applicable. There is no current standard of care for routine audiologic testing or hearing loss treatment in older adults. A recent United States Preventative Services Task Force report concluded that there was insufficient evidence to recommend screening or treatment for hearing loss in adults 50 years and older (Moyer, 2012).

e. Justification for inclusion of a placebo or non-treatment group.

All participants will receive the study intervention, either in the immediate group or the 3 month delayed treatment group.

f. Definition of treatment failure or participant removal criteria.

The intervention ("treatment") consists of aural rehabilitation, which includes basic education on age-related hearing loss and communication strategies, and provision of an over-the-counter amplifier. The session will include fitting the device and a step-by-step orientation to the device. Treatments would be

considered a failure if individuals do not complete the two-session intervention (i.e., did not attend all scheduled intervention meetings).

g. Description of what happens to participants receiving therapy when study ends or if a participant's participation in the study ends prematurely.

After participants complete the intervention, they may continue to use the amplifier and communication strategies to their needs. Contact information for Sound World Solutions and Sonic Technology Products customer support, the device manufacturers, will also be provided and available to participants. We will also provide all participants with contact information for hearing care professionals who they can follow-up with if desired. The PI of the study is an otolaryngologist with expertise in hearing loss.

5. Inclusion/Exclusion Criteria

Participant inclusion criteria:

- Age 60 years or older
- English-speaking
- Aural-oral verbal communication as primary communication modality
- Post-lingual hearing loss (Audiometric pure tone averages [0.5-4kHz] in both ears >25 dB)
- Does not currently use a hearing amplification device or hearing aid
- Signed informed consent to participate in all study related activities
- Willing to regularly use listening device once provided for the remainder of their time in the study
- Hearing handicap as measured by HHIE-S score >8
- Able to follow study instructions

Recipient/participant Exclusion criteria:

- Individuals who do not fulfill inclusion criteria
- Evidence of ear disease or pathology requiring further medical evaluation

Participants are not required to have a communication partner, but they are encouraged to participate in the intervention with an individual they speak to regularly. For participants who have a communication partner, eligibility criteria is as follows:

Communication Partner Inclusion criteria:

- Age 18 years or older
- Speak to the participant on a daily basis
- English-speaking
- Aural-oral verbal communication as primary communication modality
- Able to accompany participant to all intervention sessions & study team meetings
- Able to follow study instructions

Communication Partner Exclusion criteria:

- Individuals who do not fulfill inclusion criteria

6. Drugs/ Substances/ Devices

a. The rationale for choosing the drug and dose or for choosing the device to be used.

As previously discussed, the devices utilized in this study are low-cost, self-fit amplifiers that are currently available over-the-counter, directly to consumers, the Sound World Solutions (SWS) Sidekick and Sonic Technology's SuperEar SE9000. Neither of these devices are medical devices regulated by the FDA.

b. Justification and safety information if FDA approved drugs will be administered for non-FDA approved indications or if doses or routes of administration or participant populations are changed. **N/A**

c. Justification and safety information if non-FDA approved drugs without an IND will be administered. **N/A**

7. Study Statistics

a. Primary outcome variable.

The Hearing Handicap Inventory for the Elderly Screening Version (HHIE-S), a 10-item questionnaire to assess perceived effects of hearing loss on communication function (Ventry & Weinstein, 1983).

b. Secondary outcome variables.

See Table 1 for a list of the types of outcome variables we will utilize in the study. We plan to assess hearing and communication function as well as social and emotional function. Screening will involve hearing assessment, and an assessment of cognitive function, which may be utilized in final analyses as a covariate. We anticipate refining the surveys administered to participants based on initial experience with the first few study participants/recipients given potential issues with wording and/or time considerations.

c. Statistical plan including sample size justification and interim data analysis.

Please see Statistical Analysis Plan (SAP) in Supplemental Documents.

d. Early stopping rules. **N/A**

8. Risks

a. Medical risks, listing all procedures, their major and minor risks and expected frequency.

Audiometric screening will be performed by a trained study staff member. Audiometric findings will be reviewed and interpreted by trained professionals with a background in audiology and/or otolaryngology. Referrals for further medical evaluation will be provided as needed (e.g., impacted cerumen, etc.).

Although pure-tone thresholds will be obtained, the evaluation will not reflect a comprehensive audiologic exam. If desired, participants will also be referred to the Hearing and Speech Agency of Baltimore (HASA), a non-profit organization located in Northwest Baltimore. HASA provides full hearing testing and hearing aid fittings on a sliding scale as a resource to individuals with hearing loss and limited resources. A representative at HASA has agreed to be named as a resource for further testing, if needed. From a medical standpoint, any potential participants with concerning findings acquired from pure-tone thresholds will be referred to their primary care physician, or Dr. Frank Lin's otology clinic, for further evaluation.

There is also risk of loss of confidentiality. Participants and CHWs are embedded in the same community, and it may be readily apparent who is participating in the study. The questionnaires will involve information on social, communicative and mental functioning, which could be theoretically sensitive information or may make participants uncomfortable. However, these data are only gathered by study staff and will not be available to the CHWs. Focus groups and semi-structured interviews will involve themes related to hearing loss, potential treatments and related barriers, their experiences and feedback related to the HEARS program. All participants will be informed about the topics of discussion prior to the sessions in order for them to make informed decisions regarding participation. Personal information may be disclosed during the course of the sessions. All sessions will be audio-recorded, and will be transcribed for data analysis. All participants will be informed of the audio recording and specifics will be included in the consent form. Given the nature of focus groups and semi-structured interviews, involving more than one participant, confidentiality cannot be assured. All participants will be informed regarding procedures to maintain confidentiality and will be asked not to repeat what is said during the sessions.

Participant data and audio recordings will be kept on an encrypted and password-protected computers and database. Participants' data will be stored under coded identifiers, to which only the PI, co-investigator, and research coordinator have the key code.

b. Steps taken to minimize the risks.

Study personnel will receive training in regards to informed consent, confidentiality, and privacy requirements prior to study involvement and certifications will be maintained regularly. The PI will be available by phone to speak to research staff, participants or prospective participants regarding methods utilized in the study to minimize risks. All participant information, audio recordings, and data will be secured through the use of coded identifiers, locked filing cabinets, and password-protected computers and databases. Participants will be provided with phone numbers for the study staff in the event that they have any problems or questions.

c. Plan for reporting unanticipated problems or study deviations.

HEARS Protocol Deviations and Violations by Category

DATA COLLECTION PROCESS:
- Data collector failed to save data leading to data loss (re-surveying not an option).
- Data collector failed to save data but participant is re-surveyed
- Missing data points due to data collector entry error (within measures)
- Only partial outcomes measures were collected due to study window

INTERVENTION DELIVERY:
- Participant did not receive intervention
- Intervention started but not completed
- Intervention delivery outside window
    - o Study team delays intervention
    - o Interventionist delays intervention
    - o Participant delays intervention

3 MONTH STUDY VISIT:
- 3 MONTH STUDY VISIT outside window
    - o Study team delays visit
    - o Participant delays visit
    - o Participant unable to schedule visit (due to traveling, physical health, unable to contact)

ADVERSE EVENT
- Adverse event during study visit (study related)
- Adverse event during study visit (non-study related)
- Adverse event outside of study visit (study related)
- Adverse event outside of study visit (non-study related)

All protocol deviations will be reported to the principal investigator and documented in the participant's study chart. Adverse events (such as death or serious adverse event) requiring IRB notification will be reported to IRB in a timely manner.

d. Legal risks such as the risks that would be associated with breach of confidentiality.

We do not anticipate any substantial legal risks, including those related with breach of confidentiality. Focus group and semi-structured interview participants will be informed that they are being recorded during sessions and all will be asked to maintain confidentiality. All data on social, communicative and mental functioning will be kept secure and cannot be used, outside the context of a complete neuropsychological examination, for purposes of cognitive status or competency.

e. Financial risks to the participants.

We do not anticipate any financial risks to either the participants or interventionists (CHW's).

9. Benefits

a. Description of the probable benefits for the participant and for society.

Intervention participants will obtain audiometric screenings to assist in the identification of a possible hearing loss. If a hearing loss is suggested, they will receive additional information regarding hearing loss, its impact, and potential treatments. Intervention participants will be provided with an amplification device and receive training on how to use and set-up the device along with aural rehabilitation counseling to assist with maximizing management of their hearing loss. Consenting participants will be able to share in the experience of the new device with a community user network. Participants will receive communication and technical support with on-site trained CHWs.

For society, the study will provide insight into how hearing loss is perceived and addressed among low-income and minority older adults, populations who have traditionally had limited access to hearing health care resources. The established roles of the trained CHW's will also highlight the inherent values of these community members and their advantage in having greater access and capability to assisting fellow members of their community in offering basic hearing care.

10. Payment and Remuneration

a. Detail compensation for participants including possible total compensation, proposed bonus, and any proposed reductions or penalties for not completing the protocol.

All participants will receive a device and training materials through the HEARS intervention. No reductions or penalties will incur for not completing the intervention. Communication partners are considered volunteers who accompany their participant counterpart at all intervention and study team meetings. For any participants and communication partners who participate in the post-intervention focus group, $20 compensation is offered. See Table 4 for summary.

Table 4. Participant and communication partners compensation plan.

	Information Session & Screening	*Consent & Baseline Measures*	*Intervention*	*Follow-up Assessments (3 month post)*	*Follow-up Assessments (12 month post)*	*Post-intervention Focus Group*
Participant	--	--	Device & Training materials	--	--	$20
Communication Partner	--	--	--	--	--	$20

11. Costs

a. Detail costs of study procedure(s) or drug (s) or substance(s) to participants and identify who will pay for them.

Participants will not be assessed any costs. The study will purchase the devices directly and supply them to the study participants. The study participants will receive audiometric screening, the device, and all educational and counseling materials and support during the duration of the study at no cost.