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## A Pragmatic Clinical Trial of Hearing Screening in Primary Care Clinics: Effect of Setting and Provider Encouragement

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### Abstract

**Objectives.**—The prevalence of hearing loss increases with age. Untreated hearing loss is associated with poorer communication abilities and negative health consequences such as increased risk of dementia, increased odds of falling, and depression. Nonetheless, evidence is insufficient to support the benefits of universal hearing screening in asymptomatic older adults.

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**Conflicts of Interest:** Dr. Francis reports serving on the Surgical Advisory Boards for Advanced Bionics and Med-El. No other author reports a conflict of interest outside of funding for the study.

The primary goal of the current study was to compare three hearing screening protocols that differed in their level of support by the primary care (PC) clinic and provider. The protocols varied in setting (in-clinic versus at-home screening) and in primary care provider (PCP) encouragement for hearing screening (yes versus no).

**Design.**—We conducted a multi-site, pragmatic clinical trial. A total of 660 adults aged 65–75 years; 64.1% female; 35.3% African American/Black completed the trial. Three hearing screening protocols were studied, with 220 patients enrolled in each protocol. All protocols included written educational materials about hearing loss and instructions on how to complete the self-administered telephone-based hearing screening, but varied in the level of support provided in the clinic setting and by the provider. The protocols included: (1) no provider encouragement to complete the hearing screening at home, (2) provider encouragement to complete the hearing screening at home, and (3) provider encouragement and clinical support to complete the hearing screening after the provider visit while in the clinic. Our primary outcome was the percentage of patients who completed the hearing screening within 60 days of a routine PC visit. Secondary outcomes following patient access of hearing healthcare were also considered and consisted of the percentage of patients who completed and failed the screening and who: (1) scheduled, and (2) completed a diagnostic evaluation. For patients who completed the diagnostic evaluation, we also examined the percentage of those who received a hearing loss intervention plan by a hearing healthcare provider.

**Results.**—All patients who had provider encouragement and support to complete the screening in the clinic completed the screening (100%) versus 26.8% with encouragement to complete the screening at home. For patients who were offered hearing screening at home, completion rates were similar regardless of provider encouragement (26.8% with encouragement versus 22.7% without encouragement; adjusted odds ratio of 1.25 (95% confidence interval 0.80–1.94). Regarding the secondary outcomes, roughly half (38.9–57.1% depending on group) of all patients who failed the hearing screening scheduled and completed a formal diagnostic evaluation. The percentage of patients who completed a diagnostic evaluation and received a hearing loss intervention plan was 35.0–50.0% depending on the group. Rates of a hearing loss intervention plan by audiologists ranged from 28.6% to 47.5%, and were higher compared to those by otolaryngology providers, which ranged from 15.0% to 20.8% among the groups.

**Conclusions.**—The results of the pragmatic clinical trial showed that offering provider encouragement and screening facilities in the PC clinic led to a significantly higher rate of adherence with hearing screening associated with a single encounter. However, provider encouragement did not improve the significantly lower rate of adherence with home-based hearing screening.

## Introduction

Hearing loss is common in older adults and is a significant public health concern for millions of Americans (Tremblay, 2017; Vos et al., 2015). The prevalence of hearing loss increases with age (Goman & Lin, 2016). Prevalence data calculated by the National Institute on Deafness and Other Communication Disorders (NIDCD) suggest that 8.5% of adults aged 55–64 years have hearing loss that warrants amplification, which increases to 25% for those 65–74 years and 50% for those 75+ years (NIDCD 2021). Hearing loss is

associated with several negative consequences and a net decline in intrinsic capacity that are prioritized by the World Health Organization in its Integrated Care for Older People (ICOPE) guidelines (Wilson & Jungner, 1968). These guidelines prioritize person-centered assessment and pathways in primary care, and include a strong recommendation for hearing screening followed by provision of hearing aids for timely identification and management of hearing loss.

The primary complaint of older adults with hearing loss is the reduced ability to understand speech, especially in background noise such as in restaurants (Plomp, 1978; Summers et al., 2013). This leads to difficulty with communication in daily life (Gatehouse & Noble, 2004; Gates & Mills, 2005; Jerger, Jerger, et al., 1989; Jerger, Stach, et al., 1989; Kim & Chung, 2013). Untreated hearing loss is also associated with increased risk of dementia and cognitive decline (Ford et al., 2018; Lin et al., 2011; Lin et al., 2013; West et al., 2022; Whitson et al., 2018), increased odds of falls (Kamil et al., 2016; Lin & Ferrucci, 2012; Riska et al., 2021; Riska et al., 2022), depression (Kim & Chung, 2013; Li et al., 2014; Nachtegaal et al., 2009; West, 2017), social isolation (Kim & Chung, 2013; Mick et al., 2014; Mick & Pichora-Fuller, 2016), poorer physical functioning (Chen et al., 2014), lower levels of physical activity (Gispén et al., 2014), and reduced quality of life (Chisolm et al., 2005; Chisolm et al., 2007; Kim & Chung, 2013; Li-Korotky, 2012; Mulrow et al., 1990; Punch et al., 2019). Hearing loss is associated with underemployment and economic burden (Huddle et al., 2017; Kramer et al., 2006; Nachtegaal et al., 2012) and can negatively affect significant others and care partners of individuals with hearing loss (i.e., third-party disability) (Barker et al., 2017; Li-Korotky, 2012; Scarinci et al., 2008, 2012; Schulz et al., 2017; Wallhagen et al., 2004; West, 2021).

The majority of adults with hearing loss, however, are undiagnosed and untreated (National Academies of Sciences, Engineering, and Medicine 2016). Data from the National Health and Nutrition Examination Survey (NHANES) showed that <40% older adults 70+ years had a hearing evaluation in the previous 4 years (Nieman et al., 2016) and 36% of participants (mean age 66 years) enrolled in the Epidemiology of Hearing Loss Study reported never having a hearing evaluation (Cruickshanks et al., 1998). The diagnostic hearing evaluation itself is beneficial. The results of a hearing evaluation provide information about the type and degree of hearing loss, reveal the degree of measured and self-reported difficulty with communication, and can help identify underlying conditions that need medical and/or surgical treatment (National Academies of Sciences, Engineering, and Medicine 2016). In addition, the examiner administers a needs assessment and subsequently counsels the patients and/or their care partners regarding the hearing test results, often using the audiogram as a visual aid, all of which can be considered beneficial in terms of increased hearing loss awareness, understanding of its consequences on communication, and recommendations regarding prevention and treatment options (Klyn et al., 2019; National Academies of Sciences, Engineering, and Medicine 2016). Thus, the diagnostic assessment may encourage patients to make accommodations for their hearing difficulties, such as changes in their communication strategies, listening environments, and prevention plans.

Hearing aids are the primary, but certainly not the only, intervention for hearing loss (Ferguson et al., 2017; National Academies of Sciences, Engineering, and Medicine 2016;

Sprinzel & Riechelmann, 2010). The benefits of hearing aids include improved speech perception and communication function (Cox et al., 2014; Garcia et al., 2016; Humes, 2002; Johnson et al., 2016), reduced psychosocial implications of hearing loss (Desjardins & Doherty, 2017; Humes & Wilson, 2003; Kricos et al., 2007), and improved health and hearing-related quality of life (Chisolm et al., 2005; Chisolm et al., 2007; Cox et al., 2014; Garcia et al., 2016; Mulrow et al., 1990). Secondary benefits of hearing aids include reduced impact of hearing loss on significant others (Barker et al., 2017; Stark & Hickson, 2004) and reduced Medicare spending compared to patients with untreated hearing loss (Willink et al., 2019).

Hearing screening is among the first steps in the hearing health care pathway and primary care providers (PCP) are often the entry point for hearing health (Bennett & Barr, 2020). There are several options for hearing screening procedures available that vary in terms of time and space requirement (World Health Organization 2019, 2021). Options for PCP-directed hearing screening include one-sentence queries, questionnaires, self-administered telephone screenings, apps, and instrument-based multi-frequency screening (see review by Bennett et al., 2020). Some argue that certain hearing screening procedures are more relevant than others for ultimately identifying those individuals who are ready for hearing health care. For example, Humes (2021) argued that a self-report measure that helps quantify auditory wellness may be more informative over screening measures using pure-tones alone (Humes, 2021). Regardless of the screening procedure, however, hearing screening is not routinely performed in primary care (PC) settings, and the US Preventive Services Task Force does not recommend routine screening in their 2012 and 2020 reports because there is insufficient evidence to support universal hearing screening for asymptomatic adults age 50 years (Feltner et al., 2021; Moyer, 2012; US Preventive Services Task Force, 2021).

Shires and colleagues (2012) found that hearing screenings were performed in only 30% of adults 50–80 years of age seeking routine health maintenance by their PCP. This was much lower compared to other preventative screenings for conditions such as hypertension, breast cancer, or colorectal cancer which was addressed in 90% or more of their participants. Other data indicate that only 14% of those 65–74 years and 16% of those 75+ years report having a hearing screening during a PC visit (Kochkin, 2009).

A combination of factors conspires to produce persistently low rates of referral for hearing healthcare even in symptomatic patients. This may be due to lack of established effectiveness of screening and treatment, time constraints, and uncovered cost (Johnson et al., 2009). PCPs experience a heavy work load associated with the preventive and chronic care of numerous health conditions (Yarnall et al., 2003) and hearing loss may not be prioritized. Physicians may also be uncertain of where to refer their patients or have concerns about effectiveness and affordability of hearing loss treatments (Bennett & Barr, 2020). Other factors may include the negative impact of ageism and stigma on patient comfort discussing their hearing loss concerns, which is sometimes exacerbated if PCPs trivialize hearing loss as an expected consequence of the aging process, and lack awareness of its consequences and the benefits of treatment (Bennett & Barr, 2020; Bennett et al., 2020; Wallhagen, 2010; Wallhagen & Pettengill, 2008). These and other barriers to self-identification by patients and low rates of access to hearing health call for more detailed

study of feasibility, efficacy, and sustainability of models of universal hearing screening in older adults in the context of PC.

The primary goal of the current study was to compare three hearing screening protocols that differed in their level of support by the PC clinic and provider. The protocols varied in setting (in-clinic versus at-home screening) and in PCP encouragement for home-based screening (yes versus no). Our hypotheses were: (1) hearing screening adherence rates will be highest for patients who receive PCP encouragement, support, and space to complete screening in the PC clinic following a routine PC visit; and (2) hearing screening adherence rates for home-based screening will be higher for patients who receive PCP encouragement versus those who do not. Secondary goals were to determine the percentage of patients who failed the screening in each protocol group who: (1) scheduled, and (2) completed a diagnostic evaluation. For patients who completed the diagnostic evaluation, we also examined the percentage of those who received a hearing loss intervention plan by an audiologist and/or an otolaryngology provider.

## Methods

**Ethics approval was granted by <<removed for blind review>> University Institutional Review Board (Protocol Number Pro00070422).**

**Study Design**—We used a pragmatic clinical trial for our current study. This type of trial is distinct from explanatory clinical trials in that the results are intended to inform a clinical decision to facilitate the adoption of an intervention into real-world clinical practice (Schwartz & Lellouch, 1967). This type of trial is designed to overcome barriers in translation from explanatory clinical trials that are often performed by highly-trained investigators to determine efficacy of an intervention in highly-selected samples under controlled conditions. In pragmatic clinical trials, the focus is on recruiting the typical patients who would receive the intervention following standard clinical practice with the routine clinical provider. As such, pragmatic trials often have limited inclusion/exclusion criteria, unblinded randomization, and unobtrusive data collection (see Ford & Norrie, 2016 for a review). For our study, we chose a pragmatic clinical trial study design to determine if a routine hearing screening would be completed by an older adult who had an encounter with a PCP during a routine visit. As such, we aimed to recruit typical patients seeing their PCPs following their usual clinical practice. We also did not randomize clinical sites to our study protocols to ensure that the protocols would be simple, easy to adopt in clinic, and the least obstructive to clinical workflow. Further, we kept our data collection procedures for the patient and the PCP as unobtrusive as possible to test our hypotheses. We describe this in greater detail below.

**Primary care clinic selection**—The Primary Care Research Consortium (PCRC) Research Advisory Board (<<removed for blind review>>; coauthor) reviewed the study protocol and provided guidance on study procedures and recruitment strategy. Six PC clinics in <<removed for blind review>> were matched by a) PC specialty – three Family Medicine (FM), three Internal Medicine (IM); and b) similar numbers of patients in the target age range (65–75 years) with similar racial/ethnic demographics. Thus, each screening group

had one FM and one IM clinic participating. The medical director and practice manager at each clinic served as the point of contact for the study team.

To determine which six clinics sites would serve as participating sites, the study team approached PC practices by attending a provider staff meeting. The study team was offered <30 minutes to describe the study to the providers and have a discussion on the feasibility (i.e., clinical work flow, space and landline phone availability) and interest in participating in the study. Based on the discussion and interest of select providers in the practice, one of the three hearing screening protocols (described below) were agreed upon for the practice, and PCPs interested in the study agreed to have the study team pre-screen their patient panels for eligible participants. A clinical research coordinator rotated across the six PC sites depending on the participating providers' availability to conduct the pre-screening and enrollment.

**Engagement of PCPs**—The three hearing screening protocols were co-developed by the clinic staff and study team. Standardized operating procedures, provider case report forms, patient educational materials (Wallhagen & Strawbridge, 2017), provider encouragement scripts, and instructions for the hearing screening were provided. Co-authors XX and XX <blinded for peer review>, and an otolaryngologist and PCP respectively, worked together to develop the provider encouragement scripts and standard operating procedures, incorporating input from the clinical staff. PC staff members were trained on study procedures. PCPs, however, did not undergo extensive training on the topic of hearing loss or hearing screening as we aimed to focus on typical routine clinical practice for this pragmatic clinical trial.

**Patient Groups**—Patients were recruited from each of the six participating clinics. Each clinical site had agreed to one of the three protocols, resulting in two clinic sites per protocol. Each protocol included provision of written educational materials regarding the implications of hearing loss on communication via an educational brochure and instructions on completing the self-administered telephone-based hearing screening (TBHS). In addition, the three protocols included:

1. TBHS *at home*, with *no provider encouragement* to complete the TBHS (Home-NPE Group);
2. TBHS *at home*, with *provider encouragement* to complete the TBHS (Home-PE Group); and
3. TBHS in the *PC clinic with provider encouragement* during the visit (Clinic-PE Group).

Table 1 summarizes the design elements for each group. Supplemental Digital Content Figures 1 and 2 provide the scripts used by the PCP for the Home-PE and Clinic-PE groups, respectively.

**Patient enrollment and procedures**—A total of 660 patients (n = 110 per clinic; n = 220 per protocol) were recruited from patients scheduled for routine PCP appointments from 05/30/2017 through 07/09/2018 when recruitment goals were met. Inclusion criteria

were: (1) being seen for non-acute follow-up or annual PCP appointment, and (2) ages 65–75 years old. The lower age limit was to ensure that all patients were Medicare-eligible. The upper age limit was limited to 75 to ensure that enough patients would have hearing loss (prevalence estimated at 25%), but prevalence would not be so high that too many patients would be excluded due to prior history of hearing loss diagnosis or hearing aid use. Exclusion criteria were: (1) prior evaluation by an audiologist in the past five years and/or self-report of a hearing loss, and (2) current or prior history of hearing aid use. All patients meeting inclusion criteria underwent a verbal consent and were enrolled in the protocol assigned to their PC clinic. They were provided the study information packet that contained the study information summary sheet, educational brochure, and step-by-step instructions on completing the TBHS that was written using 11-point Arial font (see Supplemental Digital Content Figures 3–5, respectively). Demographic information (age, sex, race/ethnicity) was collected from the patient via a self-administered checklist (see Supplemental Digital Content Figure 6) prior to the patient seeing their PCP. Provider-perceived cognitive function was assessed by the PCP following their routine practice using a three-point scale (normal, mildly impaired, moderately-severely impaired) and based on their gestalt judgement of the patient during the routine visit. Patients underwent a standard ear exam via otoscopy by the provider. If cerumen was present, then it was removed at the patient’s request and following the protocol by the provider in the practice.

**Telephone-Based Hearing Screening (TBHS)**—The “triple digit” TBHS (Watson et al., 2012) was the screening approach utilized, which does not require specialized instrumentation or a sound-treated booth. It measures the ability to hear and understand three-digit numerical sequences in background noise. The TBHS results are strongly associated with average detection thresholds measured with pure tones at mid-to-high frequencies, with good sensitivity (0.80) and specificity (0.83) (Watson et al., 2012; Williams-Sanchez et al., 2014). The purpose of this screening was to identify patients who have probable hearing loss and share that information with the patient, and not to identify hearing rehabilitation candidacy. The TBHS administration instructions recommend using a quiet room and a ‘landline’ phone. In the Clinic-PE Group, a quiet room and landline phone were available after the PCP visit. For the Home-NPE and Home-PE groups, the patient instructions indicated that the TBHS should be taken in a quiet room using a landline phone in the home setting. Patients in the at-home groups were discouraged from using a cell phone for the TBHS unless that was the only available phone option. However, if a cell phone had to be used for the at-home groups, then the instructions indicated that the ear buds during the TBHS testing was required. The at-home groups were required to take the TBHS within 60 days of the PCP visit.

The publicly-available TBHS version was used, and the test system reported to the patient and the study team the results for each ear upon completion of the screening (i.e., within normal range, slightly below normal, substantially below normal, or could not test). Patients passed the TBHS if their results were within the normal range for both ears. All other results were classified as failing the TBHS. The adherence rates for completion of the TBHS for each of the three protocols was the primary outcome. Patients who failed the TBHS were contacted within approximately one week by a study coordinator to

schedule a diagnostic evaluation in the <<removed for blind review>> Clinic at no charge. Patients were considered adherent with the protocol if they scheduled/rescheduled as needed within 120 days of TBHS failure. Secondary outcomes included the number of patients in each group who failed the screening and (1) scheduled and (2) completed a follow-up diagnostic evaluation within 120 days; and the number of patients who completed the diagnostic evaluation and (3) received a hearing loss intervention plan by one or both of the participating hearing healthcare providers (audiologist or otolaryngology provider). For those who completed diagnostic testing, the rates of receiving a hearing loss intervention plan independently made by the audiologist and the otolaryngology provider were also compared. For the audiologist, a positive recommendation for a hearing loss intervention plan was determined by answering ‘yes’ (as opposed to ‘no’) to the question “In your professional opinion, is this person a candidate for hearing aids?” For the otolaryngologist, a positive hearing loss intervention plan was determined by answering “recommended for hearing aid use” (as opposed to “not recommended for hearing aid use”) to the question, “What was the final assessment for hearing aid use for patient by otologist?” A hearing aid recommendation in this study did not equate to a communication needs assessment appointment or hearing aid uptake.

**Power Analysis**—The expected rates of TBHS completion in the three groups were 25% (Home-NPE), 50% (Home-PE), and 80% (Clinic-PE). Using standard methods for the calculation of power, power was greater than 99% to declare significance for the primary contrast of interest (Clinic-PE vs. Home-NPE and Home-PE Groups) assuming alpha = 0.05 (two-tailed), total n = 600, with 200 per group. Indeed, if we assume a rate of 80% in the Clinic-PE Group, this design was 80% powered to detect differences in rates of TBHS completion in Home-NPE and Home-PE Groups as high as 69%, or difference in proportion of 11% or greater. Thus, the pragmatic clinical trial was sufficiently powered to detect even fairly small differences in TBHS completion rates among the groups.

**Statistical analysis**—For each outcome, there is a binary result (TBHS completion or not, or diagnostic assessment completion or not). The analysis was a test of difference in proportions. Follow-up pairwise contrasts were conducted to assess which groups differed significantly. Although every effort was made to balance practice samples, we realize that clinics may differ in the attributes of recruited patients. We assessed if differences in demographic profiles and comorbid conditions existed and were controlled by multinomial logistic regression, predicting adherence. We conducted follow-up sensitivity analyses pairwise group comparisons predicting TBHS completion controlling for these differences. See <<reference not included here or in the reference list for blind review>> for further details about the study methods.

## Results

### Clinic site and group demographics

Figure 1 details the CONSORT diagram as realized in this pragmatic clinical trial. Each of the six PC clinics enrolled patients until 110 patients (n = 220 per group) were consented

and enrolled. Table 2 lists the patient characteristics overall (N = 660) and for each group. See Supplemental Digital Content Table 1 for patient characteristics per site.

A total of 955 patients were screened and 780 were eligible to participate (81.7%); 120 eligible patients declined participation (15.4%). Of those, 41 (34.2%) indicated they were “not interested” and 37 (30.8%) denied a hearing problem. No clinically significant differences in demographics were found between patients who participated and those who declined participation (See Supplemental Digital Content Tables 2–4).

The average age of the 660 enrolled patients was 69.3 years (SD = 3.1); 64.1% (n = 423) were female, 35.3% (n = 233) were Black or African American and 59.7% (n = 394) were White. Cognitive function was normal per the PCP in 97.4% of patients (n = 643) (Table 2). The three groups were balanced demographically with the exception of the Home-NPE Groups and the Clinic-PE Group. The Home-NPE Group had more females [relative risk ratio 1.81 (1.20 to 2.72)] and fewer Black or African Americans [relative risk ratio 0.51 (0.34 to 0.77)] than the Clinic-PE Group (Supplemental Digital Content Table 5). These differences were primarily due to the patient characteristics at Clinic 1 compared to the other participating clinics (Supplemental Digital Content Table 1).

### Primary and Secondary Outcomes

The percentage of patients completing the TBHS in the clinic with PCP encouragement was 100% (Clinic-PE), compared to 22.7% (Home-NPE) and 26.8% (Home-PE) (Table 3, **top three rows**). Results also indicate that PCP encouragement did not result in higher adherence with completion of the TBHS at home. As seen in Table 4 (**top row left, notes g and h**), the difference between the Clinic-PE group and the two at-home groups was significant; however, given 100% adherence with hearing screening in the Clinic-PE group, controlled tests of proportions were non-estimable. For patients who were offered hearing screening at home (Table 4, **top row right, note a**), completion rates were similar regardless of PCP encouragement; adjusted odds ratio of 1.25 (95% CI 0.80–1.94),  $p = 0.33$ .

The secondary outcomes focused on following patients who *completed and failed* the hearing screening through various steps of accessing hearing healthcare. TBHS failure rates were not a primary outcome of the clinical trial, but documented for the secondary outcomes. The vast majority of patients who completed the TBHS at home were screen failures, 84.0% (Home-NPE) and 91.5% (Home-PE), whereas 54.6% of patients who completed the in-clinic screening were screen failures. Roughly half (38.9–57.1% depending on group) of all patients who failed the TBHS scheduled and completed a formal diagnostic evaluation (Table 3). The percentage of patients who completed a diagnostic evaluation and received a recommendation to acquire hearing aids by a hearing healthcare provider was 50.0% (Home-NPE), 35.0% (Home-PE), and 47.5% (Clinic-PE). Rates of hearing aid recommendations by audiologists, which were 45.8% (Home-NPE), 28.6% (Home-PE), and 47.5% (Clinic-PE), were higher compared to otolaryngology providers, which were 20.8% (Home-NPE), 15.0% (Home-PE), and 20.3% (Clinic-PE). Regression analyses (adjusting for age, sex, and race) revealed no significant effect of site (clinic vs home) or provider encouragement (yes vs no) on any secondary outcome (Table 4).

The data were also examined by following patients in each group who completed the TBHS, regardless of screening result, through various steps of accessing hearing healthcare. These results provide an indication of hearing screening efficacy from a public health perspective (Table 3). The percentage of patients (out of 220 per group) who completed the TBHS and scheduled the diagnostic evaluation were 10.9% (Home-NPE), 9.5% (Home-PE), and 28.2% (Clinic-PE); completed a diagnostic evaluation were 10.9% (Home-NPE), 9.5% (Home-PE), and 26.8% (Clinic-PE); and received a recommendation to acquire hearing aids by a hearing healthcare provider was 5.5% (Home-NPE), 3.2% (Home-PE), and 12.8% (Clinic-PE).

Overall (see Supplemental Digital Content Table 6), the results of the pragmatic clinical trial showed that 49.8% (n = 329) of adult patients aged 65–75 years (n = 660) underwent hearing screening. Of the 216 patients (65.7%) who completed the TBHS and failed, 104 (48.1%) completed formal diagnostic assessment and, of those, 47 (45.6%) were recommended to acquire hearing aids. Thus, nearly half of the older adults in this trial seen for a routine PCP visit completed a hearing screening, one-third failed the screening, ~16% completed a diagnostic hearing evaluation, and ~7% received a hearing aid recommendation.

## Discussion

This pragmatic clinical trial compared adherence rates by older adults to three different hearing screening protocols using the TBHS, in the context of a routine visit in the PC clinic setting. Specifically, we evaluated whether the location of hearing screening and provider encouragement were significant factors in screening adherence rates. Consistent with our primary hypothesis, the highest rate of adherence occurred when hearing screening was supported and facilitated in the clinic (by almost four-fold). Our second hypothesis was not confirmed; PCP encouragement for hearing screening at home did not improve adherence. Therefore, we conclude that hearing screening within the narrow time-window of 60 days following a PC visit is more effective when clinic-based testing is available, and that the rate of at-home hearing screening is not affected by provider encouragement. It is unclear whether the higher adherence rates for the in-clinic protocol were due to physician encouragement tied to immediate access to the TBHS setting or whether access and support of point of care hearing screening within the clinic was predominantly responsible.

The World Health Organization (2021) guidance on implementing hearing screening for older adults suggests that in order to maximize access, hearing screening should be available in a variety of locations such as clinical-, community- or home-based settings. We are, however, not aware of studies that have directly compared adherence by older adults as a function of setting, a factor that has proven to be a significant predictor of adherence in our study. In fact, 100% of participants who were encouraged during their PCP visit to take the screening in the clinic completed the screening (Clinic-PE) whereas only 26.8% of those who were encouraged during their PCP visit to take the screening at home (Home-PE) did so. Although acceptability of the setting has been found to be important for some stigmatizing conditions where perceived safety and confidentiality are critical (e.g., sexually transmitted infections; Graseck et al., 2010), the role of setting for hearing screening adherence has not been previously shown.

In follow-up interviews and/or focus groups with our study participants, PCPs, and staff, both patients and providers were positive about the benefits of hearing screenings for older adults in PC, and pros and cons of in-clinic and at-home screening settings were raised. Some patients favored an at-home setting due to convenience whilst others preferred having hearing screenings within the PC clinic and thought that it would increase screening adherence and improve follow-up. The PCPs and clinical staff were in favor of initiating at-home screenings within the clinic, but also mentioned that in-clinic screening was also favorable if barriers (e.g., physical space, cost, clinic work flow) could be addressed to reduce the burden (<<reference removed for blind peer review>>). These comments highlight the need to balance the greater certainty of follow-through with hearing screening available in the clinic setting, against the reduced feasibility posed by space needs and impact on clinic work flow that may limit its generalizability and routinization to all PC clinics. Whereas 100% adherence for in-clinic hearing screening is unprecedented in the literature, a screening method that does not require a quiet room and a landline phone could prove similarly effective at lower costs. Furthermore, the cumulative efficacy of at-home screening may prove similarly effective over a longer time horizon.

Comparing at-home versus in-clinic hearing screening (Home-NPE and Home-PE vs Clinic-PE; Supplemental Digital Content Table 6), we noted not only striking differences in hearing screening adherence, but also in screen failures (88.1% for at-home vs 54.5% in-clinic). As 54.5% of screen failures in the in-clinic group likely includes all individuals with a potential hearing loss, this figure represents a “gold standard” for hearing screening in the PC setting. By comparison almost one-third (32.7%) of patients with suspected hearing loss were likely missed in the groups who were screened at-home, with negative cost-effectiveness implications (reference removed for blind peer review). We speculate that those in the Home-NPE and Home-PE groups who elected to screen had some concerns about their hearing whereas those in the Clinic-PE group completed the hearing screening primarily due to convenience, support and access to TBHS, and possibly the view that hearing screening was part of their routine PCP visit. In addition, patients were asked to screen via the TBHS procedure while using a landline phone, and only use a cell phone with ear buds for screening if it was the only option. According to the Centers for Disease Control and Prevention (Blumberg & Luke, 2018), 29.2% of adults 65+ years use only wireless phones. Thus, some participants may not have completed the TBHS at home because they did not have access to a landline telephone or ear buds for use with a cell phone. Another potential reason for the difference seen in setting is that the at-home groups may have had lower health literacy. Our TBHS instructions were written at the 8<sup>th</sup> grade level (based on an online Flesh-Kincaid calculator). Health literacy may have been more important for the at-home groups given they did not have the clinical support provided for patients in the -in-clinic group. Understanding the facilitators and barriers for hearing screening uptake in various settings and for different populations warrants further research.

The lack of influence of PCP encouragement on hearing screening adherence in the home setting runs contrary to research on other types of screenings, such as for cancer. Peterson and colleagues (2016) conducted a systematic review on the impact of patient-provider communication for adherence with cancer screening. They found in nearly all reviewed studies that provider recommendation was significantly associated with screening adherence.

Furthermore, they concluded that provider enthusiasm and encouragement for screening was particularly influential. In our study, the physician encouragement provided to patients consisted of language read from a script that focused on (1) the opportunity to take a free hearing screening and obtain a free diagnostic hearing test and otologic exam by hearing healthcare specialists, and (2) the impact of hearing loss on communication and one's ability to understand medical information (See Supplemental Digital Content Figures 1 and 2 for scripts). The levels of enthusiasm with which these scripts were read to patients were unknown as the PCPs were not provided with instructions or demonstrations regarding its delivery. In addition, the PCPs in this trial did not undergo any formal education or training about hearing loss, hearing management, or optimal patient-provider communication strategies surrounding the importance of hearing healthcare. Training and education of PCPs about the prevalence and impact of untreated hearing loss and their role in managing hearing loss for their older patients may be important for reducing barriers for initiating hearing healthcare in the PC setting (Bennett & Barr, 2020; see Bennett et al., 2020 for scoping review).

For both in-clinic and at-home settings and regardless of whether provider encouragement was provided, screening failure led to similar rates of formal diagnostic evaluation, 46.9% for the two at-home groups, and 49.2% for the in-clinic group. A reasonable expectation is that the more motivated (or potentially symptomatic) patients who followed through with screening at home would seek a formal diagnostic assessment at a higher rate than the in-clinic group, but this was not the case. Also of interest was that physician encouragement (or not) for the two at-home groups had no effect on screening adherence, that is, the first step in the hearing healthcare pathway. These unexpected results may reflect the need for a longer time horizon with which to evaluate the effects of repeated education and encouragement by the PCP. There would, however, need to be a process by which the PCP would be made aware of the screening result and be prompted to encourage audiologic follow up during the current or subsequent visits, which was not a goal of this trial. More research is also needed to understand why half of the patients who failed a hearing screening (regardless of setting) did not follow up with a diagnostic assessment (even at no cost), at least in the short term, and how knowledge of these results by the patient and the PCP affects subsequent communication-related and health-seeking behaviors and clinical care.

The availability of hearing screening in the PC clinic resulted in the highest number of patients completing the hearing screening and ultimately receiving a hearing evaluation and hearing loss intervention plan, compared to patients who completed the screening at home. Central to the public health implications of this clinical trial is the two- to three-fold higher likelihood that patients offered hearing screening in the clinic setting will enter the formal hearing healthcare pathway, and an up to a four-fold likelihood that they will receive a diagnosis, hearing loss education, and treatment recommendation. Whereas at-home screening missed a significant proportion of individuals with hearing loss, screening failure resulted in similar rates of hearing health uptake independent of setting and physician encouragement. The percentage of PC patients who were asked to undergo screening, then subsequently failed and followed up with a diagnostic assessment, was 10.2% for the at-home group (45/440; both groups) and 26.8% (59/220) for the in-clinic group. In addition to the benefits of a hearing loss diagnosis from a healthcare provider including

increased awareness and access to communication strategies, some of these individuals were also received treatment with hearing aids. The percentage of the original PC patient cohort who ultimately received a hearing loss intervention plan was 4.3% for the at-home group (19/440; both groups) and 12.7% (28/220) for the in-clinic group. From a population/public health perspective, hearing screening in the PC clinic was therefore more efficacious in identifying and addressing hearing loss within the time window of this trial. Subsequent examination of the current trial data demonstrated that the in-clinic screening was even more cost effective than at-home screenings <<reference removed for blind peer review>>.

Guidelines that promote the integration and routinization of hearing screening within PC may have the broadest impact on patient communication and hearing-related health through diagnosis and/or intervention whether using formal audiologic services or even self-directed care models such as over-the-counter devices and services (National Academies of Sciences, Engineering, and Medicine 2016). Furthermore, the efficacy and benefits of hearing screening in PC are likely to grow with education of PCPs and repeated annual exposures of patients to education even for home-based screening. However, practicality of in-clinic hearing screening using TBHS as conducted in the current pragmatic clinical trial can be optimized in the future, such as using patient reported screening instruments.

### Study Limitations

This pragmatic clinical trial had several limitations. First, pragmatic clinical trials, by design, do not include measurement of several variables (e.g., health literacy, technology use) that may influence or explain study results. For example, we did not measure health literacy of patients and our instructional materials were written at the 8<sup>th</sup>-grade level, which may be too high and may have contributed to lower uptake of hearing screening in the at-home groups. Second, patients were encouraged to use a landline phone for the TBHS screening, and it is known that close to 30% of older adults exclusively use wireless phones. For those who had to use cell phones, they were asked to use ear buds for screening. Therefore, some patients in the at-home hearing screening groups may not have completed the TBHS because of lack of easy access to landline phones or ear buds. In addition, we do not know the ambient noise level conditions of the homes, which might have contributed to the higher failure rates for the at-home groups even though the TBHS testing is performed in background noise. Furthermore, we do not know if other screening procedures would have resulted in higher adherence in the at-home groups, however, comparison of screening methods was not the focus of this trial. Third, as noted earlier, the PCP encouragement was read from a script that was focused on obtaining a free screening and assessment and the content only mentioned the impact of hearing loss on communication and ability to understand medical information. Patients may have been more motivated to follow through with hearing screening at home if they also understood other possible health-related implications of untreated hearing loss, such as association with increased risk of dementia or falls (Curhan et al., 2019; Gurgel et al., 2014; Riska et al., 2022). Fourth, patients received the diagnostic assessment after a failed hearing screening at no cost. This may not represent real-world hearing healthcare service delivery and may have inflated completion rates for diagnostic assessments compared to protocols where patients incur costs for follow-up care with specialists. Nevertheless, even with the opportunity to

obtain a diagnostic assessment at no cost, only about half (48.1%) of patients who failed the hearing screening completed this assessment. Fifth, we do not know if patients followed through with treatment recommendations at facilities outside of this clinical trial. Sixth, we followed patients for only a short-term (60 days) after one exposure to a hearing screening opportunity from the PCP, and in the larger context of health screening, it is recommended that screening should be a continuous process (Wilson & Jungner, 1968). It is unknown how these results would change with serial exposure to information about hearing loss in the PC setting and subsequent encouragement or opportunities to complete a hearing screening and follow-up hearing healthcare by the PCP. Seventh, we did not provide extensive training for PCPs on hearing loss, the consequences of untreated hearing loss, and the importance of early diagnosis and treatment of hearing loss. We also did not coach the PCPs on how to optimize the content and quality of their encouragement surrounding hearing screening or hearing health. Such training and coaching should be considered in future trials. Finally, consistent with the principles of a pragmatic clinical trial, we did not randomize the clinic sites to a screening protocol, but the sites agreed upon the protocol that would be most feasible at their site. As such, we may be limited in understanding fully the barriers of hearing screening in PC. Nonetheless, our qualitative sub-study (under re-review—removed for blind peer review) revealed themes related to facilitators and barriers from a workflow and resource perspective, and that point to future work needed to further understand these facilitators and barriers to implementing hearing screening in PC.

The results of this clinical trial provide strong indication of the short-term feasibility of hearing screening in PC settings, including clinics that serve racially-diverse patients. Sustainability of hearing screening in a variety of PC clinics, however, is required to effect long term public health impact. Furthermore, appropriate work flow and protocols used in subsequent PC visits should be assessed for their efficacy and sustainability in supporting provider follow up of screening results, and repeated encouragement to complete the screening process. Ready access to reports in the electronic medical record, and other features such as the ability to program clinical alerts, can be leveraged to achieve broad and long-term adoption. The Early Auditory Referral-Primary Care (EAR-PC) study, for example, has demonstrated a higher rate of screening, referral to audiology and listing of hearing loss on problem lists by PC providers who received electronic best practice alerts during the appropriate encounter type (Zazove et al., 2017). It is therefore possible that the at-home screening protocols in this trial would perform better over time if such a prompt was implemented and appropriately followed in subsequent visits. The implementation of hearing screening in PC settings and understanding of its general- and hearing-health impacts will therefore require multiple considerations and strategies that address both provider and patient factors.

## Conclusions

Provider encouragement did not result in a significantly higher proportion of patients completing a TBHS at home, but all patients who were offered and supported to complete a TBHS in the PC clinic did so. Although adherence rates for at-home hearing screening were lower, these patients were much more likely to fail the screening than those who completed it in the PCP clinic. This suggests that patients who may have concerns about

their hearing may also be more motivated to complete a hearing screening, with or without provider encouragement. There was, however, a two-three fold higher completion rate of diagnostic assessments (that is, formal entry into the hearing healthcare pathway) in the group provided with in-clinic screening as compared to the at-home screening groups. Across all groups, half the patients seen for a routine PCP visit were motivated to complete a hearing screening. Of those, two-thirds failed the hearing screening, half of those scheduled and completed a diagnostic assessment, and a little less than half of those received a hearing aid recommendation from a hearing healthcare provider. Understanding the most efficient and cost-effective method to increase hearing screening adherence would increase access to hearing healthcare and is the focus of future work. Based on current evidence, availability of hearing screening in the PC clinic as part of a routine visit seems to be a critical factor for increasing adherence with completion of hearing screening by older adults, and subsequent access to hearing healthcare. More research, however, is needed to understand the facilitators and barriers of implementing and routinizing hearing screenings within the PC setting, including the quality and content of the patient-provider interaction surrounding hearing and increasing awareness by the patient and provider about accessible and affordable hearing rehabilitation options.

## Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

## Acknowledgments

Although the data collection of this study began before January 1, 2019, we intend to post the data that support the findings of this study openly and make the data available in the Duke University Digital Repository.

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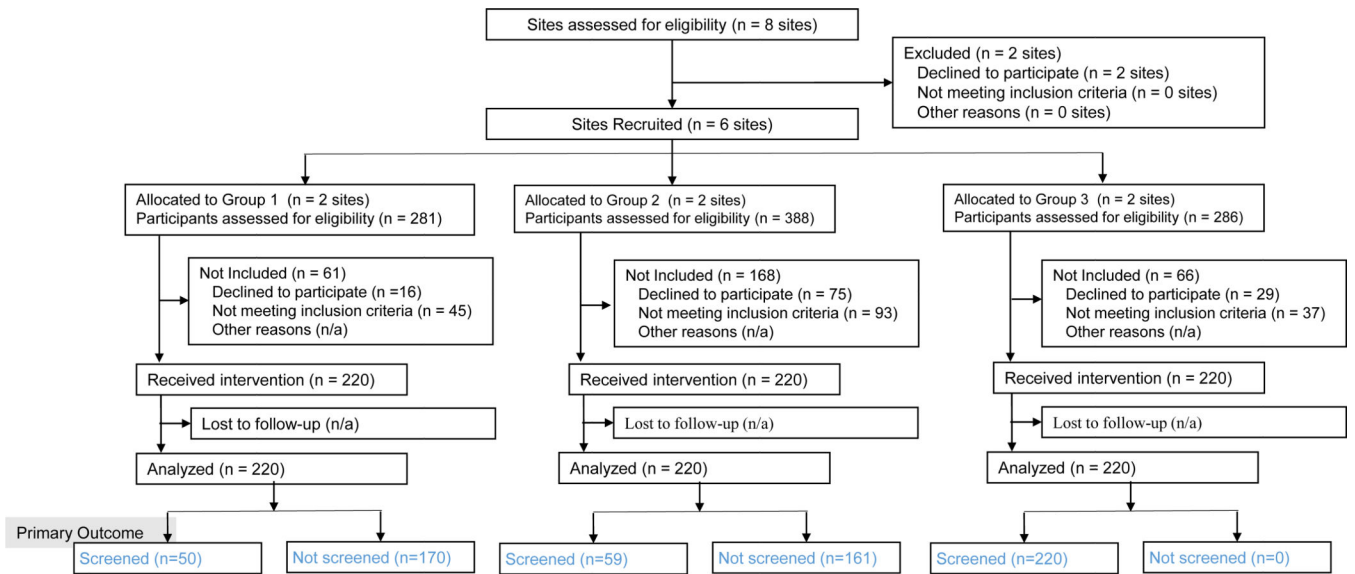
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**Figure 1.** The CONSORT flow diagram for the study. Notes: Total approached (n = 959); Total assessed for eligibility (n = 955); Total not Included (n = 295); Total Ineligible (n = 175); Total Declined (n = 120); \*Primary outcome defined as dialed the telephone screening phone number and completed the test at or within two months (i.e., 60 days) of PCP visit

**Table 1.**

The design elements across the three groups.

Design Elements	Home-NPE Group	Home-PE Group	Clinic-PE Group
<b>Self-administered Telephone-based Hearing Screening</b>			
Test instructions provided in the clinic	X	X	X
Patient instructed to take test at home	X	X	
Test offered in clinic after the PCP visit			X
<b>Provider Encouragement/Counsel on the Importance of Hearing Screening</b>			
Provider encouragement during PCP visit		X	X
<b>Educational Materials (Brochure)</b>			
Written information on warning signs of hearing loss, consequences of hearing loss, and possible interventions	X	X	X

Abbreviations: PCP = primary care provider

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Table 2.

Patient characteristics overall and as a function of each group.

Characteristic	All N=660	Home-NPE N=220	Home-PE N=220	Clinic-PE N=220
Age (years), mean (SD)	69.3 (3.1)	69.5 (3.1)	69.4 (3.0)	69.1 (3.0)
Sex				
Male	237 (35.9%)	63 (28.6%)	84 (38.2%)	90 (40.9%)
Female	423 (64.1%)	157 (71.4%)	136 (61.8%)	130 (59.1%)
Race/ethnicity				
More than one race/ethnicity	10 (1.5%)	4 (1.8%)	3 (1.4%)	3 (1.4%)
American Indian or Alaska Native	1 (0.2%)	0 (0.0%)	0 (0.0%)	1 (0.5%)
Asian	5 (0.8%)	0 (0.0%)	3 (1.4%)	2 (0.9%)
Black or African American	233 (35.3%)	60 (27.3%)	80 (36.4%)	93 (42.3%)
Hispanic or Latino	1 (0.2%)	0 (0.0%)	1 (0.5%)	0 (0.0%)
Native Hawaiian or other Pacific Islander	1 (0.2%)	1 (0.5%)	0 (0.0%)	0 (0.0%)
White or Caucasian	394 (59.7%)	149 (67.7%)	128 (58.2%)	117 (53.2%)
Unknown/Prefer not to answer	15 (2.3%)	6 (2.7%)	5 (2.3%)	4 (1.8%)
Provider-Perceived				
Normal	643 (97.4%)	213 (96.8%)	217 (98.6%)	213 (96.8%)
Mildly Impaired	16 (2.4%)	7 (3.2%)	3 (1.4%)	6 (2.7%)
Moderately-severely impaired	1 (0.2%)	0 (0.0%)	0 (0.0%)	1 (0.5%)

**Table 3.**

Proportion of patients in each group for the primary and secondary outcomes.

	Home-NPE	Home-PE	Clinic-PE
<b>TBHS completed<sup>a</sup></b>	<b>N=220</b>	<b>N=220</b>	<b>N=220</b>
Agreed and not completed within 60 days of PCP visit or refused	170 (77.3%)	161 (73.2%)	0 (0%)
Completed TBHS within 60 days of PCP visit	50 (22.7%)	59 (26.8%)	220 (100%)
<b>Screening Failure Result<sup>b</sup></b>	<b>N=50</b>	<b>N=59</b>	<b>N=220</b>
Failed TBHS	42 (84.0%)	54 (91.5%)	120 (54.6%)
Passed TBHS	8 (16.0%)	5 (8.5%)	100 (45.5%)
<b>Formal diagnostic assessment scheduled<sup>c</sup></b>	<b>N=42</b>	<b>N=54</b>	<b>N=120</b>
Formal diagnostic assessment not scheduled	18 (42.9%)	33 (61.1%)	58 (48.3%)
Formal diagnostic assessment scheduled	24 (57.1%)	21 (38.9%)	62 (51.7%)
<b>Formal diagnostic assessment completed<sup>d</sup></b>	<b>N=42</b>	<b>N=54</b>	<b>N=120</b>
Formal diagnostic assessment not completed	18 (42.9%)	33 (61.1%) <sup>e</sup>	61 (50.8%)
Formal diagnostic assessment completed	24 (57.1%)	21 (38.9%) <sup>e</sup>	59 (49.2%)
<b>Audiologist recommended hearing aid use<sup>e</sup></b>	<b>N=24</b>	<b>N=21</b>	<b>N=59</b>
Not recommended for hearing aid use	13 (54.2%)	15 (71.4%)	31 (52.5%)
Recommended for hearing aid use	11 (45.8%)	6 (28.6%)	28 (47.5%)
<b>Otologist recommended hearing aid use<sup>f</sup></b>	<b>N=24</b>	<b>N=20</b>	<b>N=59</b>
Not recommended for hearing aid use	19 (79.2%)	17 (85.0%)	47 (79.7%)
Recommended for hearing aid use	5 (20.8%)	3 (15.0%)	12 (20.3%)
<b>Audiologist or otologist recommended hearing aid use<sup>f,g</sup></b>	<b>N=24</b>	<b>N=20</b>	<b>N=59</b>
Not recommended for hearing aid use	12 (50.0%)	13 (65.0%)	31 (52.5%)
Recommended for hearing aid use	12 (50.0%)	7 (35.0%)	28 (47.5%)

<sup>a</sup>Among enrolled participants (N=660)<sup>b</sup>Among participants with completed TBHS (N=329); not a study outcome<sup>c</sup>Among participants with TBHS failure (N=216)<sup>d</sup>Among participants with TBHS failure (N=216); within 120 days of TBHS; formal diagnostic assessment by audiologist and/or otologist<sup>e</sup>Among participants with completed diagnostic assessment by audiologist within 120 days of TBHS (N=104)<sup>f</sup>Among participants with completed diagnostic assessment by otologist within 120 days of TBHS (N=103)<sup>g</sup>1 participant in Home-PE group completed audiologist assessments and did not complete the otology assessment within 120 days of TBHS; not included

Abbreviations: PCP = primary care provider, TBHS = telephone based hearing screening, Clinic-PE = clinic screening with provider encouragement group, Home-NPE = home screening with no provider encouragement group, Home-PE = home screening with provider encouragement group, OR = Odds Ratio

Table 4.

Regression results for the primary and secondary outcomes.

	Clinic-PE Group vs Home-NPE and Home-PE Groups		Home-NPE Group vs Home-PE Group	
	Unadjusted OR (95% CI)	Adjusted OR (95% CI)	Unadjusted OR (95% CI)	Adjusted OR (95% CI)
TBHS completed <sup>a</sup>	---	---	1.25 (0.81 to 1.92)	1.25 (0.80 to 1.94)
Formal diagnostic assessment scheduled <sup>b</sup>	1.16 (0.67 to 2.00)	1.48 (0.83 to 2.66)	0.48 (0.21 to 1.08)	0.55 (0.24 to 1.28)
Formal diagnostic assessment completed <sup>c</sup>	1.05 (0.61 to 1.81)	1.29 (0.72 to 2.31)	0.48 (0.21 to 1.08)	0.54 (0.23 to 1.26)
Audiologist recommended hearing aid use <sup>d</sup>	1.55 (0.69 to 3.47)	1.49 (0.63 to 3.54)	0.47 (0.14 to 1.64)	0.47 (0.14 to 1.64)
Otolaryngology provider recommended hearing aid use <sup>e</sup>	1.18 (0.43 to 3.25)	1.33 (0.45 to 3.93)	0.67 (0.14 to 3.24)	0.70 (0.14 to 3.38)
Audiologist or otologist recommended hearing aid use <sup>f</sup>	1.23 (0.56 to 2.73)	1.18 (0.50 to 2.79)	0.54 (0.16 to 1.82)	0.54 (0.16 to 1.84)

<sup>a</sup> Among enrolled participants (unadjusted N=660; adjusted N = 645), within 60 days of PCP visit

<sup>b</sup> Among participants with TBHS failure (unadjusted N=216; adjusted N = 212)

<sup>c</sup> Among participants with TBHS failure (unadjusted N=216; adjusted N = 212); within 120 days of TBHS; formal diagnostic assessment by audiologist and/or otolaryngology provider

<sup>d</sup> Among participants with completed diagnostic assessment by audiologist within 120 days of TBHS (unadjusted and adjusted N=104)

<sup>e</sup> Among participants with completed diagnostic assessment by otolaryngology provider within 120 days of TBHS (unadjusted and adjusted N=103)

<sup>f</sup> Among participants with completed diagnostic assessment by otolaryngology provider within 120 days of TBHS (unadjusted and adjusted N=103)

<sup>g</sup> p-value for unadjusted comparison of Clinic-PE vs Home-NPE and Home-PE groups via Fisher's exact was <0.001 for a non-directional test.

<sup>h</sup> because no patients in the Clinic-PE group failed to complete the TBHS on site, controlled tests of proportions were non-estimable

Note: adjustment factors = age, sex (Male, Female), race (Black or African American, Other)

Abbreviations: PCP = primary care provider; TBHS = telephone based hearing screening; Clinic-PE = clinic screening with provider encouragement group, Home-NPE = home screening with no provider encouragement group, Home-PE = home screening with provider encouragement group, OR = Odds Ratio