ADVANCED APPLICATIONS IN DIGITS-IN-NOISE TESTING TO DETECT AND DIFFERENTIATE HEARING LOSS

by

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A thesis submitted in partial fulfilment of the requirements for the degree

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The language used in the thesis is English (U.K.). Stylistic and language variations required by the specific journals where the manuscripts of the studies were submitted are indicated where applicable.

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Dedicated to women in science

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PLAGIARISM DECLARATION

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15 October 2020

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I

ETHICS STATEMENT

The author, whose name appears on the title page of this thesis, has obtained, for the research described in this work, the applicable research ethics approval.

The author declares that she has observed the ethical standards required in terms of the University of Pretoria's Code of ethics for researchers and the Policy guidelines for responsible research.

PUBLICATIONS AND RESEARCH OUTPUTS

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ABSTRACT

Title:	Advanced applications in digits-in-noise testing to detect and differentiate hearing loss
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More than half a billion people have disabling degrees of hearing loss, which, left untreated, has debilitating consequences to the individual and society. Prevalence is expected to increase rapidly within the next thirty years, making hearing loss a significant public health matter. Thus, increasing efforts should be made towards detection and treatment. Many people with hearing loss reside in low- and middle-income countries, where the capacity to provide care, especially clinic-based models of care, is limited. Furthermore, the inaccessibility has been exacerbated by the COVID-19 pandemic. The digits-in-noise (DIN) test has been a more accessible screening tool over the past two decades, measuring a speech recognition threshold (SRT) that has a high association with standard pure tone audiometry. The test has the benefit of being provided directly to the public over digital modes like smartphones, using familiar stimuli and a simple procedure that does not require calibration. One example is the *hearWHO* DIN test that has been widely used and promoted as a free hearing screening test to the public. Aside from detecting hearing loss, no studies have developed methods to differentiate and classify hearing loss further. Therefore, this study investigated more advanced DIN test methods that could serve this purpose.

Study I evaluated if a combination of two DIN test paradigms (antiphasic and diotic) could accurately categorise hearing into (a) normal hearing (pure tone average [PTA] ≤ 25 dB HL), (b) bilateral sensorineural hearing loss (SNHL; PTA > 25 dB HL), or (c) unilateral SNHL (PTA > 25 dB HL in the poorer ear and ≥ 20 dB interaural PTA difference) or conductive hearing loss (CHL; air conduction PTA > 25 dB HL and ≥ 20 dB air-bone gap). After establishing normative antiphasic SRTs across a sample of 489 adults with varying types and degrees of hearing, 393 participants completed a second diotic DIN test. The antiphasic DIN test had sensitivity and specificity of 90% and 84% to detect hearing loss. Furthermore, the combined antiphasic and diotic DIN test approach with fixed SRT cut-offs could correctly categorize 75% of the sample. Using a fixed antiphasic and sloping diotic SRT cut-off (varying slope and offset)

could increase classification to 79%. False-negative rates for both procedures were below 10%.

Study II investigated a different approach to determine if CHL could be accurately distinguished from bilateral SNHL using a combination of pure tone audiometry and a diotic DIN test. An analyses of 122 adults with bilateral SNHL and 36 with CHL was conducted. Binomial logistic regression determined the effect of pure tone thresholds, SRT and age on the likelihood of having CHL or bilateral SNHL. A model including low-frequency PTA (0.5 & 1 kHz), diotic DIN SRT, and age had sensitivity and specificity of 97.2% and 93.4%, respectively, to distinguish CHL from bilateral SNHL.

Instead of establishing a hearing loss type, Study III aimed to determine if a low-pass (LP) and high-pass (HP) speech filtering technique could estimate pure tone audiometry in separate low and high-frequency bands. Previous work has used LP filtered masking noise to increase the sensitivity of the DIN test to high-frequency hearing loss. However, this study filtered speech at 1.5 kHz to ensure minimal speech information presented above or below the filter cut-off frequency. Results indicated better test-retest reliability (Intraclass correlation coefficient [ICC] = 0.71; 95% confidence interval [CI] 0.52 to 0.82) of the HP DIN test than the LP DIN test (ICC = 0.39; 95% CI -0.01 to 0.63). The HP DIN SRT was more strongly correlated to all the PTA averages (four frequency, low-frequency and high-frequency) than the unfiltered, broadband (BB) or LP DIN test. Subsequently, the HP DIN test showed increased sensitivity and specificity to detect hearing loss in any PTA average, compared to the BB or LP DIN test. The LP DIN test had a weaker correlation to low-frequency thresholds than the BB DIN test. As a result, a combined LP and HP DIN test approach could not accurately predict an audiometric slope or configuration. For ears with normal hearing (PTA ≤ 15 dB HL), the HP DIN showed a stronger correlation (rs = 0.36) to extended high frequencies (8 to 16 kHz) than the BB DIN (rs = 0.26).

As an implementation research approach, study IV investigated the global use and uptake, test characteristics and performance of an antiphasic DIN test as provided on the free World Health Organization smartphone hearing screening test (*hearWHO*). The data of 242 626 tests conducted by adults (> 18 years) conducted between February 2019 and May 2021 were evaluated. The test was completed in nearly every country globally (n = 179/195), with the greatest uptake seen in China and India. Uptake was most significant in the Western Pacific (32.9 %) and European (24.8 %) WHO regions. As expected, referral rates were typically higher for older age groups in most WHO regions, except for the African and Eastern Mediterranean regions, where overall *hearWHO* test uptake was lowest. There was a high uptake of tests (44%) by young adults under 30 years.

The sequential antiphasic-diotic DIN test approach to classify hearing loss has the potential to optimise care pathways using remote and contactless testing by identifying unilateral SNHL and CHL as cases requiring medical referral. In contrast, bilateral SNHL cases could be referred directly to a hearing care professional or be served using non-traditional models. Furthermore, considering restrictions on traditional audiological assessments due to an infectious disease like COVID-19 and under-resourced settings, alternative methods that enable audiological care with minimal physical contact may reduce mortality and infection risk whilst optimising care pathways and resource allocation. This DIN test approach and the combined pure tone audiometry and diotic DIN test method could allow accurate detection of CHL without the use of bone conduction testing conducted in sound-proof booths. The DIN test could further sensitively discriminate hearing, especially occurring in high-frequencies when using HP speech filtered stimuli, and shows potential to detect early signs of hearing loss occurring in the extended high frequency ($\geq$ 8 kHz) range. As an applied public health practice, the test reaches an important target audience of younger adults positioning it as an important measure for public health advocacy to prevent hearing loss due to unsafe listening practices.

This study project provides empirical evidence that DIN test methods can support improved detection and classification of different hearing loss types. These advances contribute to growing research to optimise the DIN test efficiency and sensitivity as a screening and potential triaging tool. Furthermore, these classification methods can provide simple, applied solutions that support alternative service delivery models like over-the-counter or direct-to-consumer pathways.

KEYWORDS

digits-in-noise test

speech recognition in noise

mobile health

low-pass filtering

high-pass filtering

low-touch audiometry

no-touch audiometry

hearing loss classification

sensorineural hearing loss

conductive hearing loss

ABBREVIATIONS

ABG	Air-bone gap
AUROC	Area under the receiver operating characteristic
BB	Broadband
CHL	Conductive hearing loss
CVC	Consonant-vowel-consonant
dB HL	Decibel hearing level
dB SNR	Decibel signal-to-noise ratio
DTC	Direct to consumer
DIN	Digits-in-noise
EHF	Extended high frequency
FDA	United States Food and Drug Administration
HF	High frequency
HP	High-pass
ICC	Intraclass correlation coefficient
ISO	International Organization for Standardization
kHz	Kilohertz
LF	Low-frequency
LMICs	Low- and middle-income countries
LP	Low-pass
LTASS	Long term averaged speech spectrum
MATLAB	Matrix Laboratory
Ms	Millisecond
OTC	Over-the-counter
PTA	Pure tone average
SNHL	Sensorineural hearing loss
S_0N_0	In-phase (diotic)
SPSS	Statistical package of the social sciences
SRT	Speech recognition threshold
$S_\pi N_0$	Out-of-phase (antiphasic)
WHO	World Heath Organization

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CHAPTER 1: INTRODUCTION

1.1. Background

Hearing loss is one of the most prevalent, disabling health conditions globally. Conservative estimates indicated that in 2020, approximately 1.6 billion people globally had some extent of hearing loss, and nearly half a billion of a disabling degree (GSMA, 2020b; Vos et al., 2020; World Health Organization, 2021). Unsurprisingly, hearing loss ranked 3rd as a leading contributor to disability in the Global Burden of Disease study (Haile et al., 2021; Vos et al., 2020). For the next thirty years, disease projections expect rapidly increasing hearing loss prevalence (56.1 %) due to population growth, increasing life expectancy and demographic shifts (Haile et al., 2021; Vos et al., 2020). These estimates are compelling evidence to consider hearing loss as a significant public health issue. Furthermore, auditory deprivation caused by unmanaged hearing loss can have adverse impacts, including depression (Mener et al., 2013), cognitive decline and dementia (Livingston et al., 2017) and limited employment opportunities (Shan et al., 2020). The resultant global economic loss is staggering, with close to one trillion US dollars lost annually due to unaddressed hearing loss, 57% of the cost from outside high-income countries (McDaid et al., 2021).

There is much to be gained from reducing hearing loss prevalence and severity. Besides the benefit to the individual by avoiding pervasive effects of hearing loss, simply a 5% reduction in prevalence could reduce global monetary loss conservatively by almost 50 billion US dollars per year (McDaid et al., 2021). Nevertheless, despite much available and congruent evidence of the extensive effects, hearing loss remains largely undiagnosed for substantial portions of the global population, leaving rehabilitation options consistently underutilized. In acknowledgement of this mounting burden, industry partners, researchers, and consumer advocates alike have called for action to develop and implement strategies for improved hearing healthcare, supported at the World Health Assembly in 2017 (World Health Organization, 2017). The need for health advocacy and accessible hearing solutions were similarly highlighted in the 2016 *US National Academies of Sciences, Engineering and Medicine* report on priorities for improved access and affordability of hearing care for adults (Lin et al., 2016) and the more recent *World Report on Hearing* in 2021 (World Health Organization, 2021). Targeted themes of the resolutions and reports are focused on prevention of hearing loss, technology to support care, and policy.

1.2. Factors affecting access to clinic-based models of care

Awareness of hearing loss and its sequelae is improving, yet it is still not considered urgent as a lack of resources, especially in low-and-middle-income countries (LMICs), forces other

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health conditions to receive priority (Wilson et al., 2017). Exacerbating matters is the fact that hearing loss incidence falls disproportionately in regions with lower socioeconomic status. Nearly 80% of people with disabling hearing loss reside in LMICs, where the local capacity to scale up diagnostics and intervention are insufficient to meet the demand (Stevens et al., 2013). In addition, many countries lack effective programs and personnel to curtail hearing loss due to occupational noise exposure (Verbeek et al., 2014), ototoxicity and common ear conditions such as chronic otitis media (Olusanya et al., 2014; Wilson et al., 2017). Large proportions of hearing loss could be prevented by targeted screening, medical and device-based interventions, and community-orientated education. Unfortunately, there are significant gaps in the capacity of healthcare systems across income settings to provide adequate hearing services (World Health Organization, 2021). An analysis of the workforce providing specialist ear and hearing care indicates a severe shortage of trained professionals (World Health Organization, 2013, 2021). In fact, 93% and 76% of low-income and lower-middle-income countries had less than one audiologist per million people compared to the 65% of high-income countries with more than ten audiologists per million (World Health Organization, 2021). While higher-income countries had better human resources to provide care, it is still abject considering the ratio to the population.

Early detection is crucial, and once an ear or hearing condition has been identified, a person can benefit from either clinical, rehabilitative or environmental interventions. The nature and type of hearing loss typically direct the rehabilitation route. Hearing loss due to ear diseases (e.g., otitis media, otosclerosis) can be treated using medication or surgery. However, most hearing loss is sensorineural (SNHL), affecting the inner ear (e.g., age-related or noise-induced hearing loss), and therefore, irreversible. In these cases, the most common rehabilitative option is hearing aids. However, less than 15% of people with hearing loss in LMICs who could benefit from hearing aids have them (World Health Organization, 2004, 2021). Hearing aid coverage in LMICs (ratio of hearing aid users to people with hearing loss) ranges between 1.5% to 12% (Bisgaard et al., 2021). Even in well-resourced settings, people often delay help-seeking after becoming aware of their hearing loss (Davis et al., 2007; Simpson et al., 2019; Yong et al., 2019). In the United States (US), for example, around 17.5 million older adults have a hearing loss of a significant degree that would make them eligible to wear hearing aids, but only about 20% seek them out (Perez & Edmonds, 2012). Similarly, the Blue Mountains Hearing Study showed that 39% of adults over 50 years do not seek help for their hearing loss in Australia, and 58% do not own hearing aids (Schneider et al., 2010). As a result, global hearing aid coverage is only about 10 to 11% (Bisgaard et al., 2021).

Hearing loss in most instances has a slow progression, and those affected may not realize the extent of the loss. Another potential factor is that diagnostics and treatment are a lengthy and

costly process where assessment and finding a device-based management option rely heavily on skilled staff with access to audiological equipment (Lin et al., 2016; Yong et al., 2019). This standard of practise was utilised to rule out medically treatable hearing loss types, such as conductive hearing loss (CHL) due to otitis media. Mobile and digital health approaches using consumer technology and near-universal internet connectivity provide new prospects to address the abovementioned constraints by scaling access using decentralized service delivery. More recently, alternative approaches were proposed to treat the most common forms of mild-to-moderate hearing loss. In 2016, the US Food and Drug Administration (FDA) published a recommendation report waiving the prerequisite of a medical assessment before getting a hearing aid (US Food and Drug Administration, 2016), which was passed into law in 2017 (US Food and Drug Administration, 2017). This report paved the way for alternative self-test diagnostics and hearing devices such as over-the-counter (OTC) hearing aids or direct-to-consumer (DTC) devices, low-cost alternatives to professionally fitted hearing aids. With initial evidence that amplification between traditional hearing aids and alternative amplification products (such as OTCs and DTCs) are relatively similar (Tran & Manchaiah, 2018), these devices are becoming viable options for persons with hearing loss. These technological options may significantly alter the role of hearing healthcare providers and manufacturers.

1.3. Digits-in-noise (DIN) test development, implementation, and practice to support early hearing loss detection.

To date, there have been several developments in hearing care that offer self-tests and national hearing screenings to the general public. These tools are generally designed to make the initial engagement with hearing healthcare more accessible. One commonly used approach has been the DIN, offered as a hearing screening solution over landline telephone (Jansen et al., 2010; Smits et al., 2004; Van den Borre et al., 2021; Watson et al., 2015; Watson et al., 2012), and more recently, digital mediums such as computers and smartphones (Potgieter et al., 2016). The DIN determines a speech recognition threshold (SRT) by presenting spoken digit-triplets (e.g., 5-2-7) in long term averaged speech spectrum (LTASS) masking noise. The correlation to pure tone audiometry is high, and the DIN has sensitivity and specificity of more than 80% to detect SNHL (De Sousa et al., 2020; Potgieter et al., 2018; Smits et al., 2004), qualities rated highly for successful screening. Probably one of the most noteworthy features of the DIN is that it can be conducted accurately without the need for headphone calibration or sophisticated audiological equipment (Potgieter et al., 2016; Smits et al., 2004) since the SRT does not measure absolute thresholds. The use of simple, familiar speech material (i.e., spoken digits) limits the contribution of top-down auditory processing (Smits et al., 2013). Therefore, it can be used in various clinical populations, including young

children (Koopmans et al., 2018) or people with limited linguistic skills (Kaandorp et al. 2015; Smits et al., 2013). Compared with other smartphone applications (apps) or web-based hearing screenings that use pure tones, the DIN has been validated more extensively and considered a more accurate self-test for consumer technology (Irace et al., 2021).

The first DIN was the Dutch national hearing screening test. Its successful implementation and large-scale uptake (Smits et al., 2006) led to other research teams and countries also offering DIN tests using the same approach (Jansen et al., 2010; Vlaming et al., 2011; Watson et al., 2012; Zokoll et al., 2012). While landline telephones are arguably more accessible than personal contact-based appointments, landline penetration is much lower in LMICs. For instance, in South Africa, only 14% of the population have access to a landline telephone (Statistics South Africa, 2013). Smartphones and mobile internet connectivity, on the other hand, are increasing rapidly. In 2020, there were nearly 4 billion mobile internet users globally, an increase of 250 million since the end of 2019 (GSMA, 2020a). Most (90%) new users were connecting from LMICs (GSMA, 2020a). Therefore, offering the test as a downloadable application was a more feasible and accessible approach. The first smartphone-based hearing test was released in South Africa in 2016, called *hearZA^TM (Potgieter et al., 2016)*. This was followed by the release of an American version in 2018 (*hearScreenUSA^TM*) and, in partnership with the World Health Organization, the *hearWHO^TM* app in 2019 (Swanepoel et al., 2019).

These digital DIN approaches described above can and have been leveraged for several purposes and are feasible considering that mobile devices and the internet have become an integrated part of daily life. The DIN used as a consumer application aims to boost public awareness of hearing health (De Sousa et al., 2018). Interestingly, data shows that significant proportions (90%) of older adults between 50 and 90 years, a critical audiological cohort, use internet services such as Facebook to engage with and share content regarding health information (Tennant et al., 2015). Digital health promotion tools, like the *hearZA^TM* or *hearWHO^TM* platforms, increase personal agency by enabling access, knowledge, decision-making, and engagement with the healthcare system. For example, aside from the initial screening, the *hearZA^TM* app provides a profile to track hearing over time, uses a location-based referral system to connect people to their closest hearing healthcare provider, and incorporates a decision support tool providing information to encourage help-seeking (De Sousa et al., 2018; Swanepoel, 2017). Other consumer offerings of the DIN could include free-standing devices in pharmacies and stores or screening directly on commercial websites to generate referrals. For instance, in the United States, *Best Buy* provides a free DIN hearing evaluation via its website and offer several DTC hearing aid intervention options (Best Buy,

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2021). Hybrid care models (i.e., a combination of online and face-to-face care) are another potential avenue that has been implemented successfully (Ratanjee-Vanmali et al., 2020a, 2020b). Hearing health professionals can offer web-based DIN screening on their practice websites, and following a failed test, prospective patients can provide their information to be contacted by an audiologist for diagnostic assessment.

Further steering audiological care into a new service delivery framework has been brought about by the COVID-19 pandemic. Across health disciplines, there were rapid shifts to telemedicine and eHealth. As audiological care is driven primarily by technology, the pandemic has dramatically changed how audiological services are provided globally. Social distancing conditions to constrain infections warranted the implementation of no or low-touch audiological services (Swanepoel & Hall, 2020). This was especially necessary for older audiological cohorts at greater risk of COVID-related illness (Centers for Disease Control and Prevention, 2020; Swanepoel & Hall, 2020). Traditional, sound booth-based audiometry is generally necessary for suspected ear disease. However, less controlled environments with fewer tests with less physical contact could suffice for many people with common, bilateral SNHL (Swanepoel & Hall, 2020). The DIN as an accessible, digital tool may support these telehealth measures by detecting and prioritizing cases that require in-person care, versus hearing loss that could be served in alternative no-or low-touch modes.

1.4. Different DIN approaches and procedures

To date, there are several different test platforms, measurement procedures, masking noises and calculation methods to improve DIN test precision, efficiency and sensitivity (Van den Borre et al., 2021). Generally, most DIN test procedures model the initial Smits et al. (2004) version. The original DIN test procedure consisted of 23-digit triplets adaptively presented in an up-down 2 dB SNR procedure, which had good test-retest reliability (measurement error of 1 dB) and a strong correlation to pure tone average (PTA; $r = 0.77$) (Smits et al., 2004).

As a self-test screening procedure, reducing the test time to a minimum to avoid fatigue confounds and lower the test drop-out rate is practical. The duration of a single DIN is approximately 3 minutes (Potgieter et al., 2016), so when implemented as a monaural test, it takes approximately 6-7 minutes to complete the test for both ears. Over the years, several methods to increase test efficiency have been presented. One option to reduce test time was to lower the number of trials. Watson et al. (2012) showed that the number of triplets could be reduced to 15 steps without significantly reducing the SRT-PTA association (Watson et al., 2012). Other test versions varied the number of presented digit-triplets based on stopping criteria. For example, Dillon et al. (2016) included a stopping rule in the *Telscreen* DIN test to

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end when SNR variability was below 1 dB; if not reached, the test ended at a maximum of 24 digits triplets (Dillon et al., 2016). Moore et al. (2019) used an alternative approach where the number of reversals was fixed instead of the number of trials (Moore et al., 2019). The test still followed an adaptive tracking procedure but started at a higher SNR (e.g., 14 dB SNR) and used an initially large step size of 6 dB. A reversal occurred after the first incorrect response, and the step size was altered to 3 dB steps. The second incorrect response prompted another reversal, further following a two down, one up procedure. The test was terminated after six reversals (Moore et al., 2019). However, if the primary goal is only to establish a 'pass' or 'fail' result, one could use a procedure presenting digit triplets at a fixed SNR instead of the staircase method (Smits, 2017). In a simulated setup, this procedure reduced the number of presentations from 25 adaptively presented trials to approximately eight trials with nearly equal pass-fail rates to the adaptive version (Smits, 2017). This significantly increases efficiency; however, the SRT, an informative measure of functional hearing, cannot be obtained. Earlier implementations of the DIN tests used monaural test paradigms (Smits et al., 2004; Smits et al., 2013; Watson et al., 2012; Williams-Sanchez et al., 2014; Zokoll et al., 2012), providing the relative function of each ear. However, another way to cut test time in half is to simply measure both ears at the same time as done in several DIN variants (De Sousa et al., 2020; Ozimek et al., 2009; Potgieter et al., 2016; Potgieter et al., 2018; Vlaming et al., 2014).

Next to keeping the procedure as short as possible, it is critical to maintain a precise, reliable test with low measurement error. Denys et al. (2019) presented a method where the step sizes were altered based on the correct recognition of individual digits in the presented triplets (Denys et al., 2019). In the conventional up-down staircase procedure, whole triplets are scored, meaning that all digits have to be recognised accurately to be considered correct (Smits et al., 2004). This triplet-scoring procedure targets a 50% recognition probability. Denys et al. (2019) targeted different recognition probabilities of 79%, 57% and 35% based on individual digit scoring and found the best measurement precision using the 79% criterion. Therefore, altering the step sizes using the 79% target recognition probability could produce a test with equal test-retest reliability to the conventional adaptive test but with fewer trials (Denys et al., 2019).

Besides adjustments to the procedure to improve test efficiency, different studies have investigated ways to improve the test sensitivity and specificity by increasing the SRT-PTA relationship. For example, alternative maskers, as opposed to continuous, broadband (BB) speech-weighted noise, have been explored to improve detection of the test to hearing loss occurring in the higher frequency (HF) range (Jansen et al., 2014; Leensen et al., 2011;

Vercammen et al., 2018; Vlaming et al., 2014; Motlagh Zadeh et al., 2020). This is a pragmatic approach since HFs are generally the most affected portion of the frequency spectrum, especially in cases of SNHL (Dubno et al., 2013). Furthermore, these versions of the DIN test are feasible, applied options for the detection of noise-induced hearing loss in occupational noise contexts (Leensen & Dreschler, 2013; Sheikh-Rashid et al., 2017), or for younger adolescents who are at risk for hearing loss due to recreational sound exposure (Rashid et al., 2016). Specifically, low-pass (LP) masking noise has been used to mask speech in lower frequencies, emphasising hearing performance in high frequencies. This approach was presented by Leensen et al. (2011) for a consonant-vowel-constant (CVC) words-in-noise test, which showed a higher correlation to PTA, and excellent sensitivity of more than 95% to detect high-frequency hearing loss (Leensen et al., 2011). Another study by Jansen et al. (2014) showed similar effects for a LP CVC words-in-noise test, but overall test characteristics to detect hearing loss did not exceed that of a BB DIN (Jansen et al., 2014). The LP noise-masking approach was also applied to a DIN test by Vlaming et al. (2014), showing high SRT correlation (r = 0.79) to high-frequency PTA (3 to 6 kHz) and accuracy of more than 85% to classify hearing loss more than 20 dB HL (Vlaming et al., 2014). Vercammen et al. (2014) also made use of a LP DIN test but did not see a significant increase in sensitivity for an older audiological cohort of 40 to 60-year-olds (Vercammen et al., 2018). This could have been due to the relative homogeneity of the sample. It should be kept in mind that while the LP filtering method improves the SRT-PTA relationship, some reports show that it comes at the cost of decreased test-retest reliability (Denys et al., 2019; Jansen et al., 2014; Vlaming et al., 2014).

Initial versions of the DIN either sequentially measured each ear or presented stimuli identically to both ears (diotic) to keep test time to a minimum. However, the diotic test is not sensitive enough to detect unilateral or very asymmetric SNHL since performance relies on the functionally better ear (De Sousa et al., 2020). Neither monaural nor diotic tests can adequately detect CHL, as the loudness attenuation caused by the loss can be overcome by increasing the presentation level of the test (De Sousa et al., 2020). The first attempt to improve the test's sensitivity to detect different hearing loss types was made by De Sousa et al. (2020). This study used an antiphasic stimulus paradigm where target speech (i.e., digits) was presented binaurally with a 180° phase shift while keeping masking noise diotic (De Sousa et al., 2020). This testing paradigm was able to better distinguish normal hearing from hearing loss in the poorer ear (including unilateral SNHL, bilateral SNHL and CHL) with a higher receiver operating characteristic curve (0.94) compared to the diotic DIN (0.77). While the antiphasic test paradigm improved the DIN's ability to detect different types of hearing loss, it will not be possible to distinguish between the different types from only a single antiphasic SRT. Following up on an initial test with other DIN variants (e.g., diotic, monaural,

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or filtered noise) for those who fail the antiphasic test could potentially allow for categorization into bilateral SNHL, unilateral SNHL or conductive hearing loss (De Sousa et al., 2020).

1.5. Study rationale

Significant developments have been made toward increasing the DINs efficiency and sensitivity to different types and configurations of hearing loss. However, DIN testing has mainly been restricted to screening for hearing loss without further distinctions. Some studies have used the DIN as a diagnostic measure of speech recognition in noise, for instance, during cochlear implant work-ups (Kaandorp et al., 2015). However, no studies have implemented strategies to categorize hearing loss type or degree of audiometric slope in both low and high-frequency ranges to enhance the test's diagnostic utility. Policymakers, research and consumer advocates are showing a growing interest to reform the provision of hearing care for increased access to affordable listening devices (Lin et al., 2016; Warren & Grassley, 2017). As a result, developments in accurate self-test paradigms independent of audiological equipment or skilled staff are necessary to support these newer service models. Advanced approaches to DIN screening and potential categorisation of hearing loss type and configuration could contribute to accessibility of hearing care and in clinical and consumer-based models of hearing care. This research project aimed to describe and evaluate advanced DIN approaches towards detecting and categorizing hearing loss.

The following research questions were posed in completion of the main aim:

1. *Can a sequential antiphasic and diotic DIN screening procedure triage and classify hearing loss based on type?*

2. *Can low and high pass filtered DIN tests estimate audiometric hearing loss slope?*

3. *Can a combination of pure tone air conduction audiometry and the DIN test detect conductive hearing loss without the use of bone conduction?*

4. *What is the global use and outcome of the publicly available hearWHO smartphone-based DIN test?*

CHAPTER 2: BACKGROUND

DIGITAL TECHNOLOGY FOR REMOTE HEARING ASSESSMENT-CURRENT STATUS AND FUTURE DIRECTIONS FOR CONSUMERS

This chapter provides background information on the currently available hearing screening options available directly to the public, as well as a critical discussion of the advantages, limitations and priorities for future research and test implementations.

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2.1. Abstract

Globally, more than 1.5 billion people have hearing loss. Unfortunately, most people with hearing loss reside in low- and middle-income countries (LMICs) where traditional face-to-face services rendered by trained health professionals are few and unequally dispersed. The COVID-19 pandemic has further hampered the effectiveness of traditional service delivery models to provide hearing care. Digital health technologies are strong enablers of hearing care and can support health delivery models that are more sustainable. The convergence of advancing technology and mobile connectivity is enabling new ways of providing decentralized hearing services. Recently, an abundance of digital applications that offer hearing tests directly to the public has become available. A growing body of evidence has shown the ability of several approaches to provide accurate, accessible, and remote hearing assessment to consumers. Further effort is needed to promote greater accuracy across a variety of test platforms, improve sensitivity to ear disease, and scale up hearing rehabilitation, especially in LMICs.

2.2 Introduction

Hearing is key to everyday functioning, communication and relationships in a hearing world. Unfortunately, more than 1.5 billion people globally have hearing loss; for nearly half a billion people, it is of a disabling degree [1]. The size of this global health burden and the lack of access to hearing health care requires radical health care delivery changes, as highlighted in the recent World Report on Hearing [1]. The emergence of digital health technologies has been identified as an important trend to support scalable hearing health delivery models that are sustainable [2,3]. Digital health technologies have already demonstrated use as powerful enablers of hearing healthcare [4,5].

Unaddressed hearing loss has a significant impact on individuals and society and is a leading contributor to the global burden of disease [6]. Untreated or late-diagnosed hearing loss has clear links to social isolation [7], loneliness [8], cognitive decline [9], dementia, unemployment [10] and general health, including rate of hospitalizations [11]. Hearing loss treatment, in most cases hearing aid provision, can significantly improve a person's function and participation to increase quality of life [12]. Despite excellent treatments available, access to hearing health care is typically unavailable, especially in low and middle income countries (LMICs) where the number of patients per healthcare provider is exceedingly high, and resources are few [13,14]. For instance, in LMICs (e.g., sub-Saharan Africa, Argentina and Mexico), there is typically fewer than one audiologist per million people [13,15]. Some types of hearing loss (e.g. noise-induced) can be prevented but, for other types (e.g. age-related hearing loss), early diagnosis and treatment are needed. In either case, regular hearing assessment plays a pivotal role in tracking hearing status and diagnosing hearing loss. The World Health Organization proposes early identification as one of the strategies to deal with the global burden of hearing loss [1]. Alternative ways to decentralise hearing assessment into rural areas could also reduce costs and improve widespread uptake. Digital technologies have increasingly demonstrated the potential to increase hearing health access via remote self- or community health worker facilitated testing [5,16-18].

Digital options for self-testing have become even more relevant during the COVID-19 pandemic, which has restricted traditional services, given the need for social distancing. Traditional hearing evaluation setups are often in confined spaces like soundproof booths, with long appointments and several tests involving equipment placement on and off the patient, all of which increases the risk of infection [19]. This is especially challenging in typical patients with hearing loss due to their advanced age and resultant mortality and morbidity risk

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[20]. It is thus no surprise that the use of technology to engage with the healthcare system has increased significantly amid the pandemic with a big move to telehealth. It is also unlikely that the utility of these technologies to provide healthcare will dissipate when the pandemic ends. While much research has been done on telehealth within the hearing healthcare space, the landscape for remote hearing assessment is quickly changing due to better access to mobile technology and internet connectivity. Globally, 3.8 billion people were mobile internet users by the end of 2019, an increase of 250 million since the end of 2018, of whom 90% of new users were from LMICs [21]. Therefore, remote care may aid in removing the ongoing access hurdles of formal audiological services and by providing context-appropriate solutions during the pandemic.

2.3. Remote hearing tests for public use

Traditional hearing healthcare services have proven ineffective to promote equitable access due to their resource-intensive and centralized nature, especially in LMICs. As a result, many digital applications have been developed to enable remote access. They can be classified as either clinical applications, used in a medically regulated settings that are often decentralized, or consumer applications available directly to the public [22]. This review focusses on the status and potential directions of publicly available options that enable hearing assessment for consumers.

2.3.1. Pure tone threshold tests

A traditional hearing assessment includes gold standard pure tone audiometry in a formal, face-to-face appointment to diagnose hearing loss. This test describes the hearing sensitivity in each ear, obtained by assessing the lowest threshold intensity (decibel hearing level) across frequencies ranging from 250 Hz to 8000 Hz. Many hearing evaluation applications are publicly available online or can be downloaded on smartphones via app stores like Google Playstore or Apple iStore, yet few are clinically validated against gold-standard measures [23,24]. Some applications use a form of traditional pure tone audiometry to measure hearing thresholds across a specific frequency range [24]. However, as a sustainable solution, these tests pose a challenge due to varying test accuracy across devices [25]. This is because device calibration cannot be performed on all platforms, which is a component essential in quality control to ensure that the sound level presented to the user is consistent with the level intended for assessment (Table 2.1). Applications that apply a calibration function for more accurate results are usually downloadable smartphone apps from the iOS platform. This is possible because they are part of the Apple ecosystem available to users who own a set of standardized Apple hardware and software (Apple earbuds, iPhone with iOS operating system). An example is the uHear application, one of the most validated consumer

applications in peer-reviewed literature [23]. Peer and Fagan (2015) [26] used the uHear application on an iPhone 4 coupled to Apple earbuds and showed comparable results to formal audiometry at higher frequencies. In general, accuracy of lower frequency thresholds, especially outside a soundproof booth, is lower due to the interference of ambient noise. A more recent study by Barczik and Serpanos (2018) replicated these results across the conventional frequency range using a newer iPhone 6 and Apple earbuds [25]. Two other studies found inaccurate results with the uHear application. The authors attributed the inaccuracies to the use of uncalibrated insert earphones [27,28]. These findings emphasize the need for calibrated devices when conducting pure tone audiometry on consumer devices. With that in mind, Apple recently released a pure tone audiometry module with calibration standards for their earphones as part of their research framework [22]. This development will likely support availability of pure tone tests directly to the public.

An advantage of this pure tone approach is that it may also serve as the basis to augment hearing, as done in traditional hearing aid fittings, using the same consumer electronics. One development along these lines is the "*headphone accommodation*" feature released for iOS 14 and Apple AirPods Pro in September 2020. This feature is reported to provide similar functions to a hearing aid by increasing the audibility of softer voices and tuning environmental sounds according to the user's needs [29]. While these advances in both hearing evaluation and amplification could provide a solution for people with milder forms of hearing loss, one major drawback is the high cost of Apple devices and app-incompatibility on other devices. Consequently, the availability and penetration of Apple smartphones is limited in LMICs [30].

2.3.2. Speech-based hearing tests

Mobile applications that do not use tonal stimuli usually employ a speech-in-noise procedure to measure hearing at conversational loudness levels [24]. One measure commonly used is the digits-in-noise (DIN) test which presents a series of three spoken digits (e.g., 3-5-8) in background masking noise [31]. The DIN varies the noise level relative to that of the digits up and down to find the ratio, termed the speech recognition threshold (SRT), where 50% of the digits are accurately recognized. The DIN SRT measure has strong reliability and validity, and high sensitivity and specificity to detect hearing loss measured with pure tone audiometry [31-35]. Moreover, unlike audiometry, the DIN is accurate across different devices and headphone types without the requirement of calibration (Table 2.1) [35]. This contributes to the DIN's sustainability as a digital hearing evaluation since it can be provided on several virtual platforms.

The first DIN test was developed and released as the Netherlands' national hearing test in 2004 for use over landline telephones [34]. DIN translations were developed in other countries

and dialects, including the USA, France, Switzerland, United Kingdom, Australia, Poland and Germany also for landline telephone [32,36,37]. More recently, the test was released on digital platforms, both online and as downloadable apps [35]. The first smartphone-based version, called *hearZA* [22], was released in South Africa in 2016. The World Health Organization released their *hearWHO* hearing screening app in 2019 and web app versions are also being used by consumer electronic companies like Bose [38]. The switch to digital devices had the added benefit of more easily operated user interfaces, and allows more high fidelity broadband test signals instead of limited bandwidth signals offered by landline telephones [35]. Uptake of the DIN on digital devices has increased use dramatically [39]. With an estimated 81% of the global adult population being smartphone subscribers by 2025 [40], the digitization of self-tests like the DIN provides widespread access for more sustainable and scalable hearing care options.

Currently, DIN applications serve primarily as a hearing screening tool. Follow-up with a registered professional is recommended when a hearing loss is detected. Since the test is accurate across a range of consumer electronics, it is easy to implement as an additional, 24-hour service for audiological websites to generate referrals [41]. Prospective patients who suspect a hearing loss can screen their hearing online and have the option to leave their information to be contacted by a hearing professional. Ratanjee et al. (2019) investigated the characteristics, behaviours and readiness of persons seeking hearing healthcare online as part of a hybrid online and face-to-face care model. Interestingly, they showed that many people completed a digits-in-noise test online outside the typical 9 am to 5 pm workday [42]. Therefore, the person seeking hearing care has the benefit of accessing services at times more convenient to them. Hybrid care models like these could be sustainable across the patient journey as patients have indicated high satisfaction with this approach [43]. Another option is to provide these tests as freestanding applications on tablets or computers for people to use directly in facilities like pharmacies, clinics and even retail stores.

2.4. Challenges

Remote hearing tests for the public and consumers are a practical way to increase access to services by capitalizing on the growth in personal digital technologies like smartphones. However, detecting hearing loss is only the beginning of the hearing health care journey. Some consumer hearing evaluations can link potential patients to healthcare providers, but they do not resolve the problem of ill-equipped healthcare systems in LMICs, or reduce infection risk (e.g., COVID-19) by minimizing face-to-face contact. Pure tone audiometry remains the gold-standard measurement to provide hearing aid fitting. Traditionally, the way to obtain a hearing aid includes several visits to a professional who performs diagnostics of the auditory system

and fits a hearing aid based on prescriptive gain and output targets. However, the Food and Drug Administration (FDA) published a nonbinding recommendation report in 2016 waiving the requirement for a medical evaluation before obtaining a hearing aid [46]. Furthermore, US President, Joe Biden, signed an executive order on 9 July 2021 which includes a directive to issue proposed rules within 120 days that will allow hearing aids to be sold over the counter [47]. As a result, the audiological landscape will rapidly change as newer categories of direct-to-consumer hearing aids (DTCs), that can be ordered online, and over-the counter hearing aids (OTCs), that do not require a professional to fit, will become more accessible [48]. As technology advances, 'hearables', which are wearable smart-computing earbuds, may also become more widespread [49]. Remote assessment can serve all these new rehabilitation options and is an essential area for future application. While progress has been made toward accurate pure tone audiometry through commercially available digital technology, there are persistent issues regarding test validity, accuracy and access. Therefore, improving the accuracy of pure tone tests would provide a way to self-program DTC and OTC hearing aids or even allow a smartphone to become an accessible, programmable intervention device, creating a more comprehensive and sustainable care pathway. An alternative is to look at ways other than pure tones to fit hearing aids. An example is the method used by Blamey, Blamey and Saunders (2015), who use a simple online speech perception test to measure hearing and fit hearing aids. Their work show it is possible to use predicted audiometric thresholds, derived from the speech perception test to accurately fit hearing aids [50].

Another challenge is how to serve people with more complex ear and hearing problems, such as differences in hearing loss between the left and right ear, or specific cases of ear disease (e.g., otitis media, wax impaction). In these circumstances, a medical assessment by an ENT doctor is recommended [51]. Currently, most consumer tests can only detect or indicate the severity of a hearing loss but cannot discriminate between types of hearing loss. A way to screen for potential ear disease will be of particular importance for people in LMICs, where the prevalence of ear disease like otitis media is higher than in high-income countries [52].

Whilst smartphone usage and mobile internet connectivity are increasing globally, it does not guarantee digital proficiency, which is characteristically higher for people who are younger, educated, employed and live in more urban areas [53]. Furthermore, in LMICs, a lack of literacy and digital skills is the main barrier to the use of mobile technology and the internet [21]. Older adults, in particular, who make up the largest audiological cohort, may be hesitant about their ability to perform online hearing assessments with difficulty navigating complex screens, instructions, and user interfaces [54]. Irace et al. (2020) reviewed smartphone applications for hearing assessment in the elderly and found that many smartphone applications did not include simple interfaces and instructions to accommodate dexterity or

mild cognitive impairment, hindering the use of touchscreens. In some instances, application instructions failed to indicate that the tests should be conducted using headphones [24]. Digital proficiency should, therefore, be a key factor considered when designing online applications to ensure usability for key demographics of people with hearing loss. Interestingly however, in LMICs like Kenya, smartphone penetration and usage amongst persons with hearing loss is similar to those without disabilities [55]. Digital devices already provide assistance to support persons with hearing loss to connect with others and access services including banking and payments [55].

A vital aspect to consider, and also a potential risk in the realm of digital healthcare, is data security. There are many applications available at no cost to the user, which could lead to uninformed test users falling trap to applications that sell data to third parties and risk their data privacy [24]. In addition, mobile health applications are targets of potential data theft. Vendors and providers should ensure that their applications meet the regulatory data security guidelines, and test users should carefully examine these applications before use [56].

Table 2.1.

Summary of remote hearing assessment applications for consumers and their characteristics

Stimulus Type	Pure tone audiometry applications	Digits-in-noise tests
Quantitative output	Hearing threshold estimation representative of the gold-standard audiogram	Speech recognition threshold or percentage-correct scores
Application	Screening on smartphone applications and website applications	Website applications Smartphone applications for direct consumer use. Freestanding applications in clinics
Advantages	Provides thresholds resembling the formal audiogram. Possibility to use thresholds to augment hearing loss using consumer electronics.	Quick to conduct. Less sensitive to ambient noise. Device and headphone calibration not required.
Limitations	Variable results across test devices and headphones. Require calibration to ensure accurate results. Sensitive to ambient noise in the test environment.	Results typically used for screening. Language dependent and requires translation and validation in other languages for widespread global uptake.
Examples of validated tests	uHear [25,26], Audiogram Mobile [44]	hearZA [33,35], hearWHO [33], USA computerized DIN [45]

2.5. Future work

Online and app tests using pure tone audiometry provide valuable output that approximate gold standard audiometry in clinical practice. However, they are only accurate for a handful of

devices when calibration functions can be applied and do not include bone conduction options available in clinics. On the other hand, speech-in-noise tests like the DIN do not rely on calibration and are well-validated. But they do not currently provide frequency-specific information that could be used to program hearing aids. One option to address the calibration issue of remote audiometry, and to facilitate diagnosis and program hearing aids using the DIN and other self-assessments, could be to ship calibrated self-test kits on digital devices directly to patients. Importantly, these advanced clinical self-test options could also allow the detection of possible ear disease. Our research has shown that when both pure tone audiometry and DIN testing are completed together, conductive hearing loss may be distinguished from sensorineural hearing loss [33]. This is important, since conductive hearing loss is typically related to ear diseases like otitis media, whereas mild/moderate sensorineural hearing loss may be appropriately treated remotely using self-fit hearing aids.

Other, related efforts conducted directly on consumer electronics can be used to detect ear disease and discriminate between types of hearing loss. For example, developments in DIN testing [33] are combining different stimulus procedures (antiphasic, diotic, monaural presentation) to discriminate conductive and unilateral sensorineural hearing loss from bilateral sensorineural hearing loss [33]. However, tests directed for public use should be as short and straightforward as possible to ensure maximum accuracy. Optimizing the test procedure for the shortest possible test duration while maintaining high test accuracy is important. A simple solution could be the provision of short case history questions that factor into the online test result and recommendation. Another, more advanced approach that can be embedded within a commercial self-test kit described above, includes the use of a simple video-otoscope that uses machine learning to classify potential ear disease [57].

Previous work on speech-in-noise tests used noise filtering techniques to increase sensitivity to hearing loss within a specific frequency range. Low-pass filtering stationary speech shaped noise was first introduced by Leensen et al. [58]. The premise of the filtering technique is to assess speech recognition of a specific frequency range by masking the adjacent frequencies. In most forms of hearing loss, high frequencies are the first part of the hearing spectrum lost [59]. By attenuating the background masking noise in the higher frequencies, higher frequency speech information is easier to recognize for people with normal hearing. However, people with high-frequency hearing loss do not have this advantage since they have reduced hearing ability within this frequency range [60]. This low-pass technique has increased the sensitivity and specificity of the digits-in-noise test to high-frequency hearing loss [61,62]. Future investigations into filtering methods to estimate hearing loss within low- and higher frequencies ranges could create new methods to prescribe and fit hearing aids without pure tone audiometry.

2.6. Conclusions

Digital health technologies are enabling remote hearing assessments to the public that are accessible, scalable and sustainable. These test options are timely, given the significant discrepancy in need for hearing care and the ability of formal care models to ensure service delivery. The COVID-19 pandemic has further deterred people from accessing services due to the risk of infection. Digital hearing assessment, while not a solution in itself, is providing opportunities to decentralize initial hearing care access by capitalizing on increasing mobile internet connectivity. Future work needs to investigate methods to ensure greater test accuracy, sensitivity to ear disease and ways to scale hearing rehabilitation using integrated digital solutions including hearing aids and other amplification options.

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CHAPTER 3
METHODOLOGY

3.1. Research objectives

3.1.1. Study aim

This study aimed to develop functions of the digits-in-noise (DIN) test to improve test sensitivity and ability to differentiate between hearing loss types. Four research objectives were designed, each constituting a research study submitted as an article to an accredited, peer-reviewed journal.

3.1.2. Research objectives

- Study I: To determine predictors and normative ranges of the antiphasic and diotic DIN test and to evaluate if a combination of the two DIN tests can categorize hearing as (a) normal bilateral hearing, (b) bilateral sensorineural hearing loss (SNHL), or (c) unilateral SNHL or conductive hearing loss (CHL).
- Study II: To investigate whether CHL (bilateral, asymmetric or unilateral) can be differentiated from sensorineural hearing loss (SNHL) using pure tone air-conduction audiometry and a DIN test.
- Study III: To investigate the test characteristics of a low-pass (LP) and high-pass (HP) DIN test and its relationship to pure tone thresholds.
- Study IV: To evaluate uptake, user characteristics and performance of the World Health Organization (WHO) smartphone-based hearing screening test (*hearWHO*) as a global hearing health promotion initiative.

3.2. Ethical considerations

The Humanities Research Ethics Committee, University of Pretoria, approved the project protocol (Appendix B). Health care research must adhere to ethical standards to promote respect and protect the rights of research subjects (South African National Health Act, 2013). The project described here was conducted within an ethical framework to ensure the well-being of research participants.

Protection from harm

To adhere to the beneficence's ethics principle, researchers are responsible for implementing strategies that protect participants from harm, loss of privacy, emotional distress or physical discomfort (Barrow et al., 2020). The research in this project was outlined within a predictive

ethics paradigm (Stevenson et al., 2015), meaning that risks to the study were considered prior to carrying out the research procedures. This involved specifying the research hypothesis in advance and designing the research so that the risks are predictable (Stevenson et al., 2015). There were minimal risks involved when participating in the research study. All potential risks were conveyed in writing in the informed consent letters and discussed verbally with the participants before providing consent. Furthermore, the benefits of participating far outweighed the potential risks. Benefits included receiving a free hearing evaluation. Where auditory or other health-related problems were identified, the appropriate referrals to professionals were made.

Voluntary and informed participation

One of the most critical protective principles in ethical research is protecting participants' autonomy while fully disclosing the study's features and rationale. This means that a person should be capable of deliberating about the study and acting under that consideration (Stevenson et al., 2015). All practices that participated in the research (Study I and II) provided written permission to assist with data collection (Appendix C and D) - the hearX Group and WHO provided permission to access *hearWHO* data for Study IV (Appendix E). All participants provided written informed consent after information was provided verbally and in writing about the nature and purpose of the study (Appendix F and H). All participants were provided the opportunity to ask questions about the study, ensuring that they fully understood what participating involved. For Studies I to III, all participants provided written informed consent. For Study IV, participants accepted a disclosure statement in the hearWHO application that their data may be used anonymously for research.

Right to privacy

Researchers must keep shared information in strict confidence and undertake procedures for anonymity or confidentiality (Stevenson et al., 2015). In Study IV, data was provided anonymously by the hearX group, meaning that the researcher could not connect a participant to the data. Furthermore, the data provided did not disclose any personal information, aside from age and gender. In Studies I to III, there was a high degree of contact between the participant and researcher. Therefore, anonymity was not possible. Instead, data was kept confidential by password protecting participants identifying data and submitting names with an alphanumeric code. The link to the participant code with the name and contact information was only available to the researcher in the case of emergency.

Release of findings

Results of the four separate studies were submitted to accredited, peer-reviewed journals for publication (Leedy & Ormrod, 2015). In this way, the study results were made available to the

scientific community and research participants. The results and methodology were described and reported in a way that can be replicated in other investigations. Participants were made aware that their data would be analysed and reported as scientific articles or conference presentations (Appendix F and I). However, their data would not be reported in a manner that the information could be traced back to the participant's identity.

Data storage

According to the University of Pretoria guidelines, data must be stored securely for a minimum of 15 years. Data will be stored electronically and in hard-copy at the Department of Speech-Language Pathology and Audiology, University of Pretoria.

3.3. Diotic and antiphasic DIN testing as a hearing screening and triage tool to classify type of hearing loss

3.3.1. Research design

This study employed a quantitative, cross-sectional research design to determine normative speech recognition thresholds (SRTs) for the antiphasic DIN test. After all the participants completed the antiphasic DIN test, an additional diotic DIN test was completed to determine if hearing loss could be categorized as (a) normal hearing bilaterally, (b) bilateral SNHL, or (c) unilateral SNHL or CHL (bilateral, asymmetric or unilateral). The time dimension was cross-sectional as all data were obtained from participants in a single session (Brink et al., 2006). Furthermore, the study was quasi-experimental as the normative SRTs and accuracy of the combined antiphasic-diotic DIN test approach were examined, without using a control group and without random assignment (Brink et al., 2006; Leedy & Ormrod, 2015).

3.3.2. Research participants

Non-probability, purposive sampling was used to recruit adults over 18 years (no upper age limit) with normal hearing or hearing loss of varying types. Participants were recruited from private audiology practices (Appendix C and D), a university clinic and screening programs organized in Pretoria, South Africa. Prospective participants were not invited to participate if they were previously diagnosed or currently presented with cognitive impairment, as they may have had difficulty self-administering the test and thus could have confounded the results. For prospective participants where bone conduction audiometry could not be performed in a soundproof booth (i.e., the participants tested via screening programs), tympanometry was used to indicate the presence of possible middle ear pathology. These prospective participants were excluded from participation if any other tympanogram was obtained besides Type A (based on the Jerger classification) (Katz et al., 2015). Participants were identified as having

normal hearing or hearing loss based on a pure tone frequency average (PTA 0.5 to 4 kHz). Participants were recruited when they presented with normal hearing bilaterally (n = 243; PTA ≤ 25 dB HL), bilateral symmetric SNHL (n = 172; PTA > 25 dB HL), unilateral SNHL (n = 42; PTA > 25 dB HL in the poorer ear and ≥ 20 dB interaural PTA difference), or CHL (n = 32; air conduction PTA > 25 dB HL and ≥ 20 dB air-bone gap [ABG] in the affected ears). A smaller group of participants with mixed hearing loss (n = 17, air and bone conduction PTA ≥ 25 dB HL in the poorer ear and PTA ABG ≥ 20 dB in the affected ears) were excluded. The rationale for their exclusion was based on the fact that most of these mixed hearing loss cases had severe hearing loss, and due to audiometer and bone conductor maximum output limits, could have produced false ABGs.

3.3.3. Research equipment and materials

Diagnostic audiometry

Diagnostic pure tone air- and bone-conduction audiometry were performed as part of a standard audiometric test battery at several audiological practice sites. All audiometers had to be calibrated and compliant with industry standards (ISO 389-1(1998) and 389-2 (1994) and were used in combination with an ISO 6189 (1993) compliant booth. The modified Hughson-Westlake method established pure tone thresholds (Hughson & Westlake, 1944) in a soundproof booth. An additional portion of participants was assessed as part of a hearing screening initiative. Tympanometry was conducted using a MAICO ERO SCANTM Pro (USA) on these participants. If participants tympanometry indicated Type A, air-conduction thresholds were established in a quiet, office-like setup using a hearTest™ (hearX Group, Pretoria, South Africa) smartphone-based audiometer. This procedure was done to rule out possible middle ear pathology and subsequent CHL as bone-conduction audiometry could not be performed on this group of participants. The hearTest™ application operated on a Samsung J2 Galaxy smartphone (Android OS, 5.1) and connected to supra-aural Sennheiser HD280 headphones (Sennheiser, Wedemark, Germany).

DIN testing

A research version of the DIN test was conducted on a Samsung Trend Neo smartphone connected to Sennheiser HDA220 headphones (Sennheiser, Wedemark, Germany). The test followed the procedure described in Potgieter et al. (2016) and De Sousa et al. (2020) (De Sousa et al., 2020; Potgieter et al., 2016). Twenty-three digit triplets were selected for presentation at the beginning of the test from a pre-constructed list of 120 digit-triplets (De Sousa et al., 2020; Potgieter et al., 2016; Smits et al., 2013). The selection of triplet for presentation was based on a randomised procedure. Digits included both mono-and bi-syllabic numerals between 0 and 9. Triplets were created with 500 milliseconds (ms) intervals

at the start and end of each triplet and 200 ms silent gaps with 100 ms of jitter in between individual digits (Potgieter et al., 2016). Long term averaged speech spectrum (LTASS) noise overlapped with the digits (De Sousa et al., 2020; Potgieter et al., 2016; Smits et al., 2013). The noise level was fixed at 70 dB sound pressure level (dB SPL), while the test altered the speech level when triplets were presented at negative signal to noise ratios (SNRs). In order to preclude clipping of the stimuli, the speech level became fixed, and the noise level varied once SNRs became positive (De Sousa et al., 2020; Potgieter et al., 2016). The test used an antiphasic test paradigm (out-of-phase; SπNo), where the speech had a 180° phase shift between the ears, keeping the noise identically in-phase (diotic) (De Sousa et al., 2020). Furthermore, stimuli could be presented diotically, meaning that identically phased speech and noise were presented to both ears simultaneously (De Sousa et al., 2020; Potgieter et al., 2016).

Before the test was executed, test users were instructed to select a comfortable listening intensity using a sliding scale on the smartphone touchscreen (Figure 1). Afterwards, the test commenced at 0 dB SNR. Participants were instructed to enter the three digits on the smartphone touch screen interface in the order they were heard. Where they were uncertain, they were instructed to guess. Correct responses lowered the SNR in 4 dB steps for the first three triplets, and incorrect responses increased the SNR in 2 dB steps. This procedure was implemented to prevent floor and ceiling effects during antiphasic testing (De Sousa et al., 2020). After the initial three steps, the test continued in an adaptive procedure in 2 dB SNR steps. The SRT was calculated by averaging the last 19 digit triplets (De Sousa et al., 2020; Potgieter et al., 2016).

3.3.4. Research procedures

Prior to testing, written informed consent was provided by all participants (Appendix F). The participating audiologists or researchers provided verbal and written instruction on the data collection procedure (Appendix C and D). Data was captured electronically on the smartphones, as well as on a data collection sheet (Appendix G). Pure tone air conduction audiometry was conducted to establish hearing thresholds at 0.5 to 8 kHz using calibrated audiometers and a soundproof booth. Where necessary, bone conduction audiometry was also performed, together with pure tone masking procedures (Hood, 1960). Pure tone audiometry was performed on a mobile audiometer (hearTest™) after tympanometry indicated Type A for a sub-group of participants ($n = 89$) tested as part of a hearing screening initiative by the researcher. Tympanometry evaluated middle ear functioning in terms of the external ear canal volume, middle ear pressure, and tympanic membrane compliance (Martin & Clark, 2003). Type and degree of hearing loss were determined based on a four frequency (0.5 – 4

kHz) PTA. The sample was categorised into PTA hearing categories which included normal bilateral hearing (PTA ≤ 25 dB HL), bilateral symmetric SNHL (PTA > 25 dB HL bilaterally), unilateral or asymmetric SNHL (PTA > 25 dB HL in the poorer ear and ≥ 20 dB interaural PTA difference) and CHL (air conduction PTA > 25 dB HL and ≥ 20 dB air-bone gap [ABG] in the affected ears) (Figure 3.1).

After pure tone thresholds were established, participants performed DIN testing. The DIN application followed the procedures described above (equipment and materials). Each participant was provided with a smartphone connected to headphones and independently completed DIN testing. Participants were provided with verbal instruction. In addition, the research application provided a screen re-iterating the test procedure. A few older participants required assistance from the audiologist or the researcher to type the digits heard onto the keypad. In these instances, the participant read aloud the recognised digits (in order). Each participant (n = 489) first completed an antiphasic DIN test. Afterwards, participants (n = 393) conducted a second diotic DIN. Antiphasic and diotic DINs were not counterbalanced, as this study investigated the results as it would be implemented as part of a sequential antiphasic and diotic DIN procedure. Participants who conducted both a diotic and antiphasic DIN were included for Study II's hearing category classification aim. On the basis of antiphasic and diotic DINs, participants were classified into different hearing categories. This classification assumed that (i) antiphasic DIN SRT ≤ cut-off indicated normal hearing; (ii) only antiphasic DIN SRT > cut-off indicated unilateral or asymmetric SNHL or CHL, and (iii) both antiphasic and diotic DIN SRTs > cut-off indicated bilateral SNHL (Figure 3.1).
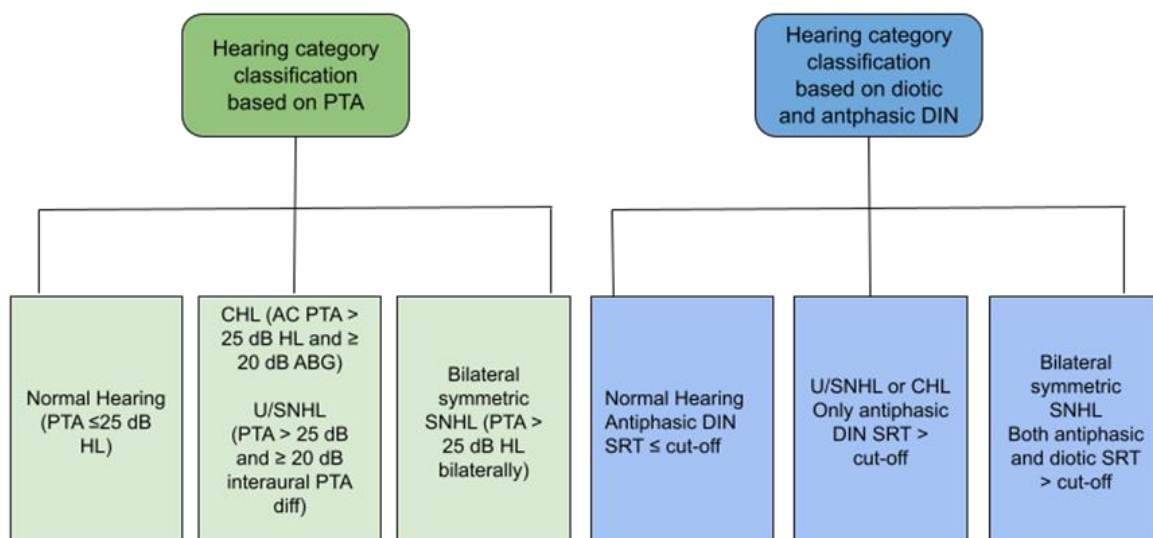
Figure 3.1. *Hearing loss classification for Study II based on PTA and DIN results.*

3.3.4. Data processing and analysis

Data processing was completed to organise data in a structured manner, thereby establishing patterns, identifying outliers and excluding missing data (Brink et al., 2006). Statistical Package Social Sciences (SPSS) v26 (Chicago, Illinois) was used for quantitative data analyses. Figures were completed in *R* (v3.6.1; R Core Team, 2019).

Descriptive and inferential statistics were used during data analysis. Descriptive statistics were used to describe the distribution (means and standard deviation) of participant age and SRT (diotic and antiphasic) performance across hearing loss types. Inferential statistics included multivariate linear regression analyses in determining the variance in the diotic and antiphasic DIN SRT that could be explained by better and poorer ear PTA and age (adjusted R^2). Testing for assumptions included assessing linearity using partial regression plots and a plot of studentised residuals against the predicted values. Durbin-Watson statistics were used to assess if residuals were independent (Field, 2009). Multicollinearity was assessed to ensure that tolerance values were not greater than 0.1. Leverage values were assessed to ensure no values greater than 0.2 and Cooks distance values above 1. Spearman correlations were used to determine the correlation between DIN SRT, better and poorer ear PTA because not all variables were normally distributed, as assessed by Shapiro-Wilk's test ($p < 0.05$). The area under the receiver operating characteristic (AUROC) analyses were conducted to determine sensitivity and specificity of the diotic and antiphasic DIN tests for different cut-off values. The targeted disorders were mild (poorer ear PTA > 25 dB HL) and moderate hearing loss (poorer ear PTA > 40 dB HL). Binomial logistic regression analyses were performed to derive AUROC curves covarying for age.

3.4. Pure tone audiometry without bone conduction thresholds: Using the DIN test to detect CHL

3.4.1. Research design

Study II investigated how a combination of pure tone air conduction audiometry and a diotic DIN SRT could differentiate bilateral SNHL from CHL. This was done using a quantitative, quasi-experimental design. As above, the design was considered quasi-experimental due to the omission of control and random assignment (Brink et al., 2006; Leedy & Ormrod, 2015). The quantitative data (SRTs and pure tone thresholds) was used to determine a binomial logistic equation to determine the risk of a CHL.

3.4.2. Research participants

The study extracted data of participants with CHL and SNHL from Study I. Therefore, recruitment, inclusion and exclusion criteria are the same as Study I. To be included in this analytic sample, participants had to have CHL (n = 36; unilateral, asymmetric or bilateral symmetric) or bilateral SNHL (n = 158). CHL was defined as air conduction PTA > 25 dB HL and ≥ 20 dB air ABG in the affected ears. Bilateral SNHL was defined as bilateral symmetric SNHL PTA > 25 dB HL, less than 20 dB interaural difference between the ears, and less than 20 dB PTA ABG.

3.4.3. Research equipment and materials

Study II followed the exact equipment and materials presented in Study I. Diagnostic audiometry was performed by various participating audiologists using calibrated equipment to establish pure tone air- and bone-conduction audiometry. Furthermore, a research version of the DIN was presented on a Samsung Trend Neo smartphone connected to Sennheiser HDA220 headphones (Sennheiser, Wedemark, Germany).

3.4.4. Research procedures

The research procedure is described above in Study II (see above for details). After the audiologist or researcher conducted pure tone audiometry, participants were provided with a smartphone connected to headphones and independently conducted testing after verbal and on-screen instruction. Each participant independently completed DIN testing.

3.4.5. Data processing and analysis

Descriptive and inferential statistics were used during data analysis. Descriptive statistics (means, range and standard deviation) were used to describe the study population regarding age and SRT performance across hearing loss types. Binomial logistic regressions were constructed to ascertain the effects of age, pure tone thresholds or PTA, and SRT on the likelihood that participants had CHL or bilateral SNHL. Linearity of the continuous variables with respect to the logit of the dependent variable was assessed via the Box-Tidwell (1962) procedure (Box & Tidwell, 1962). A Bonferroni correction was applied when using all terms in the model, resulting in statistical significance being accepted when $p < 0.01$ (Tabachnick & Fidell, 2014). All continuous independent variables had to be linearly related to the logit of the dependent variable (i.e., CHL/ bilateral SNHL). There had to be no evidence of multicollinearity with tolerance values greater than 0.1. Furthermore, there had to be no residuals deviating more than three standard deviations from the mean. Using these probability equations, category prediction (CHL vs SNHL) was evaluated on the study sample. Receiver operating

characteristic (ROC) curves were generated to determine cut-points for optimal sensitivity and specificity for each model. Furthermore, positive predictive values (the percentage of correctly predicted CHL cases compared to the total number of cases predicted as having CHL) and negative predictive values (the percentage of correctly predicted cases with SNHL compared to the total number of cases predicted as not having SNHL) were modelled for different prevalence rates of CHL. SPSS v27 (Chicago, Illinois) was used for quantitative data analyses. Figures were completed in *R* (v3.6.1; R Core Team, 2019).

3.5. Low and high-pass DIN test development and associations with pure tone audiometry

3.5.1. Research design

Study III used a quantitative correlational research design to determine the relationship and association of LP and HP speech filtered DIN SRTs with pure tone audiometric thresholds, PTA and extended high frequencies (EHFs). Correlational designs are appropriate for determining relationships between variables. Furthermore, they do not manipulate the independent variable (Brink et al., 2006). All data were collected cross-sectionally.

3.5.2. Research participants

There were two phases involved with this study. The first phase involved developing the test stimuli applied to the test procedure in the validation phase (phase II). For phase I, 20 normal-hearing adults (≥ 18 years; pure tone thresholds ≤ 15 dB HL across octave frequencies 0.5 to 8 kHz) were recruited from a student population using convenience sampling to determine recognition probabilities for individual digits between LP and HP filtering conditions.

Phase II recruited 125 adults (≥ 18 years, no upper age limit) with either normal hearing (PTA 0.5 to 4 kHz ≤ 15 dB HL) or SNHL (PTA 0.5 to 4 kHz ≤ 15 dB HL in either ear) ranging between mild to profound. Several participants were acquaintances of the researcher. Furthermore, participants were recruited through word-of-mouth campaigns and from a retirement village in Pretoria, South Africa (Appendix I). Therefore, the sampling method was non-probability, purposive; however, some participants were referrals of other research participants (snowball sampling). Prospective participants were not invited to participate if they had a diagnosed cognitive impairment or were identified with middle ear pathology, CHL or mixed hearing loss. Furthermore, if tympanometry was not Type A, they were not included in the study sample.

3.5.3. Research equipment and materials

Phase I- LP and HP digit stimuli development

Pure tone audiometry

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Pure tone audiometry (0.5-8 kHz) was conducted in a quiet office using a hearTest™ (HearX Group, Pretoria, South Africa) audiometry application (CE/FDA certified) on a Samsung A3 smartphone, connected to calibrated Sennheiser HDA300 circumaural headphones. The calibration was conducted using a Rion sound level meter and artificial ear with an adaptor plate before data collection commenced.

Digit recognition probability measurement

Individual digits (0-9) were presented using Matrix Laboratory (MATLAB) measurement software on an HP Envy Laptop. The digit material was the South African English digits used in Potgieter et al. (2016) and De Sousa et al. (2020) (De Sousa et al., 2020; Potgieter et al., 2016). LP and HP filtering was applied at 1.5 kHz using a 15th order Butterworth filter to the digit material and presented in unfiltered, broadband speech masking noise. The noise was matched to the LTASS of the unfiltered digits. Digit material from Potgieter et al. (2016) was used to create four lists of 100 digits, all from the same talker, filtered for LP and HP versions and presented using Sennheiser HDA 280 headphones. Each list consisted of the 10 digits presented in randomised order to define a 10% guess rate, mixed with the masking noise at fixed SNRs (-2 to -20 dB SNR). The digits were presented in a fixed order of 2 dB intervals, starting with highest and proceeding to lowest SNR. Masking noise started 500ms before each digit and ended 500ms after the digit. Participants entered their responses on the laptop after each digit was presented and, where they were uncertain, were instructed to guess.

Phase II- Test validation and slope estimation

Otoscopy and pure tone audiometry

Otoscopy was used to visually inspect the condition of the outer ear using a Welch Allyn otoscope. Pure tone air conduction audiometry was conducted using the hearTest™ application (HearX Group, Pretoria, South Africa) downloaded onto a Samsung A3 smartphone run on Android operating system (v8.8.0), coupled to Sennheiser HDA 300 circumaural headphones. The application allowed for automated threshold determination at 0.5 to 16 kHz using the ISO shortened ascending descending threshold seeking method (Carhart & Jerger, 1959).

DIN testing

In phase I, DIN was presented using MATLAB measurement software on an HP Envy Laptop, coupled with Sennheiser HDA 280 headphones. Participants were tested monaurally. Digit triplets were presented in LTASS noise. The test used a randomised selection of 23 digit-triplets for presentation from a list of 120 digit-triplets (Smits et al., 2013; Potgieter et al., 2016). Masking noise started and ended 500-ms before and after each digit-triplet; triplets had 200-

ms intervals between the digits. For triplets with negative SNRs, the masking level was fixed, and digits varied in 2-dB intervals. For triplets with positive SNRs, masking level varied, and digit level was constant (Potgieter et al. 2016; De Sousa et al. 2020). The standard scoring procedure previously used for the South African English DIN required that all digits in the triplet be recognised correctly before reducing the SNR (Potgieter et al. 2016; De Sousa et al. 2020). However, a preliminary study showed that the recognition probability for some digits (e.g., one) in the HP condition was low due to the filtering of low-frequency information. Therefore, the DIN procedure was changed across all filtering strategies, so the SNR was reduced in 2 dB steps when two or three digits were recognized correctly and increased when no or one digit was correct. The final SRT was calculated by averaging the SNR of the last 19 digits.

3.5.4. Research procedures

Phase I developed the LP and HP digit material for implementation into the DIN tests. Written informed consent (Appendix H) was obtained from each participant before data collection commenced. Figure 3.2. provides a summative description of the data collection procedures for Study III. Otoscopy was done to evaluate the external ear canal for inflammation, foreign objects, growths, and excessive cerumen. After otoscopy, the researcher completed pure tone audiometry (0.5-8 kHz) on each participant to establish normal hearing thresholds (a strict criterion of ≤ 15 dB HL across all thresholds). After pure tone audiometry, participants completed the individual digit recognition procedure. Each participant completed two lists of individual digits (0-9) presented at various SNRs, from lowest to highest. Each list, therefore, contained 100 individually presented digits. Participants completed this procedure by typing the digits heard on the laptop keypad on the MATLAB program. When unable to recognise the digit, they were instructed to guess.

Participants completed the lists for each ear and both LP and HP conditions. The order of LP and HP lists and presentation to the right and left ears were counterbalanced between participants (i.e., four lists in total). Psychometric curves were determined for each digit. Speech intelligibility as a function of SNR has been described by Jansen et al. (2010), Brand and Kollmeier (2002) and Vlaming et al. (2014) (Brand & Kollmeier, 2002; Jansen et al., 2010; Vlaming et al., 2014), using the following equation:

$$SI(SNR) = y + (1 - y)\frac{1}{1 + e^{4s(SRT-SNR)}}$$

In this equation, SI indicates speech intelligibility; y, guess level; SRT, speech recognition threshold; SNR, signal to noise ratio; and s, the slope at the SRT. Typically, to equalize the material, the psychometric function of each digit is averaged across the participants. From that function, mean SRT was determined at each digit. The level of each digit is then shifted to the

mean SRT so that the psychometric function intersects at the mean SRT point. In this study, the SNR equivalent to 50% correct was determined. The study aimed to use the values to apply level corrections and equalize the materials. However, after completion of the study, an error in the software script was discovered, resulting in inaccurate level corrections. The average level corrections across all digits were 0 dB, but the SD of the SNRs corresponding to the 50% point decreased only slightly (from 3.8 dB to 3.6 dB and from 4.9 dB to 4.3 dB for LP and HP filtered digits). Since the level correction average was 0 dB, it was not expected that the heterogenous material used in Phase II would be different when using equalized digits.

Phase II involved the validation procedure and slope estimation by testing participants with varying levels of hearing. Otoscopy was used to visually inspect the condition of the outer ear, followed by pure tone audiometry (0.5-16 kHz) conducted on a smartphone audiometer. Participants were excluded when they presented with visible outer or middle ear pathology. Test-retest reliability for LP and HP DIN was measured for the first 32 participants. The same instructions were provided to each participant verbally. Each participant completed one unfiltered DIN (broadband [BB] DIN), two LP and two HP DINs in each ear (10 DINs per participant) consecutively in short intervals. A short rest period was provided after the initial five DIN tests when required. For the rest of the sample (*n*=93), each participant completed one unfiltered DIN, one LP DIN and one HP DIN per ear (6 DINs per participant). All participants started with the unfiltered DIN. A counterbalanced test procedure was used to alternate presentation between left and right ears and between LP and HP DIN.

Development of LP and HP stimuli (Phase I)
- Determine psychometric slope for each digit to ensure average level correction of 0 dB.
- 20 participants with normal hearing recruited to listen to four lists of individual digits presented at different SNRs.
- Digits presented in LP and HP conditions- Speech filtered using 1.5 kHz 15th order Butterworth filtered presented in LTASS noise Generate LP and HP LTASS noise.

Generate new testing procedure in MATLAB
- Adapated procedure of De Sousa et al. (2020) and Potgieter et al. (2016).
- Adaptive up-down tracking procedure; 2 dB SNR down for 2 or 3 digits correct; 2 dB SNR increase for 0 or no digits correct.
- SRT is calculated by averaging the last 19 SNRs.
- Monaural test procedure.

LP and HP DIN association with PTA (Phase II)
- Test-retest for LP and HP DIN completed on 32 participants (for each ear).
- One BB, LP and HP DIN test completed on 125 participants of varying hearing. ability on each ear (monaural test procedure).

Figure 3.2. *Summary of the test procedure for Study III*

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3.5.5. Data processing and analysis

Data was captured electronically through generated text files from the MATLAB software (MathWorks.com). Furthermore, data was captured on a Microsoft Excel spreadsheet to be used for analyses on IBM SPPS v27 (Chicago, Illinois). Figures were generated in *R* (v3.6.1; R Core Team, 2019). Descriptive statistics (mean, standard deviation, median, percentiles and range) were used to describe participant age, pure tone threshold distribution and SRT performance (unfiltered BB, LP and HP SRT). Intraclass correlation coefficient (ICC) for LP and HP filtered DIN was conducted to determine the systematic difference in test-retest between participants. ICC was conducted as a mean rating of the number of observations (i.e., test-retest, $k = 2$), absolute agreement and a two-way mixed-effects model. In addition, measurement error between test-retest for LP and HP DIN was calculated by determining the quadratic mean of within-subject SDs. Spearman's correlations were used to correlate individual frequencies and PTAs to BB, LP and HP DIN. Multivariate linear regressions were completed to determine the PTA predictors of BB, LP and HP DIN. Stepwise linear regression was assessed to determine the most significant pure tone audiometric frequencies that could predict BB, LP and HP DIN. Stepwise regressions are a valuable method of regressing multiple variables but simultaneously removing the variables that do not significantly contribute to the equation. Before conducting linear regression, assumptions were tested, including assessing linearity and homoscedasticity using partial regression plots and a plot of studentised residuals against the predicted values. Durbin-Watson statistics were used to assess if residuals were independent (Field, 2009). Multicollinearity was assessed to ensure that tolerance values were not greater than 0.1. Leverage values were assessed to ensure no values greater than 0.2 and Cooks distance values above 1.

3.6. Global use and outcomes of the hearWHO mHealth hearing test app

3.6.1. Research design

A retrospective, quantitative, descriptive research design (Brink et al., 2006; Leedy et al., 2014) was employed to establish uptake, user characteristics and performance of a globally available, free smartphone-based DIN test (*hearWHO*). The tests conducted from test release in March 2019 to May 2021 were pooled, and therefore, analysed retrospectively. Descriptive research is used when characteristics of a phenomenon are investigated as they naturally occur (Brink et al., 2006). This study design was appropriate as the aim was to determine the hearWHO test uptake and performance without determining any cause-effect relationships (Brink et al., 2006).

3.6.2. Research participants

Study I included an anonymised dataset supplied by the hearX Group and the World Health Organization (WHO) (Appendix D) . Data included *hearWHO* tests of adult users (≥ 18 years) who completed the test between February 2019 and May 2021. Data of tests that were completed for users younger than 18 years was excluded since the *hearWHO* test cut-offs are based on adult normative criteria. The sampling method can be considered probability, random sampling as participants had an equal chance of being included in the sample (i.e., the researcher had no control over who completed the *hearWHO* test (Brink et al., 2006)

3.6.3. Research equipment and materials

Users completed the *hearWHO* DIN test by downloading the free application on an Android or iOS operated smartphone connected to headphones or earbuds. People were made aware of the application through global marketing campaigns, word-of-mouth endorsements, or searching for hearing test applications on smartphone app stores. Users could conduct the test in either English, Mandarin or Spanish, although the Spanish and Mandarin versions were only released on the 3rd of March 2021, two years after the initial launch. Before releasing these language versions, English was the only test option. The application required users to select their birth year, native language and connect their headphones prior to testing. The DIN uses the same procedure, stimuli and antiphasic test paradigm described in Study I (equipment and materials) and De Sousa et al. (2020) (De Sousa et al., 2020).

Before the test was executed, test users were instructed to select a comfortable listening intensity using a sliding scale on the smartphone touchscreen (Figure 1). Afterwards, the test commenced at 0 dB SNR. Users were instructed to enter the three digits in the order heard on the smartphone touch screen interface (Figure 3.3). Where they were uncertain, they were instructed to guess. Correct responses lowered the SNR in 4 dB steps for the first three triplets, and incorrect responses increased the SNR in 2 dB steps. This procedure was implemented to prevent floor and ceiling effects during antiphasic testing (De Sousa et al., 2020). After the initial three steps, the test continued in an adaptive procedure in 2 dB SNR steps. The SRT was calculated by averaging the last 19 digit triplets (De Sousa et al., 2020; Potgieter et al., 2016).

3.6.5. Data processing and analysis

Data was extracted by the hearX Group and provided as an anonymized Microsoft Excel spreadsheet for analyses. IBM SPPS v27 (Chicago, Illinois) was used to generate descriptive statistics. Figures were completed in *R* (v3.6.1; R Core Team, 2019).   Descriptive statistics (frequency, mean, median, standard deviation) were used to report uptake across ages,

genders, world regions and countries. SRT performance was evaluated across age and gender by fitting third-order polynomials on a visual plot. Furthermore, uptake was assessed across test dates.

Figure 3.3. *The hearWHO application interface and process.*

CHAPTER 4

DIOTIC AND ANTIPHASIC DIGITS-IN-NOISE TESTING AS A HEARING SCREENING AND TRIAGE TOOL TO CLASSIFY TYPE OF HEARING LOSS

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Note: This manuscript was edited in accordance with the editorial specifications of the journal and may differ from the editorial style of the rest of this document

4.1. Abstract

Objectives: The digits-in-noise test (DIN) is a popular self-test measure that has traditionally been used to screen for hearing loss by providing either a *pass* or *refer* result. Standard approaches either tested each ear monaurally or used a binaural diotic version where identical digits and noise were presented simultaneously to both ears. Recently, a dichotic, *antiphasic* version was developed, increasing sensitivity of the DIN to unilateral or asymmetric sensorineural hearing loss (SNHL) and conductive hearing loss (CHL). The purpose of this study was to determine predictors and normative ranges of the antiphasic and diotic DIN and to determine if a combination of diotic and antiphasic DIN could accurately categorize hearing into (a) normal, (b) bilateral SNHL, or (c) unilateral SNHL or CHL.

Design: The analytical sample consisted of 489 participants between the ages of 18 and 92 years with varying types, symmetry and degrees of hearing loss. Degree and type of hearing loss were determined based on standard clinical four frequency (0.5 – 4 kHz) pure tone air and bone conduction threshold averages. The sample consisted of bilateral normal hearing (n = 293), bilateral SNHL (n = 172), unilateral SNHL (n = 42) and CHL (n = 32). All participants (n=489) first completed an antiphasic DIN (digit stimuli 180° out-of-phase between ears), while 393 of the sample also completed a diotic DIN. Two procedures were assessed for their ability to categorize hearing into one of the three hearing groups. The first used a fixed antiphasic

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cut-off combined with a cut-off formed by a linear combination of antiphasic and diotic speech recognition threshold (SRT) or binaural intelligibility level difference (BILD).

Results: Poorer ear pure tone average (PTA) was the strongest predictor of antiphasic DIN score, whereas better ear PTA explained more of the variance in diotic SRT. The antiphasic DIN sensitivity and specificity was 90% and 84% respectively for detecting hearing loss, with outstanding area under the receiver operating characteristics (AUROC) values exceeding 0.93 to identify hearing loss in the poorer ear. The first fixed SRT cut-off procedure could categorize 75% of all participants correctly, while the second procedure increased correct categorization to 79%. False negative rates for both procedures were below 10%.

Conclusions: A sequential antiphasic and diotic DIN could categorize hearing to a reasonable degree into three groups of (a) normal hearing, (b) bilateral SNHL, and (c) unilateral asymmetric SNHL or CHL. This type of approach could optimize care pathways using remote and contactless testing, by identifying unilateral SNHL and CHL as cases requiring medical referral. In contrast, bilateral SNHL cases could be referred directly to an audiologist, or non-traditional models like OTC hearing aids.

Keywords: digits-in-noise, antiphasic, diotic, hearing loss, conductive hearing loss, sensorineural hearing loss, unilateral hearing loss.

4.2. Introduction

Hearing loss is often a slowly progressing chronic condition and those affected may not realize that they have it. According to the Global Burden of Disease Study (Global Burden of Disease 2016), hearing loss is one of the most common impairments, adding up to about 1.3 billion people globally. Prevalence is highest among older adults, with a third of people over 65 years affected by hearing loss of a disabling degree (World Health Organization 2020). Routine hearing screening has been suggested to bolster early uptake of intervention and increase public awareness of hearing loss (Wilson et al. 2017). The earlier a person takes up intervention, the greater the prospects of reducing the consequences, such as social isolation, depression and cognitive decline of hearing loss to a minimum (Cacciatore et al. 1999). However, only about 20% of adults seek help for hearing loss (Davis et al. 2007) and often delay help-seeking for a number of years (Davis 1995; Simpson et al. 2019). Therefore, much can be gained from routine screening and subsequent early rehabilitation. Unfortunately, adult screening programs are poorly recognized among the lay public (Lin et al. 2016) and not widely available, especially in low-and middle-income countries (Olusanya et al. 2014). In the past 15 years, there has been a shift towards more accessible screening methods, including speech recognition, that individuals can perform without a trained professional. Additionally,

the desirability of remote, contactless self-screening has recently been emphasized by the Covid-19 pandemic.

Self-test measures are meant to support large scale detection of hearing loss. However, the question around continuity of care is the follow-up for a person identified with hearing loss. Hearing screening tests usually only detect hearing loss, without discriminating types of hearing loss. Some provide information on causes and general treatment possibilities or include location-based referral to hearing aid dispensers (Swanepoel et al. 2019). However, some types of hearing loss, such as unilateral or asymmetric sensorineural hearing loss (SNHL) or conductive hearing loss (CHL), require referral to a physician (AAO-HNS 2014) according to best practice recommendations. Screening tests that can triage persons and directly refer for either diagnostic hearing assessment or medical evaluation could streamline diagnosis and treatment. Another potential problem with large scale consumer screening, especially in low- and middle-income countries, is the limited infrastructure and availability of hearing health professionals (Mulwafu et al. 2017). Even in high-income countries, diagnosis and treatment may be delayed due to high client-to-audiologist ratios (Kamenov et al. 2021). To reduce the load on overburdened healthcare systems and increase accessibility to services, over the counter (OTC) hearing aids and other amplification devices have sparked wider interest in the past few years (Humes et al. 2017). Giving precedence to cases that require standard contact-based appointments (e.g., unilateral SNHL or CHL) above those who can proceed directly with device-based intervention (e.g., age-related SNHL) is an important consideration for self-test screening.

The digits-in-noise test (DIN), which measures bottom-up speech recognition in noise, has become progressively more popular over the last 15 years. Using an adaptive procedure, the test determines the signal-to-noise ratio (SNR) at which 50% of digit-triplet recordings (e.g., 4-3-7), presented in speech-shaped masking noise, are recognized correctly (i.e., speech recognition threshold [SRT]). The DIN as a diagnostic speech-in-noise test has a steep psychometric slope and correlates highly ($r = 0.86$) with commonly used sentence-in-noise tests (Plomp et al. 1979; Smits et al. 2004). DIN tests are cognitively less demanding than many other speech-in-noise tests because most listeners are familiar with digits, limiting the contribution of top-down processing (Smits et al. 2013). Although factors such as cognition still factor into DIN test performance (Moore et al. 2014), the correlation between DIN and pure tone average (PTA) thresholds is higher than between PTA and other speech-in-noise tests (Jansen et al. 2010). In addition, the DIN is a robust self-test that can be conducted without calibrated equipment (Potgieter et al. 2016; Smits et al. 2004). It has, therefore, been widely implemented as an alternative to pure tone hearing screening in adults. The first DIN was released as a National Hearing Test over landline telephone in the Netherlands in 2004 (Smits

et al. 2004) and had a large-scale uptake of more than 160,000 tests two and a half years after its release (Smits et al. 2005). Many more language and dialect versions of the DIN have been developed, some of which have been offered to the public as either landline or internet-based screening tests (Jansen et al. 2010; Motlagh Zadeh et al. 2020; Ozimek et al. 2009; Van den Borre et al. 2021; Watson et al. 2012). To increase global accessibility, including low-and-middle income countries, newer versions used a downloadable app where the test could be completed on iOS or Android operated smartphone or other mobile devices like the World Health Organization's official hearing test app, hearWHO (Potgieter et al. 2016; Potgieter et al. 2018; Swanepoel et al. 2019).

Though based on the original version of Smits et al. (2004), procedural differences between adaptations of the DIN exist. Some successively test each ear (Jansen et al. 2010; Smits et al. 2004; Watson et al. 2012) while others use binaural, identical stimuli presented to both ears (diotic; Potgieter et al. 2016; Potgieter et al. 2018) which is advantageous in terms of test duration. Monaural and diotic DIN SRTs agree strongly with PTA with correlations between 0.7 and 0.9 and have high sensitivity and specificity (> 80%) to detect sensorineural hearing loss (Jansen et al. 2010; Koole et al. 2016; Potgieter et al. 2018; Smits et al. 2004; Watson et al. 2012). However, diotic DIN SRTs fail to detect unilateral SNHL due to the dominance of the better ear for this task (De Sousa et al. 2020c). Furthermore, both monaural and diotic SRTs are mostly unaffected by attenuation caused by CHL when presented at suprathreshold levels (De Sousa et al. 2020b). Antiphasic presentation of the DIN has been shown to improve sensitivity to different hearing loss types (including unilateral SNHL and CHL) by using interaural 180° phase reversed speech presented in diotic noise (i.e., NoSπ; De Sousa et al. 2020b). Antiphasic presentation involves mechanisms of both binaural interaction and unmasking. Normal-hearing individuals benefit by better isolating target speech from noise and obtain about 6-8 dB lower SRTs (De Sousa et al. 2020b; Smits et al. 2016). However, peripheral hearing loss (including unilateral SNHL or CHL) significantly diminishes this antiphasic benefit (i.e., the binaural intelligibility level difference, BILD) because of disruption in interaural timing, binaural unmasking, and asynchronous neural action of the affected ears (Hartley et al. 2003; Jerger et al. 1984; Thornton et al. 2012; Welsh et al. 2004). Regression analysis predicting DIN SRT from poorer ear PTA showed steeper slopes and a higher correlation between PTA and antiphasic DIN SRTs compared to diotic DIN SRTs (De Sousa et al. 2020b). Antiphasic SRTs of listeners with hearing loss of any type were significantly higher than those of normal-hearing listeners. In contrast, diotic DIN SRTs of those of normal hearing listeners considerably overlapped with hearing loss groups consisting of bilateral SNHL, unilateral SNHL, and CHL. As a result, area under the receiver operating characteristic curve (AUROC) to detect hearing loss in the poorer ear more than 25 dB HL was considerably

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higher for antiphasic (94%) than diotic DIN (77%) (De Sousa et al. 2020b). Antiphasic presentation therefore provides a unique solution to improve the sensitivity of a single DIN to detect various hearing loss types and symmetries, including unilateral or asymmetric SNHL and CHL.

In a typical DIN screening procedure, the test estimates the SRT and compares the result with an established cut-off value. If the SRT is lower (better) than the cut-off, the test is a "pass" and if higher (worse), "refer". This is effective when the sole aim is to identify an affected individual. However, by following up on an initial 'referred' antiphasic test with a diotic version, according to the scheme provided in Figure 4.1, it could theoretically be possible to categorize the results as either (i) bilateral SNHL, or (ii) unilateral SNHL or CHL, given that diotic SRTs have been shown to be near-normal for listeners of the latter category. To investigate this hypothesis, we determined 1) the predictors and normative ranges for antiphasic and diotic DIN SRTs across degree and type of hearing loss; 2) the performance of a sequential antiphasic and diotic DIN procedure to detect and classify hearing loss type.
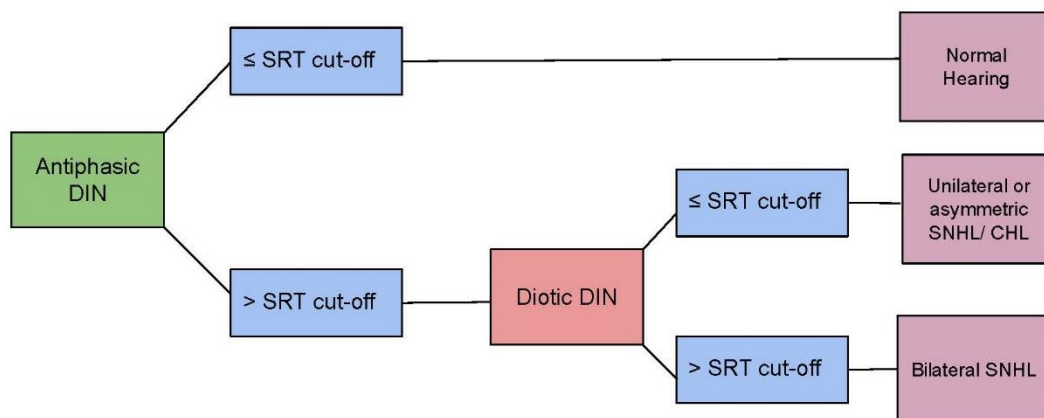
Figure 4.1. *Screening procedure for a sequential antiphasic and diotic DIN approach.*

Note. DIN indicates digits-in-noise; SRT, speech recognition threshold; CHL, conductive hearing loss; SNHL, sensorineural hearing loss.

4.3. Method

4.3.1. Participants

This cross-sectional study recruited 507 participants between the ages of 18 and 92 years (mean = 51 years, SD = 19 years) with varying types, symmetries and degrees of hearing loss. A convenience, non-probability sampling method was used to approach participants at clinical data collection sites. Participants were recruited from private audiology practices, a university clinic and hearing screening initiatives organized in Pretoria, South Africa. Type and

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degree of hearing loss was determined based on a four frequency (0.5 – 4 kHz) PTA. The sample consisted of people with bilateral normal hearing (n = 243; PTA ≤ 25 dB HL), bilateral symmetric SNHL (n = 172; PTA > 25 dB HL bilaterally), unilateral or asymmetric SNHL (n = 42; PTA > 25 dB HL in the poorer ear and ≥ 20 dB interaural PTA difference) and CHL (n = 32; air conduction PTA > 25 dB HL and ≥ 20 dB air bone gap [ABG] in the affected ears). For the unilateral or asymmetric SNHL group, only four cases were asymmetric, with the PTA in the better ear between 26 to 45 dB HL. In the CHL group, bone conduction PTA usually did not exceed 25 dB, except for one case where the bone conduction PTA in the poorer ear was 35 dB HL. Most cases of CHL were either unilateral or asymmetric (n = 21), with a smaller portion of bilaterally symmetric CHL (n = 11). A small group of mixed hearing loss (n = 18, air and bone conduction PTA ≥ 25 dB HL in the poorer ear and PTA ABG ≥ 20 dB in the affected ears) were excluded from the analytic sample. Most (n = 16) of these participants had severe or profound loss, and it was possible that false ABGs could occur due to limitations in the maximum output of the bone conductor transducer. After exclusion, the number of participants for the analyses was 489 (Table 4.1). Degrees of hearing were based on poorer ear PTA and categorized according to WHO grades of hearing impairment (World Health Organization 2020) as either normal hearing (PTA ≤ 25 dB HL), mild (PTA 26-40 dB HL), moderate (PTA 41-55 dB HL) or severe to profound hearing loss (PTA 56-120 dB HL).

From this sample, 393 participants conducted both antiphasic and diotic DIN tests. They were included for hearing category classification using sequential antiphasic and diotic DIN tests. BILD was calculated by subtracting antiphasic DIN SRT from diotic DIN SRT. Defined by better and poorer ear PTAs, participants were grouped as either having: (i) normal bilateral hearing (n = 202), (ii) bilateral symmetric SNHL (n = 123), (iii) unilateral or asymmetric SNHL or CHL (n = 68). Furthermore, participants were classified based on the results of both antiphasic and diotic DIN. This classification assumed that (i) antiphasic DIN SRT ≤ cut-off indicated normal hearing; (ii) only antiphasic DIN SRT > cut-off indicated unilateral or asymmetric SNHL or CHL, and (iii) both antiphasic and diotic DIN SRTs > cut-off indicated bilateral SNHL. See Figure 4.1.

4.3.2 Procedures and equipment

The Humanities Research Ethics Committee of the University of Pretoria, South Africa approved the study protocol (number: HUM003/0120). All participants were informed of the study aims and procedures and provided written informed consent before participation.

Qualified audiologists conducted pure tone air and bone conduction audiometry at different test sites as part of a standard audiometric test battery using diagnostic audiometers calibrated to industry standards. The modified Hughson–Westlake method was used to establish

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thresholds (Hughson and Westlake 1944). The majority (n = 400) of the participants were tested inside a soundproof booth, while 108 normal-hearing participants were tested in a quiet office-like environment using a hearTest™ (hearX group, Pretoria South Africa) smartphone-based audiometer. The hearTest™ application ran on a Samsung J2 Galaxy smartphone (Android OS, 5.1) and connected to supra-aural Sennheiser HD280 headphones (Sennheiser, Wedemark, Germany).

The South African English DIN test (Potgieter et al. 2016) was conducted on either a Samsung Trend Neo or Samsung J2 Galaxy smartphone and coupled with manufacturer supplied wired earbuds (n = 123), Sennheiser HDA 220 (n = 242) or Sennheiser HDA 280 headphones (n = 124). The test followed the same procedure and used the same stimuli as described in De Sousa et al. (2020). Twenty-three-digit triplets were randomly selected from a list of 120 different digit triplets. Triplets were constructed with 500 ms intervals at the beginning and end of each triplet, which was presented with overlapping masking noise. Consecutive individual digits were divided by 200 ms intervals with 100 ms of jitter. Speech weighted masking noise overlapped with the digit triplets, using a fixed noise level for negative SNRs. The speech level was fixed, and the noise level varied when positive SNRs were presented to prevent clipping of the signal. Masking noise was delivered diotically and the digits were either diotic (NoSo) or antiphasic (NoSπ) between the ears. Noise "freshness" was ensured by creating a long noise file and selecting successive fragments from a random offset within the first 5s to prevent possible learning of the masking noise (Lyzenga et al. 2011). Starting at 0 dB SNR, the test used fixed step sizes of 4 or 2 dB for the first 3 steps, and 2 dB steps for the following trials (De Sousa et al. 2020b). For the first three steps, SNR became progressively lower in 4 dB steps for correct responses but increased by 2 dB per step for incorrect responses. The test tracked the SNR at which 50% of the digit triplets were correctly identified (Potgieter et al. 2016; Smits et al. 2004). A digit triplet was considered correct only when all digits were entered correctly, and the SRT was calculated by averaging the last 19 SNRs. After completing a pure tone audiometry assessment, all participants completed either one antiphasic DIN (n = 489) or antiphasic DIN and diotic DIN (n = 393).

4.3.3. Statistical analysis

Statistical analysis was done using IBM SPSS v26.0. Multivariate linear regression analyses were used to determine the amount of variance in the diotic and antiphasic DIN SRT that could be explained by better and poorer ear PTA and age (adjusted R^2). There was linearity as assessed by partial regression plots and a plot of studentized residuals against the predicted values. There was independence of residuals (Field 2009), as assessed by Durbin-Watson statistics. There was no evidence of multicollinearity, as assessed by tolerance values greater

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than 0.1. There were between 1 and 7 studentized deleted residuals higher than ±3 standard deviations for antiphasic and diotic DIN SRT, which were kept in the analysis. There were no leverage values greater than 0.2, and values for Cook's distance above 1. Spearman correlations were used to determine the correlation between DIN SRT, better and poorer ear PTA because not all variables were normally distributed, as assessed by Shapiro-Wilk's test ($p < 0.05$). Area under the receiver operating characteristic (AUROC) analyses were conducted to determine sensitivity and specificity of the diotic and antiphasic DIN tests for different cut-off values. The targeted disorders were mild (poorer ear PTA > 25 dB HL) and moderate hearing loss (poorer ear PTA > 40 dB HL). Binomial logistic regression analyses were performed to derive AUROC curves covarying for age.

4.4. Results

4.4.1. Antiphasic and diotic DIN SRT- PTA correlations and predictors

Figure 4.2 shows the distribution of antiphasic and diotic SRTs across better and poorer ear PTA. Correlations of antiphasic and diotic SRTs to poorer and better ear PTA across different types of hearing loss are presented in Figure 3. Diotic DIN SRTs of participants with hearing loss substantially overlapped with DIN SRTs of normal hearing participants, especially for CHL and unilateral or asymmetric SNHL, and for bilateral SNHL < 40 dB HL (Figure 4.2D; Table 4.1). The distinction between normal hearing and any of the hearing loss categories was better for antiphasic DIN SRT than diotic DIN SRT, suggesting greater sensitivity of the antiphasic DIN (Figure 2A & B; Table 4.1). For normal hearing participants, the correlation between antiphasic DIN SRT and poorer ear PTA was slightly higher than between diotic SRT and better ear PTA. For participants with bilateral SNHL, the correlations were nearly identical between better or poorer ear PTA and antiphasic or diotic DIN SRT, respectively. Because hearing losses are symmetrical for these groups of participants, differences between better and poorer ear PTA are small. However, correlations between antiphasic DIN SRT and poorer ear PTA for CHL and unilateral or asymmetric SNHL are much higher than between antiphasic DIN SRT and better ear PTA (Figure 4.2 & 4.3). On the other hand, diotic DIN SRTs of people with unilateral SNHL were more related to the performance of the better ear than poorer ear PTA (Figure 4.3).

Multiple linear regression analysis predicting antiphasic or diotic DIN SRT from better or poorer ear PTA and age are presented in Table 4.2. Regression models that included poorer ear PTA consistently and significantly ($p < 0.05$), predicted more of the variance (adjusted R^2) in antiphasic DIN SRT across all hearing loss groups compared to models with better ear as predictor, marginally for bilateral SNHL and unilateral or asymmetric SNHL, but considerably so for CHL. Better ear PTA explained more of the variance of diotic DIN SRT for normal

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hearing and bilateral SNHL; however, the proportion of variance explained by the better ear rather than poorer ear was marginal. Diotic DIN SRT for participants with unilateral or asymmetric SNHL could not be explained by either poorer or better ear PTA. Age did not contribute significantly to all models of antiphasic DIN SRT; only for participants with normal hearing and bilateral SNHL in models with better and poorer ear PTA, and for unilateral or asymmetric SNHL in the model with poorer ear PTA (Table 4.2). Furthermore, age only significantly contributed to models of diotic DIN SRT for participants with normal hearing.
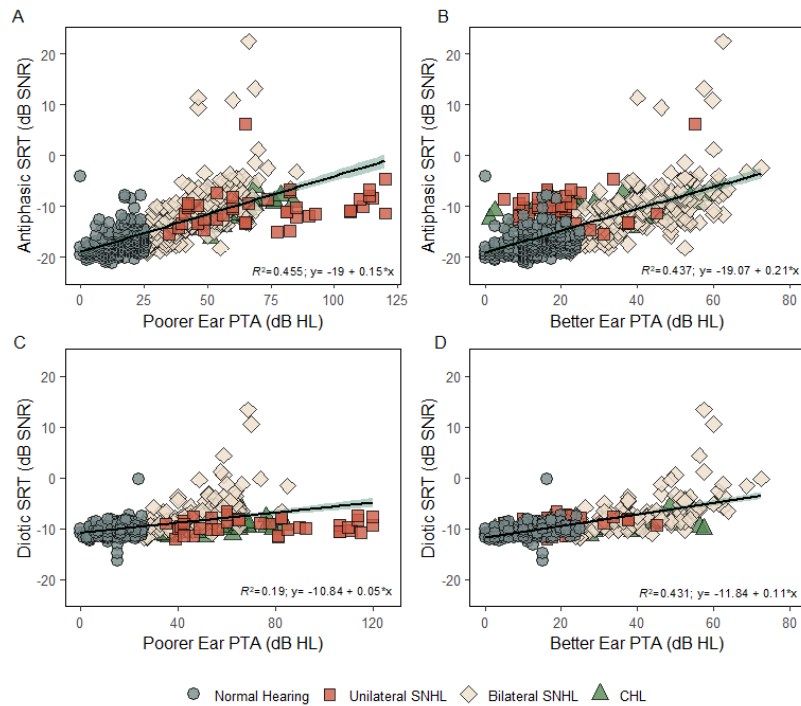
Figure 4.2. *Relationship of the antiphasic and diotic DIN SRT to poorer and better ear PTA. (A) Relationship of antiphasic DIN SRT to poorer ear PTA, (B) antiphasic DIN SRT to better ear PTA, (C) diotic DIN SRT to poorer ear PTA and (D) diotic DIN SRT to better ear PTA.*

Note. Regression lines are linear fits across the entire sample, the shading indicating 95% confidence intervals. CHL indicates conductive hearing loss, dB; decibel, DIN; digits-in-noise, PTA; pure tone average, SNHL; sensorineural hearing loss, SNR; signal to noise ratio, SRT; speech reception threshold.
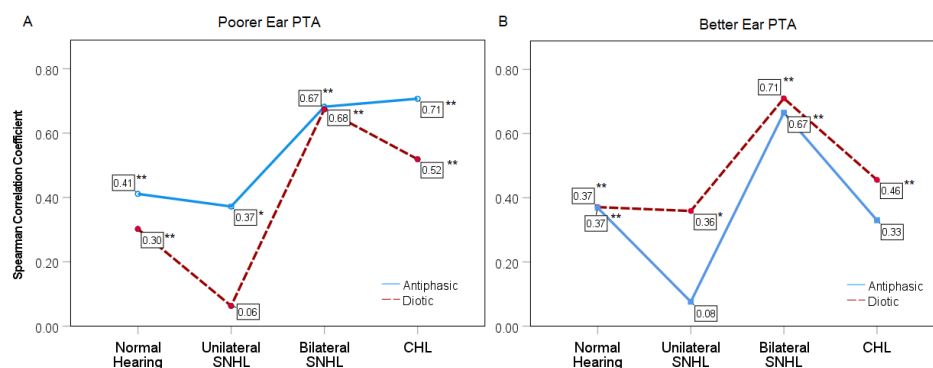
Table 4.1.

Antiphasic and diotic DIN SRTs according to degree of hearing in the poorer ear (pure tone average of 0.5, 1, 2 and 4 kHz) and hearing categories (normal, bilateral SNHL, unilateral SNHL, CHL)

			Normal (0-25 dB HL)	Mild (26-40 dB HL)	Moderate (41-55 dB HL)	Severe-Profound (56-120 dB HL)
NH & bilat SNHL (n= 415)	Antiphasic	n	243	60	66	46
		Mean age (SD)	41 (17)	62 (11)	69 (11)	71 (13)
		Mean SRT (SD)	-17.2 (2.4)	-14.6 (2.9)	-10.2 (4.7)	-6.2 (6.8)
		Range	-21.2 to -4.2	-19.2 to -5.2	-18.2 to 11.4	-13.6 to 22.5
	Diotic	n	202	42	44	37
		Mean age (SD)	40 (17)	62 (11)	66 (11)	71 (13)
		Mean SRT (SD)	-10.3 (1.3)	-9.2 (1.8)	-7.6 (2.2)	-4.0 (4.9)
		Range	-16.2 to -0.2	-11.8 to -3.8	-11 to -0.4	-9.6 to 13.4
Unilat SNHL (n=42)	Antiphasic	n		3	10	29
		Mean age (SD)	-	60 (8)	50 (21)	46 (17)
		Mean SRT (SD)		-14.3 (1.0)	-11.1 (2.2)	-9.7 (3.9)
		Range		-15.4 to -13.4	-14.6 to -7.4	-15.0 to 6.2
	Diotic	n		3	9	26
		Mean age (SD)	-	60 (8)	50 (21)	46 (17)
		Mean SRT (SD)		-10.3 (1.5)	-9.5 (1.4)	-9.1 (1.4)
		Range		-12.0 to -9.0	-11.4 to -7.6	-11.6 to -6.6
CHL (n=32)	Antiphasic	n		6	7	19
		Mean age (SD)	-	38 (22)	40 (21)	44 (15)
		Mean SRT (SD)		-14.4 (1.5)	-12.2 (3.0)	-9.8 (1.8)
		Range		-17.0 to -13.0	-16.2 to -7.2	-14.0 to -6.2
	Diotic	n		6	6	18
		Mean age (SD)	-	38 (22)	40 (21)	44 (15)
		Mean SRT (SD)		-10.7 (0.8)	-9.9 (1.7)	-8.9 (1.5)
		Range		-11.6 to -9.8	-11.6 to -7.0	-11.2 to -5.2

Figure 4.3. (*A) Spearman correlations of the antiphasic and diotic DIN SRT to poorer ear PTA among different hearing categories. (B) Spearman correlations of the antiphasic and diotic DIN SRT to better ear PTA among different hearing categories.*

Note. **Indicates significant correlations at the level of 0.01. DIN indicates digits-in-noise; PTA, pure tone average; NH, normal hearing; bilat, bilateral; SNHL, sensorineural hearing loss; CHL, conductive hearing loss.

ROC curves were constructed from the results of logistic regression models for the detection of poorer ear PTA > 25 dB HL (Figure 4.4A, B) and > 40 dB HL (Figure 4.4C, D). The first set of ROC curves were based on DIN SRT only (Figure 4A, C), while the second set included both DIN SRT and age (Figure 4.4B,D). The DIN SRT cutoff values represented the point of the most optimal trade-off of sensitivity and specificity. Antiphasic DIN SRT showed a consistent larger area under the curve (AUROC) to detect hearing loss in the poorer ear than diotic DIN SRT (Table 4.3). Antiphasic DIN was, therefore, more sensitive and specific to hearing loss than diotic DIN. The AUROC to detect hearing loss > 25 dB HL in the poorer ear

was slightly higher in antiphasic and diotic conditions when considering both SRT and age in the prediction, rather than DIN SRT alone (Table 4.3)

Table 4.2.

Multiple regression analysis predicting antiphasic and diotic DIN SRT from PTA and age for different categories of hearing.

		Variables in the Equation	p	Adjusted R^2	Model significance
Normal Hearing	Antiphasic SRT	Poorer ear PTA Age	0.061 <0.01**	0.208	< 0.01**
		Better ear PTA Age	0.173 <0.01**	0.203	< 0.01**
	Diotic SRT	Poorer ear PTA Age	0.085 < 0.01**	0.139	< 0.01**
		Better ear PTA Age	0.034 < 0.01**	0.146	< 0.01**
Bilateral SNHL	Antiphasic SRT	Poorer ear PTA Age	< 0.01** < 0.01**	0.359	< 0.01**
		Better ear PTA Age	< 0.01** < 0.05*	0.352	< 0.01**
	Diotic SRT	Poorer ear PTA Age	< 0.01** 0.032	0.360	< 0.01**
		Better ear PTA Age	< 0.01** 0.105	0.379	< 0.01**
Unilateral SNHL	Antiphasic SRT	Poorer ear PTA Age	0.011* < 0.01**	0.209	< 0.01**
		Better ear PTA Age	0.067 0.150	0.143	< 0.05*
	Diotic SRT	Poorer ear PTA Age	0.532 0.074	0.037	0.196
		Better ear PTA Age	0.127 0.222	0.089	0.073
CHL	Antiphasic SRT	Poorer ear PTA Age	< 0.01** 0.454	0.476	< 0.01**
		Better ear PTA Age	0.101 0.223	0.097	0.087
	Diotic SRT	Poorer ear PTA Age	0.046* 0.557	0.182	0.067
		Better ear PTA Age	0.013* 0.412	0.188	< 0.05*

Note. * Indicates significance at the level of 0.05; ** Indicates significance at the level of 0.01

Table 4.3.

Antiphasic and diotic DIN SRT logistic regression models for poorer ear PTA > 25 dB HL and > 40 dB HL

	Predictors	Equation	AUROC (95% CI)	Cut-off	Sensitivity	Specificity
Antiphasic SRT						
PTA > 25 dB HL	SRT	-	0.94 (0.91-0.96)	-15.7	90.1%	84.6%
	SRT, Age	p=1/ [1 + exp (-6.22 - 0.53*SRT – 0.03*age)]	0.94 (0.92-0.96)	p = 0.35	91.1%	80.1%
PTA > 40 dB HL	SRT	-	0.95 (0.93-0.97)	-13.7	90.7%	87.4%
	SRT, Age	p=1/ [1 + exp (-5.29 - 0.69*SRT – 0.01*age)]	0.95 (0.93-0.97)	p = 0.19	95.0%	80.2%
Diotic SRT						
PTA > 25 dB HL	SRT	-	0.79 (0.75-0.84)	-10.3	85.4%	49.8%
	SRT, Age	p=1/ [1 + exp (-3.61 - 0.57*SRT -0.04*age)	0.83 (0.79-0.87)	p = 0.36	80.7%	62.7%
PTA > 40 dB HL	SRT	-	0.82 (0.78-0.87)	-9.9	80.7%	60.1%
	SRT, Age	p=1/ [1+ exp (-8.19- 0.66*SRT – 0.002*age)	0.82 (0.78-0.87)	p = 0.25	80.0%	64.0%

Note. PTA indicates pure tone average; dB, decibel; HL, hearing level; SRT, speech recognition threshold; AUROC, area under the receiver operating characteristics curve; CI, confidence interval
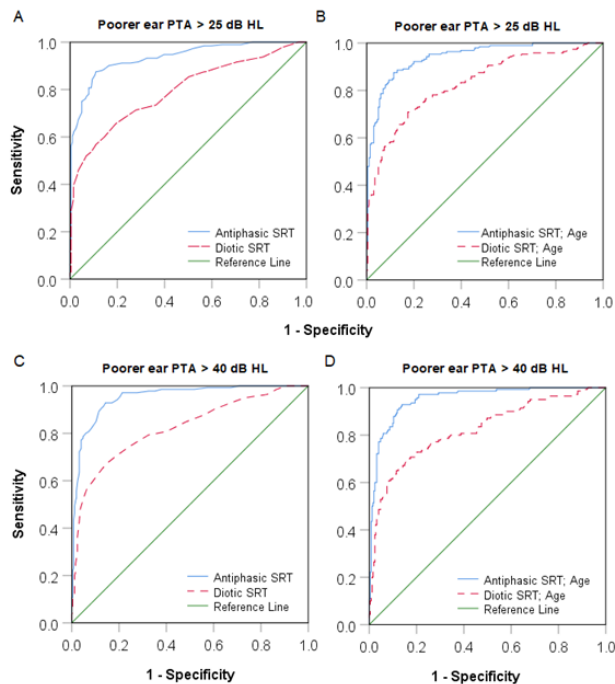
Figure 4.4. *Receiver operating characteristic curves presenting test characteristics for the antiphasic and diotic DIN SRT for detecting poorer ear PTA > 25 dB HL and > 40 dB HL. (A) ROC curves presenting DIN SRT for the detection of poorer ear PTA > 25 dB HL, (B) DIN SRT and age for detecting poorer ear PTA > 25 dB HL, (C) DIN SRT for the detection of poorer ear PTA > 40 dB HL, (D) SRT and age for detection of poorer ear PTA > 40 dB HL.*

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Note. dB indicates decibel; HL, hearing level; PTA, pure tone average; ROC, receiver operating characteristics.

4.4.2. Antiphasic, diotic DIN and BILD categorize hearing loss groups

Figures 4.5 A and B each show diotic DIN SRT against antiphasic DIN SRT for : (a) Normal, (b) Unilateral or asymmetric SNHL or CHL, (c) Bilateral SNHL. Here, we explored how the whole data set fitted these categories based on the antiphasic and diotic DIN tests' combined results. Two different procedures were examined, each resulting in three areas, capturing the most participants with normal hearing (*left area of each figure*), bilateral SNHL (*upper right area*), and unilateral or asymmetric SNHL/CHL (*lower right area*). The first procedure (Figure 4.5A) uses an approach in which a fixed cut-off value for the antiphasic DIN (represented by a vertical line) is used to discriminate between participants with normal hearing and hearing loss and, sequentially, a second fixed cut-off value for the diotic DIN is used to discriminate between bilateral SNHL and unilateral or asymmetric SNHL/CHL (represented by a horizontal line). Using this simple method, 75% of participants were classified correctly (Table 4.4). Figure 4.5 A and Table 4.4 suggest that a fixed cut-off value for the diotic DIN may not optimally discriminate between bilateral SNHL and unilateral SNHL/CHL over the entire range of antiphasic DIN SRTs. Therefore, we investigated a second procedure in which three parameters (antiphasic DIN cut-off value represented by the vertical line, and slope and offset of the sloping line) were varied to maximize the percentage of correctly classified participants (see Figure 4.5B). The maximum achievable percentage of correctly classified participants was marginally increased to 79%. Choosing two sloping lines (not shown) did not improve the maximum achievable percentage of correctly classified participants. Note that this option would also require all participants to perform two DIN tests, whereas our approach requires only participants who fail the antiphasic DIN (right of the vertical line in Figure 4.5) to perform a second, diotic DIN which is practically more feasible and saves time.

Although the maximum achievable percentage procedure was relatively accurate, a significant proportion of unilateral or asymmetric SNHL/CHL participants was misclassified as bilateral SNHL (35.3%). A detailed inspection of the data from the participants with bilateral SNHL and unilateral or asymmetric SNHL/CHL shows that there is considerable overlap between these groups within a range of antiphasic and diotic DIN SRTs. Of course, it is also possible to introduce a category 'unknown' to increase the percentages of correctly categorized participants.

In addition, we present the same two cut-off approaches based on the antiphasic DIN SRT and the derived BILD (Figure 4.5C & D). The overall percentage of correctly classified participants was the same as the antiphasic and diotic DIN SRT procedure when using either

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a fixed antiphasic and BILD cut-off (75%), or a sloping BILD cut-off (79%). As expected, the maximum achievable percentage procedure, with sloping BILD cut-off, produced the exact same categorization of participants as the antiphasic and diotic cut-off procedure (Table 4.4). For the fixed BILD cut-off, the cutoff value of 0.5 dB SNR demonstrated that participants with unilateral or asymmetric SNHL/CHL are expected to have minimal unmasking. However, the fixed cut-off procedure had a higher proportion of incorrectly identified unilateral or asymmetric SNHL/CHL with higher rates of correctly identified bilateral SNHL than the antiphasic and diotic DIN SRT procedure (Table 4.4).
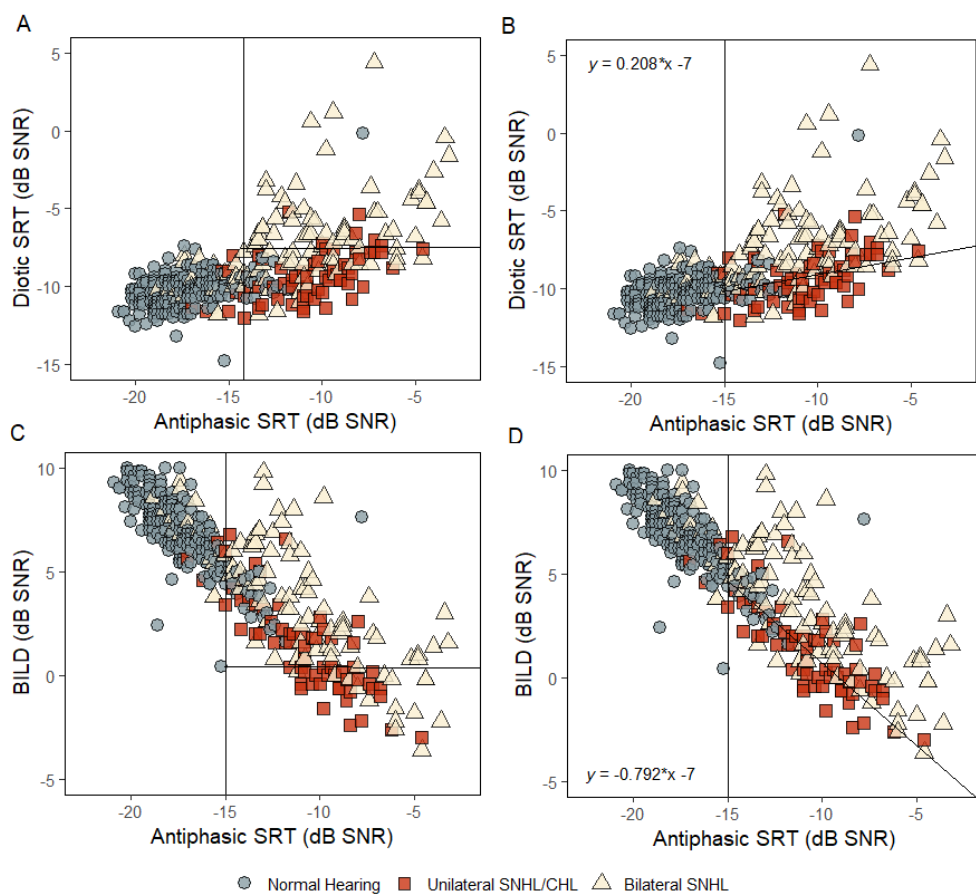
Figure 4.5. *Hearing groups based on speech recognition threshold cut-off criteria. (A) Fixed antiphasic and diotic DIN SRT cut-off, (B) Maximum achievable percentage using fixed antiphasic and sloping diotic SRT cut-off, (C) Fixed antiphasic DIN SRT and BILD cut-off, (D) Maximum achievable percentage using fixed antiphasic DIN SRT and sloping BILD cut-off.*

Note. Rectangular areas are normal hearing (*left*), bilateral SNHL (*upper right*), unilateral SNHL or CHL (*lower right*).

Table 4.4.

Percentage (number) of correctly categorized groups of hearing based on antiphasic and diotic SRTor BILD cut-offs in Figure 5 (Shaded cells = correct classification)

HL type based on PTA	Referral category based on SRT cut-off: Antiphasic -14.2 dB SNR; Diotic -7.4 dB SNR (Fig. 5A)		
	Bilateral Normal Hearing % (*n*)	Bilateral SNHL % (*n*)	Unilateral SNHL/ CHL % (*n*)
Bilateral Normal Hearing	92.1% (186)	0.5% (1)	7.4% (15)
Bilateral SNHL	23.6% (29)	43.9% (54)	32.5% (40)
Unilateral SNHL/ CHL	10.3% (7)	8.8% (6)	80.9% (55)

HL type based on PTA	Referral category based on SRT cut-off: Antiphasic -15.0 dB SNR; Diotic 0.208 * Antiphasic SRT – 7 dB SNR (Fig.5B)		
	Bilateral Normal Hearing % (*n*)	Bilateral SNHL % (*n*)	Unilateral SNHL/CHL % (*n*)
Bilateral Normal Hearing	89.1% (180)	5.9% (12)	5.0% (10)
Bilateral SNHL	16.3% (20)	71.5% (88)	12.2% (15)
Unilateral SNHL/ CHL	4.4% (3)	35.3% (24)	60.3% (41)

HL type based on PTA	Referral category based on SRT and BILD cut-off: Antiphasic -15.0 dB SNR; BILD 0.5 (Fig. 5C)		
	Bilateral Normal Hearing % (*n*)	Bilateral SNHL % (*n*)	Unilateral SNHL/CHL % (*n*)
Bilateral Normal Hearing	89.1% (180)	10.9 % (22)	0% (0)
Bilateral SNHL	16.3% (20)	69.1% (85)	14.6% (18)
Unilateral SNHL/CHL	4.4 % (3)	51.5% (35)	44.1% (30)

HL Type based on PTA	Referral category based on SRT and BILD cut-off: Antiphasic -15.0; BILD -0.792*Antiphasic SRT – 7 dB SNR (Fig 5D)		
	Bilateral Normal Hearing % (*n*)	Bilateral SNHL % (*n*)	Unilateral SNHL/CHL % (*n*)
Bilateral Normal Hearing	89.1% (180)	5.9% (12)	5% (10)
Bilateral SNHL	16.3% (20)	71.5% (88)	12.2% (15)
Unilateral SNHL/CHL	4.4% (3)	35.3% (24)	60.3% (41)

Note. HL indicates hearing loss; SRT, speech recognition threshold; dB, decibel; SNR, signal to noise ratio; SNHL, sensorineural hearing loss; CHL, conductive hearing loss.

4.5. Discussion

The antiphasic DIN sensitivity and specificity were 90% and 85%, respectively, for detecting hearing loss in our sample of participants with different types of hearing loss, with outstanding AUROC values of exceeding 0.94 to identify hearing loss in the poorer ear. These findings confirm the results from the initial development of the antiphasic DIN in a much larger sample (De Sousa et al. 2020b). The DIN has previously been used for detecting hearing loss with a *pass* or *refer* (Leensen et al. 2011; Potgieter et al. 2016; Smits et al. 2004; Watson et al. 2012). This study demonstrates that a combined antiphasic and diotic DIN approach could further categorize different hearing loss types with reasonable accuracy to direct patients for either audiological-, or, medical assessment.

4.5.1. Predictors and normative ranges of antiphasic and diotic DIN SRT

The first study objective was to determine predictors of antiphasic and diotic DIN SRT. As expected, PTA was a strong predictor of SRT across all types of hearing loss (Koole et al. 2016; Smits et al. 2004), although the relationship varied between better and poorer ear for different types of hearing loss and the different test presentations. For normal hearing and bilateral SNHL, the degree of prediction of better and poorer ear PTA for either diotic or antiphasic DIN was not expected to differ much since those groups of participants had symmetric hearing ability. Still, better ear PTA accounted for more of the variance in diotic DIN SRT, whereas poorer ear was the main predictor of antiphasic DIN SRT. The variance explained in unilateral or asymmetric SNHL was not significant for either poorer or better ear PTA when presented diotically. In diotic conditions, a person with unilateral hearing loss will recognize digit triplets presented in the better ear (De Sousa et al. 2020b). Thus, diotic DIN SRTs closely resembled normal hearing when the loss was unilateral (Table 4.1). The same was seen for CHL, either unilateral or bilateral. Previous studies showed high performance of the diotic DIN to detect bilateral SNHL with AUROC of 0.93 and sensitivity and specificity of more than 80% (Potgieter et al. 2018). Monaural DIN tests also had notable AUROC between 0.86 and 0.98 (Koole et al. 2016; Smits et al. 2004; Vercammen et al. 2018). In comparison, this study had a lower diotic performance with AUROC of 0.83 and sensitivity and specificity of 82% and 56%, owing to the broad range of hearing loss types included in the sample.

Poorer ear PTA predicted only marginally more variance in antiphasic DIN SRT than the better ear for normal hearing and bilateral SNHL, but explained considerably more of the variance for unilateral or asymmetric SNHL and CHL. Studies of binaural hearing have proposed sensitivity to phase information (or temporal fine structure) as a predictor of speech in noise ability (Neher et al. 2012; Santurette et al. 2012; Strelcyk et al. 2009). Stimulus phase is determined monaurally, requiring good monaural coding fidelity, and is relayed to the auditory brainstem where the two signals are combined (Neher et al. 2012). When target speech is presented with phase differences in the presence of a diotic masker, as with the antiphasic DIN, the central auditory system can benefit from binaural cues to better detect and code speech in acoustically complex situations (Hall et al. 1995; Neher et al. 2012; Wack et al. 2012). This phenomenon, described long ago by Hirsch (1948) and Licklider (1948), is commonly known as binaural masking level- or intelligibility level difference (Hirsh 1948; Licklider 1948). The antiphasic DIN SRT is thus a measure of binaural hearing as opposed to only the function of the better ear (De Sousa et al. 2020b). Peripheral hearing loss of any type is known to degrade coding of temporal fine structure by desynchronizing the timing of action potentials (Kortlang et al. 2016). Where hearing asymmetry exists, such as unilateral SNHL, interaural coding fidelity is disrupted, and the antiphasic advantage decreases. CHL interferes

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with phase processing by delaying and attenuating sound passing through the affected ear (Hartley and Moore 2003). If any phase detail differs between the ears due to the CHL, coding fidelity is disrupted. The degree to which antiphasic processing is disrupted by peripheral hearing loss in the current study, was more strongly correlated to the degree of hearing loss in the poorer ear. Antiphasic DIN was, therefore, highly sensitive to detect different types of hearing loss, including unilateral or asymmetric SNHL and CHL, as opposed to diotic DIN which was insensitive to unilateral or asymmetric SNHL and CHL.

Our findings did not support a substantial influence of age since covarying for age did not improve sensitivity and specificity for either diotic or antiphasic DIN SRT significantly. However, the contribution of adding age in our analysis is complex due to the wide range of hearing loss types and symmetries included, and the interaction between age and the groups of participants (Table 4.1). Previous findings on the influence of age have been mixed. Koole and colleagues (2016) also found a low correlation between DIN SRT and age after controlling for PTA although their participants only included older adults between 51 to 97 years. Other reports have shown that older people tend to perform more poorly on the DIN, after controlling for PTA (Dawes et al. 2014; Moore et al. 2014; Vercammen et al. 2018), which may be attributed to declining cognitive function (Moore et al. 2014). Nonetheless, results of the current analysis did not support the requirement for age-corrected cut-off values for the diotic and antiphasic DIN. Test-retest reliability for the DIN has been confirmed in previous reports, and has shown high agreement between test repetitions for both diotic (Potgieter et al. 2016) and antiphasic DINs (De Sousa et al. 2020a). However, it is expected that the SRT of a second test would be better than for the first test for naïve listeners, due to a procedural learning effect (Smits et al. 2013). In addition, the diotic DIN typically presents with lower measurement error (1.1 dB) than the antiphasic DIN (1.4 dB) but the between-subject variance is higher for the antiphasic DIN (De Sousa et al. 2020a). In this study, we did not include test-retest as part of our test battery, because we aimed to investigate the results as it would be implemented as a part of a sequential antiphasic and diotic DIN test procedure. In future, it may be considered to include a few training trials to minimize the effect of procedural learning

4.5.2. Sequential antiphasic and diotic DIN procedure to detect and categorize hearing into groups

Hearing loss could be categorized into three groups of (a) normal hearing, (b) bilateral SNHL, and (c) unilateral or asymmetric SNHL or CHL when allowing the second, diotic test for people who failed the initial antiphasic DIN. Groupings of these different antiphasic and diotic DIN SRTs, or antiphasic DIN SRT and BILDs, allowed for categorization of hearing loss types into these groups with reasonable accuracy.

The first method, using fixed diotic and antiphasic SRT cut-offs (Table 4.4), accurately classified normal hearing (92.1%) and unilateral or asymmetric SNHL/CHL (80.9%), but resulted in more than half (56.1%) of the participants with bilateral SNHL incorrectly classified as normal hearing, unilateral or asymmetric SNHL or CHL. Applying the same fixed cut-off procedure to the combination of antiphasic SRT and BILD accurately classified high proportions of normal hearing (89.1%) and bilateral SNHL (69.1 %); however, more than half of unilateral or asymmetric SNHL or CHL was incorrectly classified as bilateral SNHL or normal hearing. A fixed cut-off procedure for BILD may, therefore, not be an optimal procedure.

The second method, using a fixed but reduced antiphasic cut-off and a sloping diotic cut-off, captured a higher overall proportion of hearing loss (79%), including correctly categorized bilateral SNHL. However, this came at the cost of more normal hearing participants in the HL categories (10.9%) and a reduction in the proportion of correctly identified unilateral or asymmetric SNHL or CHL (20.6%). Therefore, the second method does not represent the optimal choice as a triage tool if the primary goal is to identify the maximum proportion of unilateral or asymmetric SNHL or CHL cases. Using a sloping cut-off for the BILD is essentially the same and provides the same accuracy (see Table 4.4). It is important to note that the majority of incorrect classifications using either a sloping BILD or diotic SRT cut-off, were people with normal hearing or milder forms of hearing loss in the poorer ear (PTA < 40 dB HL).

As a triage tool, people with bilateral SNHL could be eligible for a direct referral to a hearing aid provider or even, direct-to-consumer or over-the-counter hearing aids, while unilateral or asymmetric SNHL, CHL or mixed hearing loss are "red flag" cases indicative of potential ear disease that should be referred for full medical and audiological assessment (AAO-HNS, 2014). Ear diseases such as cholesteatoma, otitis media, or acoustic neuroma may have adverse or even life-threatening implications when diagnosis and treatment are delayed (Greenberg et al. 2001; Osma et al. 2000; Spilsbury et al. 2010; Suzuki et al. 2010). On this basis, it seems reasonable to recommend the first method (Table 4.4); DIN SRT screening cut-offs that most correctly categorize hearing loss types requiring medical referral (unilateral SNHL or CHL; 80.9%), even though more bilateral SNHL (32.5%) will be referred along this same path. Nevertheless, fewer than 10% of people with hearing loss are identified as having normal hearing for either cut-off method. Due to the DIN's increasing popularity as a remote self-test screening tool, these approaches could allow for self-directed first-line referrals to medical or audiological centres.

4.5.3. Other clinical applications and implications for future research

The COVID-19 pandemic has placed a significant strain on clinic-based models of audiological care due to the necessity for physical distancing. The need for remote care options has dramatically increased across health disciplines in the past year (Keesara et al. 2020). This sequential antiphasic and diotic DIN test procedure could act as a simple remote triage tool to identify and prioritize cases requiring traditional clinic-based audiometric testing as well as medical referral (unilateral or asymmetric SNHL and CHL) from those who can proceed with remote low-touch models of care (bilateral SNHL). Discriminating between unilateral or asymmetric SNHL and CHL based purely on DIN SRTs would not be possible as applied in the current study. However, differentiating unilateral or asymmetric SNHL/CHL could be supported by using brief case history questions (e.g., questions targeting specific information such as history of ear-pain, active drainage, bleeding from an ear, sudden onset or progressive hearing loss etc.).

Another potential application is to enable more accountable provision of hearing aids in non-traditional models like OTC. Conventionally, the only way to obtain a hearing aid was after an evaluation of the auditory system by a licensed professional. The US Food and Drug Administration (FDA), however, published a nonbinding recommendation report no longer enforcing the requirement for a medical evaluation before taking up amplification (FDA 2016). The US House of Representatives also passed the Over-the-Counter Hearing Aid Act of 2017 with the bill mandating that the FDA create a category for OTC hearing devices for people with mild-to-moderate hearing loss (The Hearing Review 2017). Although much research is still required on the regulation of these devices, sales of OTC or direct-to-consumer hearing devices will likely increase as indicated by current trends (The Hearing Journal 2021). A method to differentiate the risk of medical conditions as presented in this study could detect hearing loss deemed unsuitable for OTC hearing devices. Childhood hearing screening programs could also benefit from this approach, considering that CHL linked with otitis media is more prevalent among children than adults. The simple test paradigm using familiar digits in DIN tests allows for reliable responses in children as young as four years (Koopmans et al. 2018; Wolmarans et al. In Press), although young children may need an adult to facilitate the test procedure. Furthermore, suprathreshold testing provides the benefit of being less sensitive to ambient noise as school age-hearing screening is typically conducted outside a soundproof booth. A validation study of this DIN classification method in pediatric populations is recommended.

This report makes a unique contribution to the current DIN literature with respect to the diversity of hearing loss types examined, using both diotic and antiphasic approaches. The

only other study in the literature that used the DIN to determine hearing loss type (CHL from bilateral SNHL) was from our previous work, which considered a combination of pure tone air conduction audiometry and diotic DIN (De Sousa et al. 2020a). This work used binomial logistic regression analysis to examine the combined effects of PTA, diotic DIN SRT, and age to determine the likelihood that listeners had CHL as opposed to bilateral SNHL. It showed very high accuracy to discriminate between the two hearing loss types, with an AUROC of 0.94 and provided the advantage of low-touch audiometry without bone conduction audiometry. Although the current study was the first successful attempt to discriminate bilateral SNHL from other type of hearing loss, including unilateral or asymmetric SNHL, and potential referral routes based solely on the use of DIN SRTs, it should be kept in mind that the CHL and unilateral SNHL samples were small relative to the normal hearing and bilateral SNHL samples. Ideally, the validity of the proposed test method should be evaluated in a larger cohort of listeners with CHL, unilateral SNHL, and mixed hearing loss. Although not assessed in this study, it is possible that participants with poor SRTs and BILDs that are inconsistent with the degree of hearing, may have underlying auditory processing deficits. The effect of auditory processing disorders or listening difficulty on DIN test performance could also be investigated in future studies.

4.6. Conclusions

The antiphasic DIN was confirmed as a superior screening tool to the diotic DIN to detect hearing loss across a range of hearing loss types. Poorer ear PTA was the primary predictor of antiphasic SRT, whereas better ear PTA related best to diotic DIN SRT performance. Adult age did not have a significant influence on sensitivity and specificity. Age-corrected cut-offs are thus not recommended. A two-step procedure, first an antiphasic DIN and then a diotic DIN, classified hearing into three categories of (a) normal hearing, (b) bilateral SNHL, and (c) unilateral or asymmetric SNHL or CHL with a reasonable degree of accuracy. This type of approach can optimize care pathways by identifying unilateral or asymmetric SNHL or CHL as cases requiring medical referral. In contrast, bilateral SNHL confirmed categories may be referred directly to an audiologist, or support non-traditional models like OTC hearing aids

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CHAPTER 5

PURE TONE AUDIOMETRY WITHOUT BONE CONDUCTION THRESHOLDS: USING THE DIGITS-IN-NOISE TEST TO DETECT CONDUCTIVE HEARING LOSS

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Proof of acceptance: Appendix K

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5.1. Abstract

Objective: COVID-19 has been prohibitive to traditional audiological services. No- or low-touch audiological assessment outside a sound-booth precludes test batteries including bone conduction audiometry. This study investigated whether conductive hearing loss (CHL) can be differentiated from sensorineural hearing loss (SNHL) using pure tone air conduction audiometry and a digits-in-noise (DIN) test.

Design: A retrospective sample was analysed using binomial logistic regressions, which determined effects of pure tone thresholds or averages, speech recognition threshold (SRT), and age on the likelihood that participants had CHL or bilateral SNHL.

Study Sample: Data of 158 adults with bilateral SNHL (n = 122; $PTA_{0.5-4kHz}$ > 25 dB HL bilaterally) or CHL (n = 36; air conduction $PTA_{0.5-4kHz}$ > 25 dB HL and ≥ 20 dB air bone gap in the affected ears) were included.

Results: The model which best discriminated between CHL and bilateral SNHL used low frequency pure tone average (PTA), diotic DIN SRT and age with area under the ROC curve of 0.98 and sensitivity and specificity of 97.2% and 93.4%, respectively.

Conclusion: CHL can be accurately distinguished from SNHL using pure tone air conduction audiometry and a diotic DIN. Restrictions on traditional audiological assessment due to COVID-19 require lower touch audiological care which reduces infection risk.

Keywords: COVID-19, coronavirus, audiometry, digits-in-noise, speech-in-noise, speech recognition threshold

5.2. Introduction

The COVID-19 pandemic and its sudden requirement for physical distancing is prohibitive to traditional models of contact-based audiological service delivery. According to US Centers for Disease Control and Prevention (CDC) guidelines, traditional audiological services are a medium to high-risk for COVID-19 infection due to the test setup, patient proximity and length of consultations (CDC, 2020). Furthermore, the largest demographic requiring audiological services are people over 60 years of age or those medically vulnerable (e.g. diabetes, cardiac related illnesses etc.) who are at the highest risk of COVID-19 related mortality and morbidity (Grasselli et al. 2020). As is the case for many health disciplines globally, COVID-19 is accelerating the use of digital technologies and remote care options that are changing hearing health care delivery modes (Keesara et al. 2020). While being able to support existing patients remotely through telehealth, alternative methods to assess new patients will become increasingly important as the COVID-19 pandemic is likely to persist into 2021 and beyond (Gates, 2020).

Audiological assessments for hearing loss traditionally consist of a face-to-face consultation with a trained professional. Pure tone air and bone conduction audiometry are the gold standards to determine the degree, configuration, and type of hearing loss. However, audiological care that offers minimal physical interactions are currently necessary as an option to safely provide care to vulnerable populations (Swanepoel & Hall, 2020). Such services may be defined as being *low-touch*, where face-to-face contact between client and audiologist is reduced or could even be *no-touch*, where home-based test and treatment options could be provided (Swanepoel & Hall, 2020). A specific challenge with low- or no-touch models, however, is to differentiate persons with purely sensorineural hearing loss (SNHL) from those with conductive hearing loss (CHL) or possible ear disease who require medical and comprehensive audiological assessment (Swanepoel and Hall, 2020). When sensorineural hearing loss can be confirmed, air conduction thresholds may be sufficient to prescribe and fit a hearing aid which can be measured in a number of low-touch ways (Swanepoel & Hall, 2020).

Traditionally CHL or mixed hearing loss is detected and characterized by air- and bone-conduction audiometry, with the difference between these thresholds (i.e. the air-bone gap, ABG) indicating the severity of the conductive component. However, to obtain a reliable assessment of bone conduction thresholds, which can be measured down to -10 dB HL, a sound-treated booth is required. Unoccluded bone conduction audiometry requires maximum sound attenuation of at least a single-walled sound booth (ISO, 2015). Pure tone air conduction, on the other hand, can reliably be measured outside a sound-booth in controlled environments using applications that, in some cases, monitor ambient noise (Sandström et al. 2016; Swanepoel et al. 2019). Before considering amplification in CHL cases, a medical assessment, and possible intervention, is recommended. The incidence of CHL relative to SNHL in adults is very low, with a recent report indicating it being 2% in people over 70 years of age (Hoff et al. 2020). A small ABG sub-group of patients suspected of having a CHL therefore require standard sound-booth based audiological assessment and subsequent medical evaluation. Sound-booth testing, to accommodate for bone conduction audiometry, is especially challenging during the COVID-19 pandemic due to increased infection risk in confined environments with limited air circulation (Stadnytskyi et al. 2020). Furthermore, bone conduction audiometry requires skilled personnel to set-up and test, while self-testing is associated with higher variability (Margolis et al. 2010) and poorer reliability (Swanepoel & Biagio, 2011) than professional testing, especially at lower frequencies.

Where situational limitations like COVID-19 prevent the measurement of bone conduction thresholds in a sound booth, alternative means to determine an ABG could triage care for pure SNHL cases from those with potential CHL or ear disease. Tympanometry and tuning fork tests may supplement pure tone audiometry to indicate possible CHL (Silman & Silverman 1997) but rely on additional equipment and trained personnel to complete. Other options to detect ear disease include questionnaires, such as the Consumer Ear Disease Risk Assessment (CEDRA) which has sensitivity of greater than 90% (Klyn et al., 2019). A novel test method by Convery et al. (2014) used a combination of automated pure tone air conduction audiometry and a tone-in-noise task to estimate the presence and size of ABG at different test frequencies. The prediction had fairly high accuracy, being more accurate with larger ABGs and at lower test frequencies. Furthermore, the prediction had sensitivity of 80% and specificity of 77% at any ABG size if the threshold in quiet and signal-to-noise ratio (SNR) were known at 0.5 and 1 kHz. In the current study we explored a shorter procedure using a combination of speech-in-noise testing and pure tone air conduction audiometry to screen for and distinguish between CHL and SNHL.

The digits-in-noise (DIN) test has become a popular hearing screening procedure, available directly to the public as a web- or smartphone application (Smits et al. 2005; De Sousa et al. 2020; Potgieter et al. 2016; Potgieter et al. 2018). This self-administered test measures the ability to accurately recognize 50% of spoken digit triplets in the presence of speech-weighted masking noise (speech recognition threshold; SRT expressed in dB SNR). While both CHL and SNHL have elevated pure tone thresholds in quiet compared to normal hearing listeners, hearing loss due to cochlear damage typically presents with reduced frequency selectivity. Frequency selectivity relates to the ability of the auditory system to distinguish components of a complex sound (such as speech in noise) and is measured through psychophysical tuning curves. Ears with normal cochlear functioning, such as normal hearing or CHL, have psychophysical tuning curves that are sharper resulting in improved frequency selectivity (Moore 1996), whereas the tuning curves are flatter with cochlear damage. As a result the sensitivity and specificity of the DIN to detect SNHL is high (>80%) (Smits et al. 2004; Potgieter et al. 2018). However, the test traditionally is insensitive to detect CHL, since the attenuation caused by CHL affects the audibility of both digits and noise about equally at suprathreshold intensities (De Sousa et al. 2020). Thus, listeners with elevated air conduction thresholds may have relatively good SRTs when the hearing loss is conductive (Smits et al. 2004).

Since traditional bone conduction audiometry in a sound booth may be contraindicated for vulnerable populations during the COVID-19 pandemic, the main objective of this study was to determine if it is possible to accurately distinguish CHL from SNHL with the administration of pure tone air conduction thresholds and a diotic DIN test. Using air conduction tests only could enable audiological care options with minimal (low-touch) or no physical (no-touch) contact. Our hypothesis was that people with CHL would present with normal or near-normal DIN SRTs, but with elevated pure tone air conduction thresholds, whereas those with purely SNHL would have both elevated DIN SRTs and pure tone air conduction thresholds.

5.3. Method

This study received ethical approval from the Humanities Research Ethics Committee, University of Pretoria (protocol number: HUM003/0120).

5.3.1. Participants

The study was embedded as part of a normative DIN study at the University of Pretoria (Pretoria, South Africa). Data collection was conducted from June 2017 to September 2019. An additional 6 cases were added from a dataset completed in 2015. Participants were tested

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at multiple sites, where they were attending appointments at a hospital or University clinic or private audiology practice. This retrospective study pooled data from 158 adult cases between the ages of 18 and 92 years (mean = 61 years, SD = 17 years). Criteria for inclusion in the dataset were participants with bilateral sensorineural hearing loss (n = 122; $PTA_{0.5-4kHz}$ > 25 dB HL bilaterally) or CHL (n = 36; air conduction $PTA_{0.5-4kHz}$ > 25 dB HL and ≥ 20 dB ABG in the affected ears). In the CHL group, bone conduction PTA did not exceed 25 dB HL, except for one bilaterally symmetric mixed hearing loss case where the bone conduction PTA in the poorer ear was 34 dB HL indicating a mixed hearing loss with mild CHL component. There were 15 bilateral and 21 unilateral CHL cases.

5.3.2. Procedures and equipment

Tone audiometry was conducted by an audiologist as part of the selection protocol. Testing was done at various sites using audiometers calibrated to industry standards. The modified Hughson–Westlake method was used to determine pure tone air and bone conduction thresholds (Hughson & Westlake 1944). In addition, the South African English DIN test was conducted by the participants on a Samsung Trend Neo smartphone coupled with manufacturer supplied wired earbuds, or Sennheiser HDA 220 headphones. Since Potgieter et al. (2015) showed no difference between the DIN SRTs across five headphone types, it was not expected that this choice of headphone type would influence results. A detailed description of the DIN test procedure and stimuli is outlined in De Sousa et al. (2019). In summary, the test uses an adaptive one-up, one-down test procedure. Stimuli are binaurally same-phased (diotic) and digits are presented with speech weighted masking noise to determine the signal to noise ratio (SNR) at which 50% of digit triplets (e.g. 2-4-7) can be correctly recognized, the speech recognition threshold (SRT), determined by averaging the SNR of the last 19 of 23 digit triplets. Diotic presentation was not expected to have a large influence on SRTs of participants with either unilateral or bilateral CHL, since the attenuation caused by CHL affects the audibility of both digits and noise equally (De Sousa et al., 2020).

5.3.3. Statistical analysis

Binomial logistic regressions were constructed to ascertain the effects of age, pure tone thresholds or PTA, and SRT on the likelihood that participants had CHL or bilateral SNHL. Linearity of the continuous variables with respect to the logit of the dependent variable was assessed via the Box-Tidwell (1962) procedure. A Bonferroni correction was applied when using all terms in the model, resulting in statistical significance being accepted when $p < 0.01$ (Tabachnick & Fidell, 2014). Based on this assessment, all continuous independent variables

were found to be linearly related to the logit of the dependent variable (i.e. CHL/ bilateral SNHL). There was no evidence of multicollinearity, as assessed by tolerance values greater than 0.1. Furthermore, there were no residuals deviating more than 3 standard deviations from the mean. Using these probability equations, category prediction (CHL vs SNHL) was evaluated on the study sample. Receiver operating characteristic (ROC) curves were generated to determine cut-points for optimal sensitivity and specificity for each model. Furthermore, positive predictive values (the percentage of correctly predicted CHL cases compared to the total number of cases predicted as having CHL) and negative predictive values (the percentage of correctly predicted cases with SNHL compared to the total number of cases predicted as not having SNHL) were modelled for different prevalence rates of CHL.

5.4. Results

Sample demographics, pure tone averages (PTA) and diotic DIN test performance can be seen in Table 1. Frequency specific audiometric thresholds for CHL and bilateral SNHL are presented in Figure 5.1. The mean age for the CHL group was significantly lower than for the bilateral SNHL group (t[36.97] = 8.786, $p < 0.001$).

Table 5.1.
Demographics and digits-in-noise performance summary for bilateral SNHL and CHL.

Descriptors	Bilateral SNHL	CHL
Mean Age (SD)	54.0 (12.1) yrs	38.8 (15.6) yrs
Age Range	38 to 92 yrs	18 to 69 yrs
Participants (female)	122 (62)	36 (21)
Mean (SD), Poorer Ear PTA (0.5- 4 kHz)	47.2 (13.2) dB HL	54.7 (14.0) dB HL
Range, poorer Ear PTA (0.5-4 kHz)	26 to 85 dB HL	34 to 84 dB HL
Mean, BC Poorer Ear PTA (0.5-4 kHz)	42 (12.5) dB HL	16.5 (7.5) dB HL
Range, BC Poorer Ear PTA (0.5-4 kHz)	13 to 80 dB HL	4 to 34 dB HL
Mean (SD) Diotic SRT	-7.1 (3.8) dB SNR	-9.4 (1.5) dB SNR
Range, Diotic SRT	-11.8 to 13.4 dB SNR	-11.6 to -5.2 dB SNR

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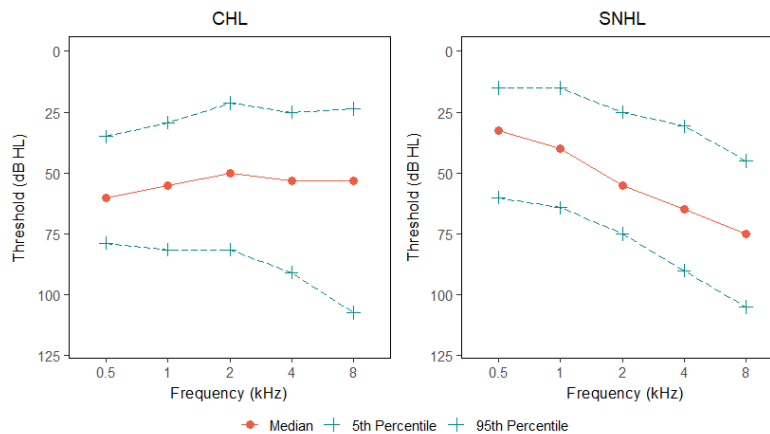
Figure 5.1. *Audiometric thresholds of the poorer ear for participants in the bilateral SNHL (right) and CHL (left) groups.*

The relationship between diotic SRT and individual test frequencies for bilateral SNHL and CHL are presented in Figure 5.2. Diotic SRTs were lower (better) for CHL than SNHL for each single test frequency. The same was found when considering pure tone averages (either averaged over 0.5 - 4 kHz, low frequencies 0.5 & 1 kHz or high frequencies (2 & 4 kHz) and diotic SRT (Figure 5.3). The probability of a participant having CHL or bilateral SNHL was determined using various models of binomial regressions. Model summaries with and without age as a predictor are in Tables 5.2 and 5.3, respectively. Models including low-frequency PTA (0.5 & 1 kHz) accounted for most of the variance in CHL, had the highest accurate category prediction, and showed the largest area under the receiver operating characteristic curve (AUROC; Figure 5.4). The low-frequency PTA (0.5 and 1 kHz) and age model differentiated CHL from bilateral SNHL with an overall accuracy of 93.7% and sensitivity and specificity of 97.2 and 93.4%, respectively. The model equation uses the average air conduction threshold of 0.5 and 1 kHz in the poorer ear, diotic SRT and age:

$$p = \frac{1}{1 + exp\left[-\left((-8.100) + (0.140 * LFPTA) + (-0.848 * Diotic\ SRT) + (-0.125 * Age)\right)\right]}$$

Without age the model equation was:

$$p = \frac{1}{1 + exp\left[-\left((-16.277) + (-0.142 * LFPTA) + (-0.988 * Diotic\ SRT)\right)\right]}$$

Positive and negative predictive values modelled for various CHL prevalence rates are presented in Table 5.4. Across varying prevalence rates, the negative predictive value remained fairly constant (96.9 - 99.9%), while positive predictive value became substantially higher with increase in CHL prevalence.

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Table 5.2.

Binomial logistic regression for discriminating CHL from bilateral SNHL including age as predictor.

	Predictors	Model Summary	Variance Explained % (Nagelkerke R^2)	Overall % correctly classified cases	AUROC (95% CI)	Sensitivity %/ Specificity% (ROC cut-off probability)
1	Poorer Ear PTA (0.5-4 kHz)* Age* Diotic SRT*	$x^2(3)=107.551$, $p < 0.001$	75.0%	92.4%	0.961 (0.931 to 0.992)	94.4 / 89.3 (0.239)
2	Poorer Ear Low Frequency PTA (0.5 & 1 kHz)* Age* Diotic SRT*	($x^2[3]=119.516$, $p < 0.001$)	80.6%	93.7%	0.982 (0.964 to 0.999)	97.2 / 93.4 (0.246)
3	Poorer Ear High Frequency PTA (2 & 4 kHz* Age* Diotic SRT*	($x^2[3]=88.081$, $p < 0.001$)	64.9 %	87.3%	0.935 (0.892 to 0.977)	88.9 / 88.1 (0.139)

Note. *Indicates significant predictors at the level < 0.01. AUROC indicates area under the receiver operating characteristic curve, CI; confidence intervals, PTA; pure tone average, SRT; speech recognition threshold.
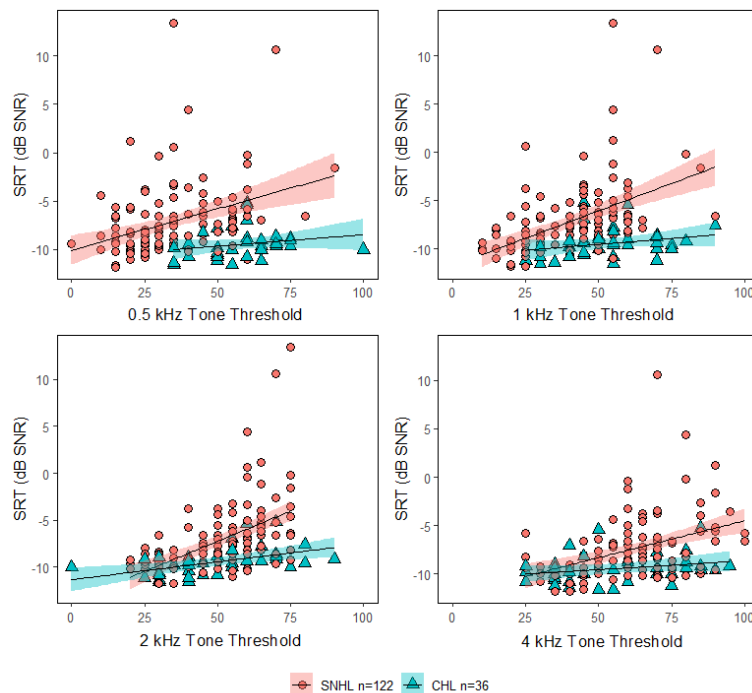
Figure 5.2. *Diotic SRT across individual poorer ear frequency thresholds for bilateral SNHL and CHL.*

Note. The lines are linear regression lines fit to either bilateral SNHL or CHL data. The shading indicates 95% confidence intervals.

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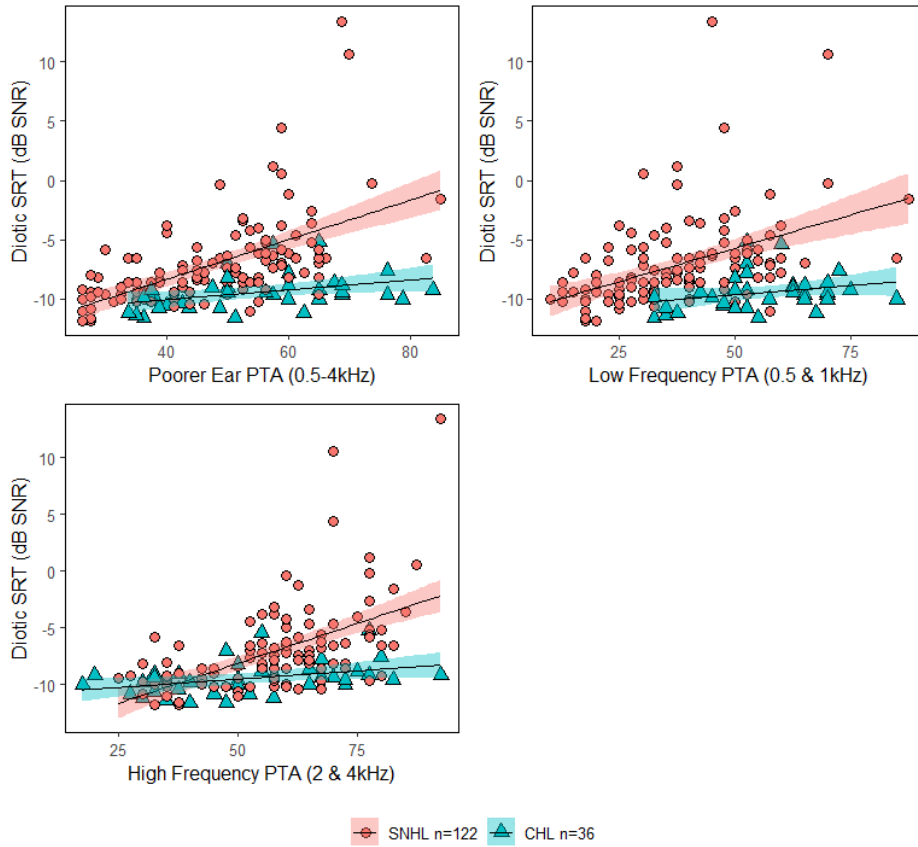
Figure 5.3. *Diotic SRT across poorer ear PTA (0.5–4 kHz), low frequency PTA (0.5 and 1 kHz) and high frequency PTA (2 and 4 kHz) for bilateral SNHL and CHL.*

Note. The lines are linear regression lines fit to either bilateral SNHL or CHL data. The shading indicates 95% confidence intervals.
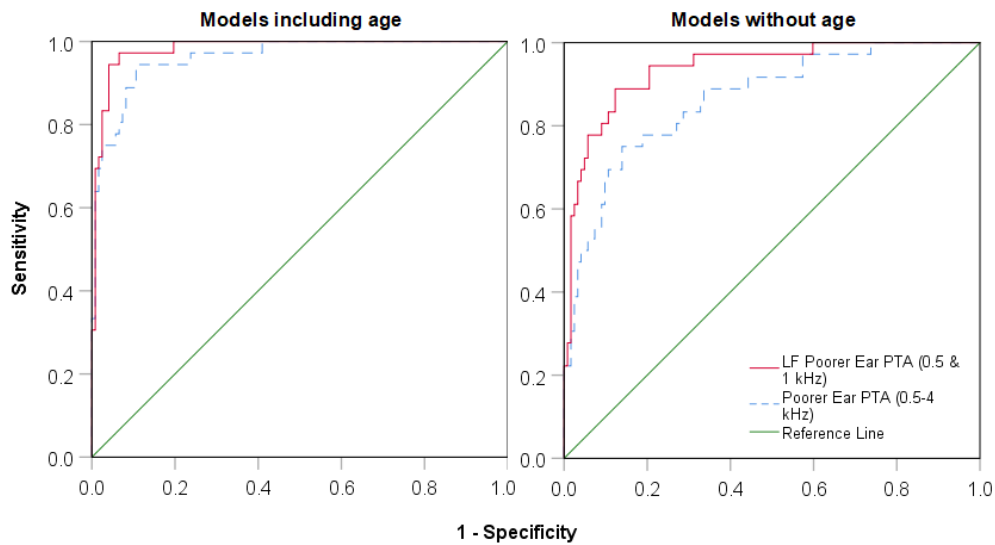
Figure 5.4. *Receiver operating characteristic curve for discriminating CHL from SNHL for LF PTA (0.5 and 1 kHz) compared to poorer ear PTA (0.5–4 kHz), with and without age as a predictor.*

Table 5.3.

Binomial logistic regression for discriminating hearing loss without age as a predictor.

	Predictors	Model Summary	Variance Explained % (Nagelkerke R^2)	Overall % correctly classified cases	AUROC (95% CI)	Sensitivity % / Specificity % (ROC cut-off probability)
1	Poorer Ear PTA* Diotic SRT*	$(x^2[2]=56.455,\ p < 0.001)$	45.7%	84.8%	0.864 (0.796 to 0.932)	80.6 / 73 (0.199)
2	Poorer Ear Low Frequency PTA (0.5 & 1 kHz)* Diotic SRT*	$(x^2[2]=87.959,\ p < 0.001)$	64.9%	89.8%	0.937 (0.894 to 0.981)	88.9 / 87.4 (0.238)
3	Poorer Ear High Frequency PTA (2 & 4 kHz) Diotic SRT*	$(x^2[2]=22.775,\ p < 0.001)$	20.4%	76.6%	0.745 (0.659 to 0.832)	69.4 /67.2 (0.246)

Note. *Indicates significant predictors at the level < 0.01. AUROC indicates area under the receiver operating characteristics curve, CI; confidence interval, PTA; pure tone average, SRT; speech recognition threshold.*

Table 5.4.

Positive and negative predictive values modelled according to a range of CHL prevalence rates for the low frequency poorer ear PTA (0.5 & 1 kHz) and diotic DIN regression models with and without age

Model	Conductive hearing loss prevalence	Positive Predictive Value (95% CI)	Negative predictive value (95% CI)
LFPTA, Diotic SRT, Age	2%	21.2% (12.5% to 33.6%)	99.9% (99.6% to 99.9%)
	10%	59.4% (43.8% to 73.4%)	99.7% (97.8% to 99.9%)
	23%*	79.4% (67.7% to 88.1%)	99.1% (94.2% to 99.9%)
LFPTA, Diotic SRT	2%	12.9% (8.3% to 19.4%	99.8% (99.4% to 99.9%
	10%	44.6% (33.3% to 56.7%)	98.6% (96.5% to 99.5%)
	23%*	68.4% (57.0% to 77.9%)	96.4% (91.3% to 98.5%)

Note. *Actual study prevalence. CHL indicates conductive hearing loss, PTA; pure tone average, DIN; digits-in-noise, LFPTA; low frequency pure tone average, SRT; speech recognition threshold.

5.5. Discussion

CHL can be distinguished from bilateral SNHL with high accuracy using a combination of pure tone air conduction audiometry and a diotic DIN test. The degree of accuracy varies depending on (i) whether age is used as a predictor, and (ii) the audiometric frequencies used, with a low frequency PTA (0.5 & 1 kHz) outperforming a four frequency PTA (0.5 - 4 kHz) and high frequency PTA (2 & 4 kHz) PTA. The average age in the CHL group was substantially lower than the SNHL group, which meant that including age in the prediction improved model accuracy. The CHL group constituted only 23% of the study sample and is not necessarily representative of the larger population of adult CHL cases. Age related SNHL has a reasonably predictable onset and progression across a large cohort (Cruickshanks et al. 1998; Roth et al. 2011, Homans et al. 2017), whereas CHL in adults is not typically age-related and is likely to have a larger spread and lower mean age when compared to typical SNHL. Nevertheless, the model accuracy remained high, even without age as a predictor, with outstanding AUROC (0.94; Mandrekar 2010) and sensitivity and specificity around 90%.

Although bone conduction audiometry remains the gold standard to determine a conductive component, it poses a number of limitations including significant variability and calibration standard errors (Margolis et al. 2013). In controlled experimental procedures, typical standard deviation for bone conduction audiometry, was reported around 8 dB, while intermediate standard deviation of 6 dB was found for the associated ABG (Robinson & Shipton 1982; Coles et al. 1991). These determinations were under laboratory conditions where the major factor was inherent variation among test administrators (Robinson & Shipton 1982). It is plausible that additional variability may be caused in listener responses. In clinical practice, this variability will likely be higher (Robinson & Shipton 1982). The high sensitivity and specificity of 97.2% and 93.4% for the prediction model using low frequency PTA and age found in this study is, therefore, particularly appealing as a screening measure to detect conductive hearing loss.

Convery and colleagues (2014) performed the only other study we could identify to use air-conduction pure tone thresholds to detect and quantify the degree of a conductive component. They administrated an automatic test battery comprising pure tones in quiet and another measure evaluating the lowest SNR at which pure tones could be detected in spectrally and temporally modulated narrowband noise. Using this combination of tests, Convery and colleagues (2014) obtained reasonably high sensitivity and specificity of 80% and 77% to identify CHL with any ABG size. For ABGs larger than 35 dB, the sensitivity and specificity of their model could improve up to 98 and 80%, respectively. The combined sensitivity and specificity for the prediction model in the current study was higher than those reported by

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Convery et al. (2014). Convery et al. (2014), however, included mixed hearing loss in their sample whereas the current study used only pure CHL apart from one mixed hearing loss case, a limitation of this study. Although the participant with mixed hearing loss was identified with CHL in the prediction, the accuracy of this model on varied degrees of mixed hearing loss should be investigated in future.

Conductive hearing loss prevalence rates may differ across populations (Moore 1999; Hoff et al. 2020; Kaplan et al. 1973; Liu et al. 2011). Results of one study cannot be generalized beyond the population of participants studied because of differences in referral patterns, access to medical care, tendency to seek medical care and other unknown factors that affect the composition of the groups (Moore 1999). Recent reports in high-income countries confirm that the prevalence of conductive pathology in adult populations with hearing loss is low, with reports between 2 and 5% (Klyn et al. 2019; Hoff et al. 2020). Positive and negative predictive values in the current study were modelled according to various disease prevalence estimates (Table 4) for illustrative purposes. Using the prediction model with age, positive predictive value was higher compared to the model without age, particularly at higher prevalence rates.

The major clinical application of the prediction model proposed in this study serves to differentiate adult hearing losses at risk of an ABG requiring further medical and audiological examination. This type of approach can enable alternative audiological service provision outside of traditional settings (i.e. sound booth) where bone conduction audiometry and other tests are typically conducted to confirm a CHL. Where traditional sound-booth clinical assessments may not be indicated, as in the case of the current COVID-19 pandemic (Swanepoel and Hall, 2020), this approach could prioritise patients who require further medical and audiological assessment whilst providing hearing aids based on air conduction tests for individuals with no conductive hearing loss risk. Considering the low prevalence of CHL compared to SNHL in adults (Hoff et al. 2020), the vast majority of patients with hearing loss could benefit from alternative low-touch models of audiological care that exclude bone conduction testing. We show here that these models could be used effectively towards treatment with hearing aids for vulnerable patients during COVID-19 (Swanepoel and Hall, 2020). This approach also has potential for other clinical applications including for resource constrained settings in low- and middle-income countries where diagnostic audiometry with bone conduction may be unavailable.

Future study of this air conduction test approach to differentiate CHL and SNHL in pediatric populations is warranted. CHL is more prevalent among children due to a higher rate of otitis media and Eustachian tube dysfunction. Already, the validity and reliability of a DIN test has been shown in children as young as 4 years (Koopmans et al. 2016). This model may thus

have further application in school screening programs which are regularly conducted in high ambient noise levels which impede accurate bone-conduction testing (McPherson et al. 2010).

5.6. Conclusion

The findings of this study show that CHL can be distinguished from SNHL using a combination of pure tone air-conduction thresholds and a diotic DIN with very good accuracy and high sensitivity and specificity. Considering restrictions on traditional audiological assessments due to an infectious disease like COVID-19, alternative methods that enable audiological care with minimal physical contact may reduce mortality and infection risk whilst optimizing care pathways and resource allocation. While this prediction model may have several potential applications, including for resource-constrained settings, it provides a timely solution to the current need for low- and no-touch models of audiological service delivery.

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CHAPTER 6
LOW AND HIGH-PASS DIGITS-IN-NOISE TEST DEVELOPMENT AND ASSOCIATIONS WITH PURE TONE AUDIOMETRY

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6.1. Abstract

Objectives: Low-pass (LP) filtered masking noise has been a strategy to sensitize the DIN to high-frequency (HF) hearing loss. This study used a different strategy, where either LP or high-pass (HP) filtered speech was presented in broadband masking noise to ensure minimal speech information in the frequency region above or below the filter cut-off frequency. This study determined the test characteristics of LP and HP filtered DIN and their relationship to PTA. Additionally, this study investigated the relationship of the DIN to extended high frequency audiometry.

Design: To develop the LP and HP DIN material, twenty normal hearing participants with pure tone thresholds ≤ 15 dB HL at octave frequencies 0.5 to 8 kHz completed a LP and a HP identification task of 100 digits presented at different SNRs (signal-to-noise ratio) monaurally to one ear, to determine digit recognition probabilities across the range of SNRs. Next, one hundred and twenty-five people with normal hearing or sensorineural hearing loss (SNHL) were recruited. Pure tone audiometry was conducted from 0.5 to 16 kHz. Each participant completed an unfiltered, LP and HP DIN for each ear. Thirty-two participants completed a retest for both the LP and HP DIN in each ear.

Results: HP DIN had moderate test-retest reliability with an intraclass correlation coefficient (ICC) of 0.71 (95% CI 0.52 to 0.82) whilst LP DIN had poor test-retest reliability (0.39; 95% CI -0.01 to 0.63). The HP DIN speech reception threshold (SRT) was more strongly correlated

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with all PTAs, and had better sensitivity and specificity to detect hearing loss across all PTA averages (four frequency, low frequency and high frequency), than either the BB or the LP DIN SRT.

Conclusions: The HP DIN had sensitivity and specificity to hearing loss that was superior to both the broad-band and LP DIN across broad-band (conventional), lower-, and higher-frequency weighted PTA. The LP DIN had poor reliability and association with PTA. The HP DIN was also more highly correlated with EHF tone thresholds (8 to 16 kHz) than BB DIN for ears with normal hearing, confirming the role of EHFs in recognizing speech in noise.

Keywords: digits-in-noise, low-pass, high-pass, extended high frequency, speech recognition in noise

6.2. Introduction

The high prevalence and extensive impact of hearing loss is a serious public health issue. Almost 1.5 billion people globally have hearing loss, with 430 million cases of a moderate or higher degree (World Health Organization [WHO] 2021). The effects of hearing loss depend not only on the degree of loss, but also on whether it is detected and treated early. Yet, the vast majority (nearly 80%) of people with hearing loss live in low-and middle-income countries where service provision is inadequate. Even in high-income countries, hearing aid uptake is low (World Report on Hearing, 2021) and those who take up treatment have typically delayed doing so for several years (Simpson et al. 2019). Early detection plays a vital role in maximizing treatment outcomes and avoiding negative effects of hearing loss. However, obstacles to effective diagnosis and treatment are rooted in limited societal awareness of hearing loss and its related consequences, stigmatization, and high out-of-pocket expenses for traditional models of care (Lin et al. 2016). As a result, alternative service-delivery methods and models have been proposed to address hearing loss assessment and treatment on a larger scale.

Global mhealth initiatives, like the hearWHO application that provides free, validated smartphone-based hearing screening, are promising health promotion and early detection tools. These consumer tests for the public have centred on speech-in-noise testing, particularly the digits-in-noise test (DIN) (Swanepoel et al. 2019). While pure tone threshold measurements are generally considered the gold-standard evaluation of hearing, their high reliance on device calibration, test facilitator and optimal test environments have rendered them ineffective as self-tests available for most consumer technology (De Sousa et al. 2021; Swanepoel et al. 2019). Speech-in-noise tests like the DIN are accurate across device and headphone types as they do not rely on the absolute presentation levels of the test stimuli

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(Potgieter et al. 2016). The DIN was originally provided over landline telephone (Smits et al. 2005; Smits et al. 2004; Watson et al. 2012; Zokoll et al. 2012), followed more recently by digital platforms including web- and smartphone-based applications for screening purposes (Potgieter et al. 2016; Swanepoel et al. 2019)

The DIN measures a speech recognition threshold (SRT) by adapting the signal-to-noise ratio of digit-triplets (e.g.,5-9-2) presented in speech-weighted masking noise to measure the level where 50% of triplets are recognized correctly (Van den Borre et al. 2021). The DIN SRT has high test-retest reliability and correlates well ($r > 0.8$) with the pure tone average (PTA) (Jansen et al. 2010; Smits et al. 2004). Its high sensitivity and specificity (> 80%) to detect elevated PTA and recent developments ensuring a rapid binaural screening (De Sousa et al. 2020) and potential differentiation of hearing loss types (De Sousa et al. 2021) have made DIN testing a preferred and widely used screening option (Potgieter et al. 2016; Smits et al. 2004; Swanepoel et al. 2019; Van den Borre et al. 2021; Watson et al. 2012)

Previous DIN research has focussed on increasing sensitivity to audiometric frequencies (Van den Borre et al. 2021). Specifically, low-pass (LP) filtered masking noise has been a strategy to sensitize the DIN to high-frequency (HF) hearing loss (Jansen et al. 2014; Vercammen et al. 2018; Vlaming et al. 2014), which is often the most impaired part of the hearing spectrum (Dubno et al. 2013). LP filtering of the masking noise was an approach introduced by Leensen et al. (2011) for a consonant-vowel-consonant (CVC) speech-in-noise test (Leensen et al. 2011). LP noise filtering assumes that when speech is masked within the lower frequency range, listeners will not as easily be able to distinguish speech based on low-frequency vowel formants and thus rely more on the higher frequencies. Therefore, listeners with HF hearing loss perform more poorly than PTA-matched listeners with hearing loss across the frequency range. This approach demonstrated sensitivity and specificity exceeding 95% to detect even mild HF hearing loss (Leensen et al. 2011). The results were repeatable, as Jansen et al. (2014) also found improved sensitivity of a LP noise filtered CVC test, compared to unfiltered broadband (BB) noise to detect HF hearing loss (Jansen et al. 2014). However, the sensitivity of the LP CVC test (R = 0.79) did not exceed that of a BB unfiltered DIN test (R = 0.86), likely due to the relative homogeneity of their participants with HF hearing loss.

Based on the gain in sensitivity of the LP CVC test, Vlaming et al. (2014) developed a HF DIN that uses the same LP noise filtering technique (1.5 kHz cut-off). Results were favourable and showed SRTs correlated highly ($r = 0.79$) with HF audiometric thresholds (PTA 3-8kHz). Furthermore, the HF DIN test demonstrated high sensitivity (87%) and specificity (93%) to detect average HF hearing loss of more than 20-decibel (dB). Interestingly, the sensitivity of the HF DIN was also higher than the BB DIN to detect lower frequencies (PTA 0.5-2kHz) (Vlaming et al. 2014). While conventional frequencies contain most of the phonetic repertoire

for speech recognition, evidence shows that speech intelligibility is also influenced by hearing in extended high frequencies (> 8 kHz) (Motlagh Zadeh et al. 2019; Polspoel et al. 2021; Valiente et al. 2016; Vitela et al. 2015; Zadeh et al. 2020). More recently, Motlagh Zadeh et al. (2020) showed that when narrower LP noise filters (2, 4 or 8 kHz) are used for the DIN, the test sensitivity to higher frequencies of 4 – 12.5 kHz improves (Zadeh et al. 2020). In addition, a 2 kHz LP noise filter produced a higher receiver operating characteristic curve (0.90) than the BB DIN (0.80). These findings suggest that LP noise filters are useful in detecting early indications of the most common forms of hearing loss. However, no studies have specifically filtered the DIN test to estimate hearing loss in both the HF and low-frequency (LF) range. Theoretically, a combined LF and HF filtering strategy could be applied to increase sensitivity in specific frequency regions of the audiogram and subsequently allow for estimations of slope and configuration of the pure tone audiogram. These data could be useful for remote fitting of hearing aids.

This study used a filtering strategy where the target speech is filtered instead of the masking noise to ensure that no speech information is present in the frequency region above or below the filter cut-off frequency. The purpose of this study was twofold. The first aim investigated the development and test characteristics of a LP and a high pass (HP) filtered DIN and their relationship to PTA. Additionally, this study investigated the relationship of the DIN to extended high frequencies.

6.3. Phase I: Development of test materials

This study received institutional review board approval from the Faculty of Humanities Research Ethics Committee (Approval Number: HUM003/0120). Participants were informed of the study aims and procedures and provided consent before participation. Phase I was the LP and HP DIN test development of speech materials, while Phase II of the study included validation of the filtered DINs and audiometric slope evaluation using the filtered DIN strategy.

6.3.2. Materials and methods

Participants

Twenty participants (2 male and 18 females) with pure tone thresholds ≤ 15 dB HL at octave frequencies 0.5 to 8 kHz who were otologically normal (International Standards Organization [ISO] 389-1, 1998) were recruited to develop test stimuli. The average age of participants was 22.3 years (SD= 2.0 years) ranging between 20 years to 26 years.

Equipment and Procedure

Pure tone air conduction audiometry was conducted in a quiet office using calibrated Sennheiser HDA 300 circumaural headphones connected to the hearTest audiometry

application (HearX Group, Pretoria, South Africa; CE/FDA certified) on a Samsung A3 smartphone. Calibration was performed using a Rion sound level meter and artificial ear with adaptor plate before data collection commenced. The hearTest application allowed for automated threshold determination at 0.5 to 8 kHz using the ISO shortened ascending descending threshold seeking method (Carhart et al. 1959).

Digits (0-9) were presented using MATLAB (MathWorks.com) measurement software on an Hewlett Packard Envy Laptop. The digit target stimuli were the South African English digits used in Potgieter et al. 2016 and De Sousa et al. 2020 (De Sousa et al. 2020; Potgieter et al. 2016). LP or HP filtering was applied at 1.5 kHz using a 15th order Butterworth filter to the digit material and presented in unfiltered, broadband, speech-weighted, masking noise matched to the long-term average speech spectrum of the unfiltered digits. Pilot testing showed that the effect on the LP and HP DIN SRTs was approximately similar for this filter frequency. The level of the masking noise matched the average level of the digits without any silences (Potgieter et al. 2016; Smits et al. 2013). Four lists of 100 digits were created, a LP and a HP filtered list for each ear. Stimuli were presented using Sennheiser HDA 280 headphones. The order of LP and HP lists, as well as presentation to right and left ears, was counterbalanced between participants. Each participant completed one LP and one HP list, presented to either the left or right ear. Each list consisted of 10 series of the 10 digits in randomized order, mixed with the masking noise at fixed SNRs, decreasing from -2 to -20 dB SNR in 2 dB steps; psychophysical method of constant stimuli. Masking noise started 500ms before each digit and ended 500ms after the digit. Participants entered their responses on the digit keyboard of the laptop after each digit was presented and, where they were uncertain, they were instructed to guess.

6.3.2. Results

Average correct identification of each LP or HP filtered digit at each SNR was calculated and, following the procedure of Potgieter et al. 2016 and Vlaming et al. 2014, logistic functions were fitted to the data using a maximum likelihood procedure to determine the recognition probability for each individual digit in LP and HP conditions. For each digit, the SNR corresponding to 50% correct was determined. Our initial aim was to use these values as correction factors to equalize the recognition probabilities of the digits. However, after completing the study, we discovered an error in the software script that resulted in incorrect level corrections. As intended, the average of the level corrections across all digits was 0 dB, but the SD of the SNRs corresponding to 50% decreased only slightly (from 3.8 dB to 3.6 dB and from 4.9 dB to 4.3 dB for LP and HP filtered digits). The slopes of the individual digit recognition functions were 7.2 %/dB for the HP filtered digits and 7.8%/dB for the LP filtered

digits. Figure 6.1 shows the digit recognition functions for the stimuli implemented in the test (Phase II).
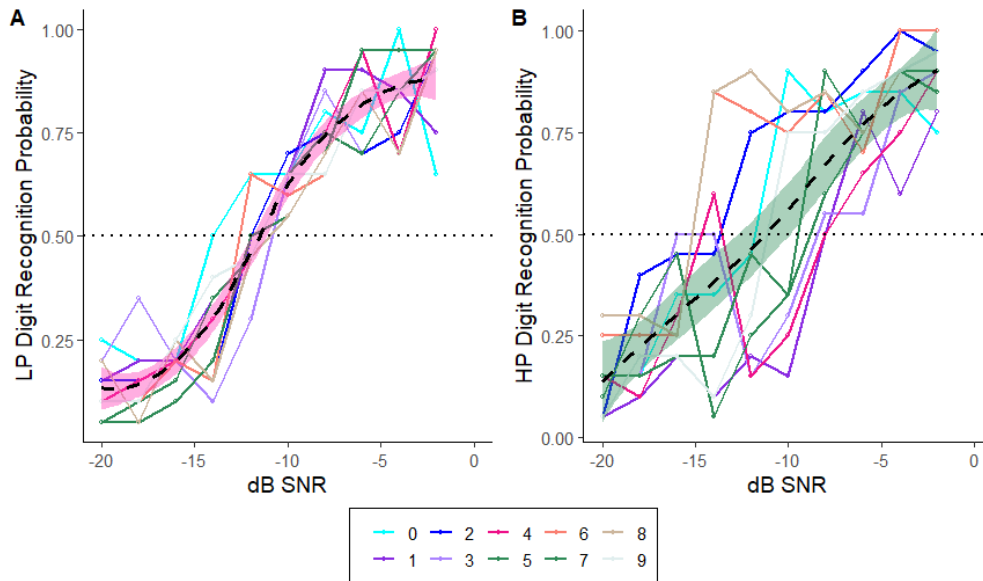
Figure 6.1. *Average speech recognition probabilities for single digits as implemented in the test procedure. (A) Digit recognition probabilities for LP filtered digits, (B) Digit recognition for HP filtered digits.*

Note. Solid lines are the recognition probabilities across SNR for individual digits. The dotted, horizontal line indicates 50% recognition probability. Dashed, curved lines indicate average recognition probability for the LP and HP filtered digits, respectively. Shading is 95% confidence intervals.

6.4. Phase II: Test validation and slope estimation

6.4.1. Materials and methods

Material from Phase I was implemented into a DIN test platform in MATLAB. Phase II determined the test-retest reliability and relationship of the LP and HP DIN SRTs to PTA. Furthermore, this phase investigated if the audiogram slope (threshold difference between low frequency [LF] and high frequency [HF] PTA) could be estimated from the LP and HP DIN SRTs.

Participants

One hundred and twenty-five people between the ages of 18 and 95 years (Mean = 54.3 years; ± 21.3 years; 89 female) participated in this cross-sectional study. Participants were approached at a university hearing clinic, retirement facility or recruited using snowball sampling. When considering individual ears, participants had normal hearing (NH; $PTA_{0.5-4kHz}$ ≤ 15 dB HL, *n* = 78) or hearing loss (HL, $PTA_{0.5-4kHz}$ > 15 dB HL, *n* = 171). One participant

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could only be assessed in the better ear, since the poorer ear lacked pure tone detection across all frequencies. Mean thresholds (0.5 to 16 kHz) and standard deviations (SDs) are presented in Figure 6.2 with percentile distributions in Figure 6.3. To provide further detail on hearing ability and inter-participant variability across thresholds, an extended high frequency range was used (0.5 to 16 kHz). Where no responses could be elicited, we used the maximum intensity of the equipment plus 5 dB as missing data for analyses (e.g., Max case in Fig. 6.3B). It is important to point out that the maximum output thresholds of the mobile audiometer at 10, 12.5 abd 16 kHz was 65-, 60- and 40 dB HL, respectively. Test-retest reliability of LP and HP DIN was assessed for the first 32 participants in the sample (mean age = 27.5 years, SD = 6.8 years). All of these participants had NH.
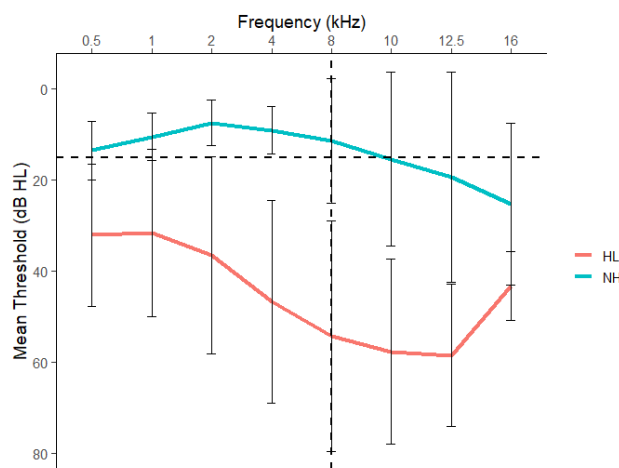
Figure 6.2. *Mean audiometric thresholds across 0.5 to 16 kHz for NH (PTA$_{0.5-4kHz}$ ≤ 15 dB HL, n = 78) and HL (PTA$_{0.5-4kHz}$ > 15 dB HL, n = 171) ears.*

Note. Error bars are standard deviation. Note that the maximum thresholds at extended high frequencies (EHF) for 10, 12.5 and 16 kHz were 65-, 60- and 40-dB HL, respectively.
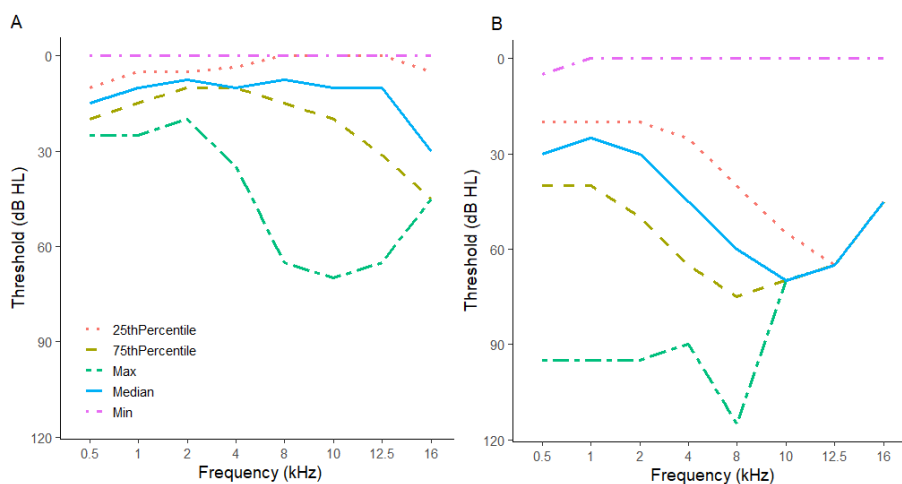
Figure 6.3. *Thresholds according to minimum, maximum, median, 25th percentile and 75th percentiles (0.5 to 16 kHz) for ears with (A) Normal Hearing (PTA$_{0.5-4kHz}$ ≤ 15 dB HL, n = 78) and (B) Hearing Loss (PTA$_{0.5-4kHz}$ > 15 dB HL, n = 171).*

Note. The maximum thresholds at extended high frequencies (EHF) for 10, 12.5 and 16 kHz were 65-, 60- and 40-dB HL, respectively.

Equipment and Procedure

Otoscopy was used to visually inspect the condition of the outer ear using a Welch Allyn otoscope. Participants were excluded when they presented with visible outer or middle ear pathology. Pure tone air conduction audiometry was conducted using the same equipment and procedure as in Phase I, except that threshold determination was done from 0.5 to 16 kHz. As in Phase I, DIN was presented using Matrix Laboratory (MATLAB) measurement software on an HP Envy Laptop, coupled to Sennheiser had 280 headphones. Participants were tested monaurally. The participants used for estimating test-retest reliability completed one unfiltered DIN (BB DIN), two LP and two HP DINs in each ear (10 DINs per participant), consecutively in short intervals. For the rest of the sample (*n*=93), each participant completed one unfiltered DIN, one LP DIN and one HP DIN per ear (6 DINs per participant). All participants started with the unfiltered, broadband DIN. Subsequent presentations to left/right ears and LP/HP, were counterbalanced to compensate for test order effects.

Digit triplets were presented in long term averaged speech weighted masking noise. The test used a randomized selection of 23 digit-triplets for presentation from a list of 120 digit-triplets (Potgieter et al. 2016; Smits et al. 2013). Masking noise started and ended 500-ms before and after each digit-triplet; triplets had 200-ms intervals between the digits. For triplets with negative SNRs, masker level was fixed and digits varied in 2-dB intervals. For triplets with positive SNRs, masker level varied, and digit level was constant (Potgieter et al. 2016; De Sousa et al. 2020). The standard scoring procedure previously used for the South African English DIN required that all digits in the triplet be recognized correctly before reducing the SNR (Potgieter et al. 2016; De Sousa et al. 2020). However, a preliminary study showed that the recognition probability for some digits (e.g., one) in the HP condition was low due to the filtering of low-frequency information. The DIN procedure, across all filtering strategies in the current study was, therefore, changed so that the SNR was reduced in 2 dB steps when two or three digits were recognized correctly and increased when no or one digit was correct. The final SRT was calculated by averaging the SNR of the last 19 presentations.

Statistical analyses

Statistical analysis was done using the Statistical Package for the Social Sciences (IBM SPSS v27.0). R studio version 3.6.1 was used for graphics. There were five cases (individual ears) that were extreme outliers, deviating more than 3 standard deviations from the mean, identified for both BB and LP DIN. These cases were excluded from the analyses. Furthermore, there were 11 cases for the HP DIN where SRTs reached a maximum response of 26 dB SNR, which were also excluded from the analyses. Intraclass correlation coefficient (ICC) for LP and

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HP filtered DIN was conducted as a mean rating of the number of observations (i.e., test-retest, $k = 2$), absolute agreement and a two-way mixed-effects model. In addition, measurement error between test-retest for LP and HP DIN was calculated by determining the SD of the test-retest differences for the LP and HP conditions and dividing it by the square root of 2. Multivariate linear regressions were completed to determine the predictors of BB, LP and HP DIN from PTA. Furthermore, stepwise multiple regression was used to determine which frequencies were significant predictors of the BB, LP and HP DIN SRT. Multivariate linear regressions were done to determine whether PTA (LF or HF PTA) could be predicted by LP and HP DIN. For all regression analyses, there was independence of residuals as indicated by Durbin-Watson statistics greater than 1.3 (Field 2009), and linearity as assessed by partial regression plots and a plot of studentized residuals against the predicted values. There was no evidence of multicollinearity as assessed by tolerance values greater than 0.1.

6.4.2. Results

Test-retest reliability

The effect of repeated testing after an initial presentation of a BB unfiltered DIN was examined for the LP and HP DIN . There was a slight mean increase of 0.2 dB SNR from the test to retest SRT for both the LP and HP DINs. Figure 6.4 shows the correlation of the LP and HP DIN test and retest SRTs as well as boxplots indicating the distribution of the LP and HP SRTs for the test and retest conditions separately. While mean test-retest differences were small, ICC analysis showed that the LP DIN had a poor ICC reliability of 0.39 (95% CI -0.01 to 0.63). Three outliers performed poorly on the initial LP DIN test. The HP DIN, on the other hand, had moderate reliability (0.71; 95% CI 0.52 to 0.82) when taking into account the confidence interval (CI) estimates (Koo et al. 2016). Measurement error was 1.2 and 1.0 for LP and HP DIN, respectively.

DIN (BB, LP & HP) SRT association with pure tone audiometry thresholds

Figure 5 shows BB, LP and HP DIN SRTs against $PTA_{0.5-4kHz}$, LF $PTA_{0.5\&1kHz}$ and HF $PTA_{2\&4kHz}$, respectively. The correlations between BB and LP DIN SRTs and PTAs were consistently weak and invariant for NH ears across the filtering conditions. For ears with HL, BB DIN SRT (Fig. 6.5A) and LP DIN SRT (Fig. 6.5B) had a comparable relationship with $PTA_{0.5-4kHz}$ and LF $PTA_{0.5\&1kHz}$, respectively; SRTs increased with increasing PTA. While BB and LP DIN SRTs had a close relationship with their respective PTAs, a few points had higher than expected SRT. In contrast to BB and LP DIN SRT, the HP DIN SRT showed notably more variance, even for NH ears, and a steeper correlation to HF $PTA_{2\&4kHz}$ than BB DIN SRT $PTA_{0.5-4kHz}$ and LP DIN SRT to LF $PTA_{0.5\&1kHz}$.
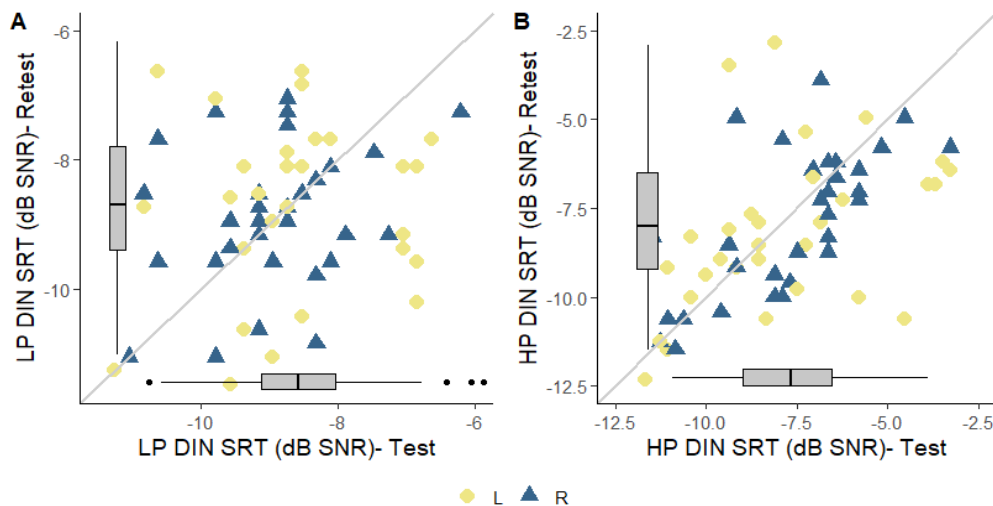
Figure 6.4. *Correlation of the (A) LP DIN Test and Retest and (B) HP DIN Test and Retest conditions according to left and right ear (n = 64 ears).*

Note. The diagonal line indicates perfect correlation. Boxplots indicate the distribution of test and retest for the LP and HP DIN. The boxes indicate 25th and 75th percentiles, the horizontal line, the median with the minimum and maximum values indicated by the whiskers. *LP indicates low-pass, HP; high-pass, DIN; digits-in-noise, L; left ear, R; right ear.*

The relationship of HP DIN SRT to extended high frequencies (EHFs) was evaluated by correlating the HP DIN to the EHF $PTA_{8-16kHz}$ for ears with NH ($n = 78$) and comparing it to the standard BB DIN. While, the maximum output of the audiometer was reached at certain of the pure tone frequencies, the percentage of participants reaching this limit was relatively low; 1.3%, 1.4%, 7.7% and 34.6% at 8-, 10-, 12.5- and 16 kHz, respectively. It was, therefore, not expected to have a significant influence on the correlations. Both BB and HP DIN SRT had a significant ($p < 0.01$) moderate, positive correlation to EHF $PTA_{8-16kHz}$, suggesting a significant effect of EHF on SRT. However, the HP DIN SRT had a stronger correlation ($rs = 0.61$) and steeper regression fit to EHF $PTA_{8-16kHz}$, compared to the BB DIN SRT correlation ($rs = 0.51$) and regression fit (Fig. 6.6).

To gain further insight into the relationship of the filtered DIN SRTs to conventional audiometry, correlations to individual frequencies were examined. All correlations were highly significant ($p < 0.01$) across individual frequencies and PTAs (Table 6.1). BB DIN SRT correlated slightly better to lower frequencies (0.5 & 1 kHz) than the LP DIN SRT. HP DIN SRT correlated more strongly to all frequencies than LP DIN SRT but had the strongest correlation to 8 kHz (Table 6.1). It can be noted that the different PTAs also had strong, positive and significant ($p < 0.01$) correlations with each other. For instance, the correlation of $PTA_{0.5-4 kHz}$ to LF $PTA_{0.5\&1 kHz}$ and HF $PTA_{2\&4kHz}$ was 0.92 and 0.96, respectively. Furthermore, the correlation of LF $PTA_{0.5\&1kHz}$ to HF $PTA_{2\&4kHz}$ was 0.78.

Table 6.1.
Spearman's correlation of BB, LP and HP DIN to individual frequencies and PTAs *(all were significant at p<0.01)*

	0.5 kHz	1 kHz	2 kHz	4 kHz	8 kHz	PTA$_{0.5-4kHz}$	LF PTA$_{0.5\&1kHz}$	HF PTA$_{2-4kHz}$
BB DIN	0.50*	0.59*	0.61×	0.65×	0.67×	0.68×	0.57*	0.68×
LP DIN	0.44*	0.55*	0.51*	0.52*	0.55*	0.58*	0.53*	0.57*
HP DIN	0.51*	0.64×	0.69×	0.77×	0.78×	0.76×	0.61×	0.81**

Note. * 0.40 - 0.59 moderate correlation ; × 0.60-0.79 strong correlation; ** 0.80-1.0 very strong correlation
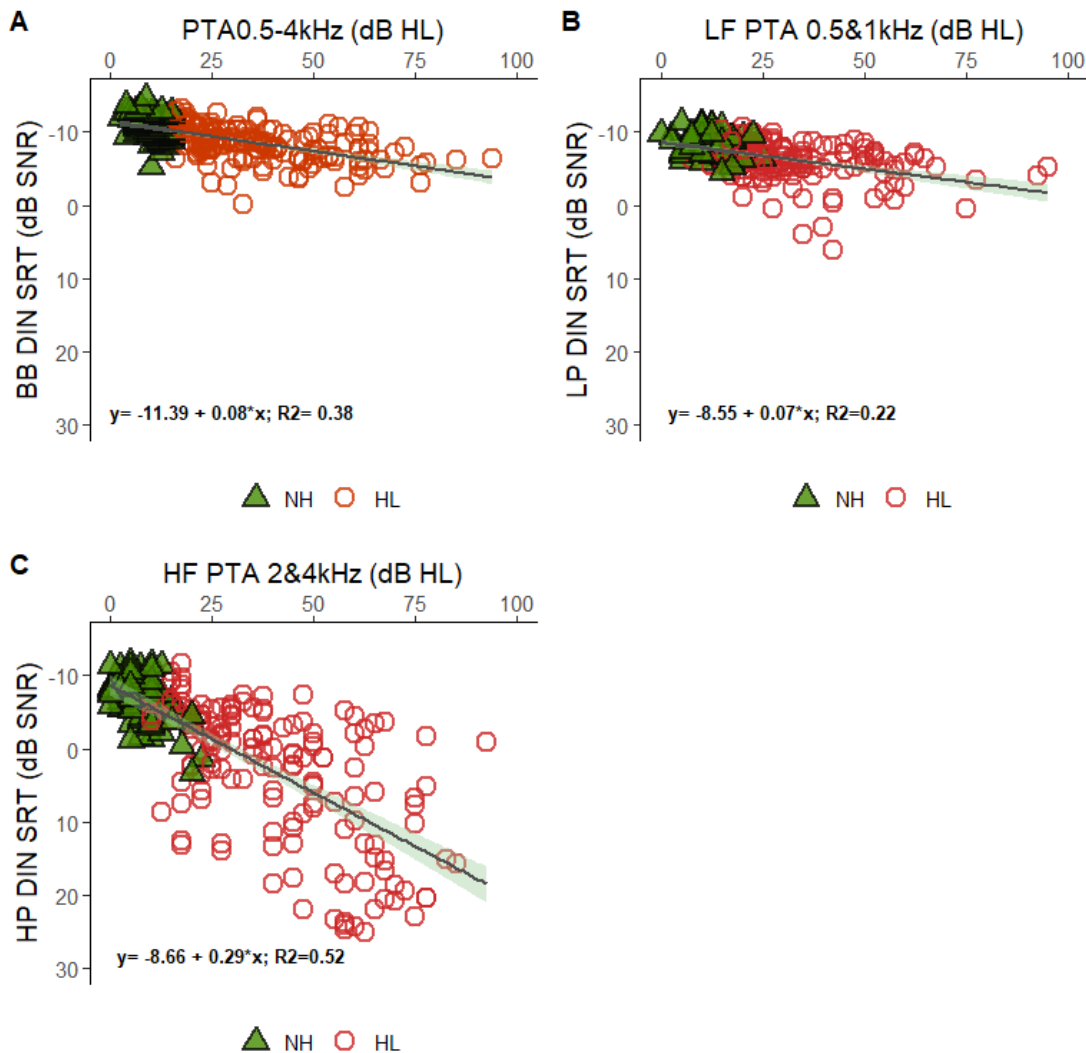
Figure 6.5. *The relationship of SRT and PTA. (A) BB SRT against PTA$_{0.5-4kHz}$, (B) LP DIN against LFPTA$_{0.5-1kHz}$, (C) HP DIN against HFPTA$_{2-4kHz}$.*
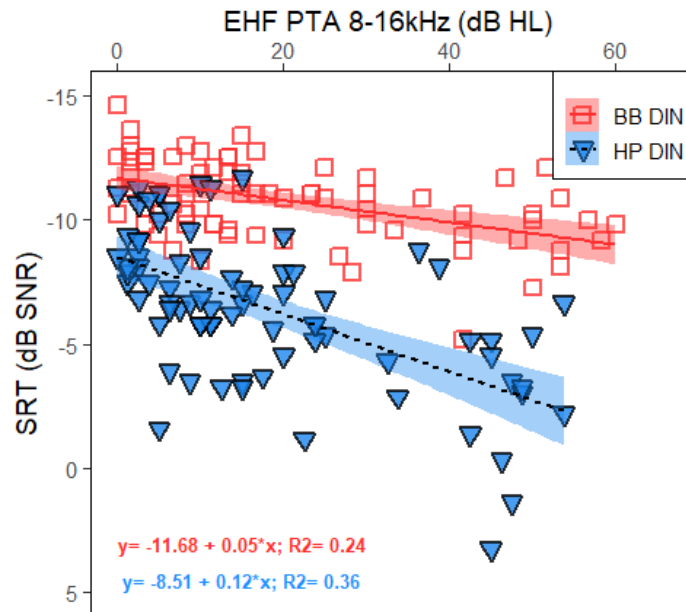
Figure 6.6. *Relationship of the BB and HP DIN to EHF PTA$_{8-16kHz}$ for ears with normal PTA$_{0.5-4kHz}$ (n = 78).*

Separate linear regressions identified the SRT variance explained by PTAs (Table 6.2). The variance explained across the PTA averages was similar for BB and HP DIN. The BB DIN SRT variance explained by PTA$_{0.5-4kHz}$ and HF PTA$_{2\&4kHz}$ was nearly identical and higher than the variance explained by LF PTA$_{0.5\&1kHz}$. As expected, the HF PTA$_{2\&4kHz}$ accounted for more of the variance than PTA$_{0.5-4kHz}$ or LF PTA$_{0.5\&1kHz}$. BB DIN SRT variance explained was similar across all PTA averages.

Table 6.2. *Multiple regressions predicting BB, LP and HP DIN from PTAs.*

	BB DIN		LP DIN		HP DIN	
	Adj. R^2	B	Adj. R^2	B	Adj. R^2	B
PTA$_{0.5-4kHz}$	0.38**	0.08	0.25**	0.07	0.47**	0.34
LF PTA$_{0.5\&1kHz}$	0.31**	0.08	0.22**	0.07	0.29**	0.31
HF PTA$_{2\&4kHz}$	0.37**	0.06	0.23**	0.05	0.52**	0.29

Note. **Model significance at the level of 0.01

Stepwise linear regression was run to determine which audiometric frequencies most significantly predicted the BB, LP and HP DIN (Table 6.3). Interestingly, the final model including only the significant predictive frequencies for the BB and LP DIN SRT, showed that the predictive frequencies were 1 and 8 kHz. For the HP DIN, the best predictors were the 4, 1 and 8 kHz thresholds, in the order of significance.

Sensitivity and specificity of the BB, LP and HP DIN to discriminate NH from HL participants

Table 6.4 shows the area under the ROC curve for the DIN tests with cut-offs to discriminate between NH and HL within the different frequency ranges. The SRT that showed high sensitivity without a substantial decrease in specificity was selected as the appropriate cut-off

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value. Table 6.3 shows that the HP DIN has a greater ability than LP or BB DIN to discriminate between NH and HL participants. The BB, LP and HP DIN had similar sensitivity to detect hearing loss in LF PTA$_{0.5\&1kHz}$ range. However, the HP DIN had better sensitivity to detect hearing loss across the PTAs, especially in the PTA$_{0.5-4kHz}$ and HF PTA$_{2\&4kHz}$ range.

Table 6.3.
Stepwise linear regression predicting BB, LP and HP DIN from individual audiometric frequencies

	Sig* Predictive Frequencies	B	Adj. R^2
BB DIN	8 kHz	0.04	0.46
	1 kHz	0.03	
LP DIN	8 kHz	0.03	0.31
	1 kHz	0.04	
HP DIN	4 kHz	0.14	0.55
	1 kHz	0.09	
	8 kHz	0.07	

Note. *Significance at the level of 0.05; BB indicates broadband, LP; low-pass, HP; high-pass, DIN; digits-in-noise

Table 6.4.
Sensitivity and specificity of the BB, LP and HP DIN to discriminate NH and HL ears

	PTA	Area under the ROC curve (95% CIs)	SRT cut-off	Sensitivity	Specificity
PTA > 15 dB HL					
BB DIN	PTA 0.5-4 kHz	0.81 (0.76 to 0.86)	-10.1 dB SNR	76.6 %	66.7 %
	PTA 0.5&1 kHz	0.77 (0.71 to 0.83)	-9.9 dB SNR	72.3 %	67.9 %
	PTA 2&4 kHz	0.83 (0.78 to 0.89)	-9.9 dB SNR	76.4 %	71.3%
LP DIN	PTA 0.5-4 kHz	0.81 (0.74 to 0.85)	-7.8 dB SNR	77.1 %	66.7 %
	PTA 0.5&1 kHz	0.78 (0.72 to 0.84)	-7.5 dB SNR	73.1 %	62.8 %
	PTA 2&4 kHz	0.83 (0.77 to 0.88)	-7.4 dB SNR	76.4 %	71.3 %
HP DIN	PTA 0.5-4 kHz	0.86 (0.82 to 0.91)	-5.1 dB SNR	80.6 %	74.4 %
	PTA 0.5&1 kHz	0.78 (0.72 to 0.84)	-4.4 dB SNR	73.8 %	71.8 %
	PTA 2&4 kHz	0.92 (0.89 to 0.96)	-4.9 dB SNR	85.7 %	81.5 %
PTA > 25 dB HL					
BB DIN	PTA 0.5-4 kHz	0.83 (0.77 to 0.88)	-9.5 dB SNR	81.1 %	71.0 %
	PTA 0.5&1 kHz	0.82 (0.76 to 0.87)	-9.3 dB SNR	77.4 %	67.5 %
	PTA 2&4 kHz	0.80 (0.74 to 0.87)	-9.5 dB SNR	76.1 %	69.5 %
LP DIN	PTA 0.5-4 kHz	0.76 (0.70 to 0.82)	-7.2 dB SNR	76.4 %	60.9 %
	PTA 0.5&1 kHz	0.77 (0.71 to 0.83)	-7.0 dB SNR	74.1 %	63.5 %
	PTA 2&4 kHz	0.75 (0.69 to 0.81)	-7.2 dB SNR	73.5 %	60.3 %
HP DIN	PTA 0.5-4 kHz	0.85 (0.81 to 0.90)	-3.8 dB SNR	86.0 %	71.7 %
	PTA 0.5&1 kHz	0.80 (74.3 to 86.0)	-2.9 dB SNR	77.5 %	66.5 %
	PTA 2&4 kHz	0.87 (0.83 to 0.91)	-3.8 dB SNR	86.0 %	70.2 %

Note. BB indicates broadband, LP; low pass, HP; high pass, DIN; digits-in-noise, NH; normal hearing, HL; hearing loss, PTA; pure tone average, dB HL; decibel hearing level

LP and HP DIN SRT association with audiometric slope

The slope of the pure tone audiogram was estimated by subtracting the LF $PTA_{0.5\&1kHz}$ from HF $PTA_{2\&4kHz}$; a larger value indicated a steeper HF audiometric slope. We then asked whether differences between DIN SRTs predict this slope. Fig. 6.7A shows that the correlation of the LP-HP DIN SRT and LF-HF PTA slopes for NH ears was weak ($rs = 0.24$, $p < 0.01$). For ears with HL, there was a stronger, moderate correlation ($rs = 0.41$, $p < 0.01$). A multiple linear regression model including both LP and HP DIN SRT was used to predict the audiometric slope, $F_{(2, 232)} = 43.07$, $p < .01$, adj. $R^2 = 0.26$. Only the HP DIN contributed significantly ($p < 0.01$) to the prediction. There was considerable variability (Fig. 6.7), and the LP and HP DIN SRTs could estimate the audiometric slope with only limited predictability, as indicated by the low adjusted R^2.

Since the BB DIN had a stronger correlation with the LF $PTA_{0.5\&1kHz}$ than the LP DIN, the same approach was used with HP DIN SRT, BB DIN SRT and the difference as predictors. (Fig. 6.7B). For the BB-HP DIN SRT, correlation with the LF-HF PTA slope for NH ears was weak and not significant ($rs = 0.03$; $p = 0.8$); for ears with HL it was moderate ($rs = 0.43$, $p < 0.01$). The regression model to predict audiometric slope from BB and HP DIN SRT, was nearly identical to the model using LP and HP DIN; $F_{(2, 232)} = 43.4$, $p < 0.01$, adj. $R^2 = 0.26$). This was likely because only HP DIN SRTs were significant ($p < 0.01$) contributors to the prediction.
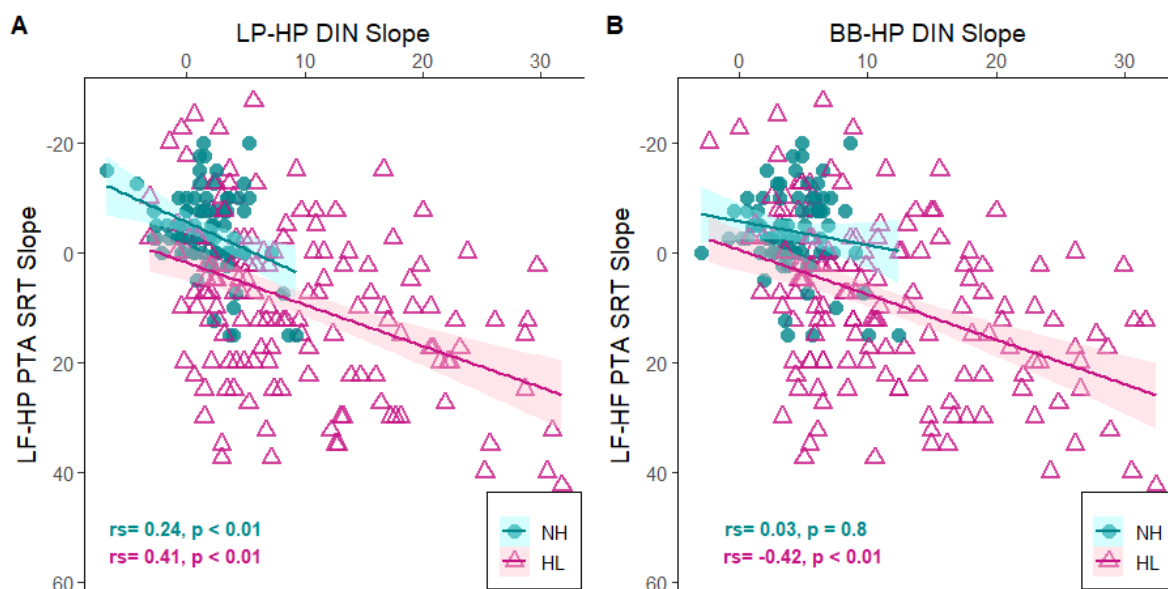
Figure 6.7. *Correlation of PTA slope with difference between DIN SRTs for NH ($PTA_{0.5-4kHz} \leq 15$ dB HL) and HL ($PTA_{0.5-4kHz} > 15$ dB HL) ears. (A) LP-HP DIN SRT difference against LF-HF PTA slope, (B) BB-HP DIN SRT difference against LF-HF PTA slope.*

Note. Lines are regression lines, with the shading indicating 95% CI.

6.5. DISCUSSION

The HP and LP filtered DIN tests described in this study were developed to determine hearing loss in audiometric LF and HF ranges, respectively. The filtering method was hypothesized to increase the spread of SRTs in both the LF and HF ranges, thereby improving sensitivity to detecting audiometric abnormalities in separate frequency bandwidths.

6.5.1. Reliability

In phase I, the aim was to equalize the HP and LP filtered digits by applying level corrections to individual digits. Due to an error in a script, the intended level corrections were not correctly applied, resulting in heterogeneous digit material. Because the average level correction was 0 dB, the measured SRTs in the present study (phase II) are not different from what would be expected from equalized digits. However, it affects the test-retest reliability (measurement error). For the current implementation, the HP and LP DIN had a measurement error (1.2 and 1.0 dB, respectively) similar to the diotic BB DIN (1.1 dB) reported in De Sousa et al. (2020). The ICC, taking the between-subjects variability into account, showed that the HP DIN had a moderate ICC (ICC = 0.71) lower than the previously reported BB DIN (ICC = 0.89). The LP DIN had poor test-retest reliability (ICC = 0.36) and, considering its low correlation to PTA and sensitivity and specificity, it can be concluded that the LP DIN has little clinical usefulness. Due to the relatively shallow slopes of the LP and HP filtered digit recognition functions (~7-8 %/dB), the heterogeneity of the recognition functions has only a small effect on the measurement error (see Figure 6 in Smits and Houtgast, 2006) (Smits et al. 2006).

6.5.2. SRT-PTA relationship, test sensitivity and specificity

This study was the first to use filtered speech signals in the DIN test, instead of previous methods that used filtered noise maskers to improve sensitivity to hearing loss within the higher (> 2 kHz) frequency range (Denys et al. 2019; Vercammen et al. 2018; Vlaming et al. 2014; Motlagh Zadeh et al. 2020). Most adults have a characteristically slow progressive hearing loss that first affects the higher frequencies, later extending into the lower frequencies. It is thus beneficial to have a screening test sensitive to hearing loss within the HF range (≥ 2 kHz) to ensure early detection. Age-related hearing loss generally has a lower limit of 1 to 2 kHz (Dubno et al. 2013), justifying the 1.5 kHz cut-off used in this study's speech filtering and previous noise filtering studies (Jansen et al. 2014; Leensen et al. 2011; Vercammen et al. 2018; Vlaming et al. 2014). The HP DIN in this study had the strongest correlation to all PTAs and significantly steeper regression slopes than the BB. Consequently, test characteristics to detect hearing loss improved across all PTA averages (four frequency, LF and HF PTA) when using HP rather than BB DIN. As expected HP DIN had the highest associations with the HF

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PTA$_{2\&4kHz}$. In general, SRTs have been shown to have a high correlation to the 2 and 4 kHz pure tone thresholds (Smoorenburg 1992).

Consistent with the HP DIN findings reported here, Vlaming et al. (2014) reported a better correlation to PTA and higher sensitivity to hearing loss in the conventional (0.5 - 4kHz) and higher frequencies (3 - 8 kHz) using a single LP DIN noise filtered at 1.5 kHz compared to BB noise (Vlaming et al. 2014). For clarity note the inverse terminology between the noise and speech filtering strategy (i.e., LP filtered noise and HP filtered speech both sensitize the test to hearing in the HFs). Similar increased sensitivity to higher frequencies (2 – 6 kHz) was achieved when LP filtered masking noise of a CVC words-in-noise test at a 1.4 kHz cut-off (Jansen et al. 2014; Leensen et al. 2011).

The LP noise filtering method presented in Leensen et al. (2011) also included data on a HP filtered noise strategy showing low correlation to PTA$_{0.5-4kHz}$ and minimal ability to discriminate between listeners with NH or HL (Leensen et al. 2011). The results indicate that audibility of the SRT in the lower frequencies was unaffected by higher frequency hearing loss, an anticipated finding since the sample had comparable low-frequency thresholds (Leensen et al. 2011). Our study found that the LP DIN performs worse than than the BB DIN. Moreover, the correlation between LP DIN SRT and LF PTA$_{0.5\&1kHz}$ was lower than between BB DIN SRT and LF PTA$_{0.5\&1kHz}$,. The HP DIN in this study improved sensitivity to the LF PTA$_{0.5\&1kHz}$, even more than the LP DIN, despite no LF speech being presented below the 1.5 kHz range. The most likely reason is the fact that the LF and HF PTA are highly correlated. It is also possible that the 1.5 kHz speech-filtering strategy removes many of the cues necessary for accurate recognition of the digits in the LP condition, resulting in markedly poor association with LF PTA. Furthermore, except for the LP DIN that had weak correlations with pure tone thresholds, the BB and HP DIN correlations to pure tone thresholds increased as the frequency increased, reflecting that the most significant variation in our study population was in the higher frequencies. Consequently, the contribution of the LP DIN in the audiometric slope prediction did not offer significant value.

6.5.3. BB and HP DIN SRT relationship to EHF

In the past, the predominant view was that pure tone frequencies above 7 kHz did not significantly contribute to speech perception since the primary phonetic speech features, like the vowel formants, fall below the EHF range (> 8 kHz) (Fletcher et al. 1950; Fletcher et al. 1929). However, a growing body of evidence has demonstrated that EHFs are commonly available in speech (Monson et al. 2012; Motlagh Zadeh et al. 2019) and play a valuable role in speech recognition in noise (Monson et al. 2019; Motlagh Zadeh et al. 2019; Polspoel et al. 2021; Motlagh Zadeh et al. 2020). The results of our study demonstrated that, for people with

normal hearing (PTA ≤ 15 dB HL), the HP DIN had a higher correlation to EHFs (8 to 16 kHz) compared to the BB DIN and added to previous evidence that hearing in EHFs influence speech recognition in noise. For instance, Motlagh Zadeh et al. (2019) demonstrated the effects of EHF hearing by using broader, LP noise filters (2, 4 and 8 kHz) on the DIN test. As bandwidth broadened to 8 kHz, the mean SRTs from the filtered versions remained significantly better than the BB DIN, suggesting that speech energy above the filter cut-offs contributed to the intelligibility of the digits (Motlagh Zadeh et al. 2019). The first interesting result from their analysis was that a large proportion (64%) of younger adults in their sample with 'normal hearing' based on conventional audiometry had elevated EHF thresholds. Secondly, reduced EHF thresholds correlated well with self-reported difficulty hearing speech in noise (Motlagh Zadeh et al. 2019).

In another recent study by Polspoel et al. (2021), the contribution of EHFs for speech recognition in quiet and noise was assessed at a fixed SNR using different speech stimuli (i.e., digits, words and sentences). Stimuli were presented in different conditions, including broadband speech and noise, LP filtered noise with unfiltered speech, and filtered speech and noise. Filter cut-offs were set at 8 kHz. The highest scores were obtained for LP filtered noise with unfiltered speech. For assessing speech in quiet, the contribution of EHFs was investigated by presenting stimuli with and without EHF information. Adding speech frequencies above 8 kHz improved recognition scores by 75%, 21.8% and 23.8% for digits, words, and sentences in noise, respectively (Polspoel et al. 2021). Together with Motlagh Zadeh et al. (2019), these results prove that EHFs play a role in listening to speech in quiet and challenging listening environments, emphasizing the importance of assessing EHFs to facilitate earlier hearing loss detection. Broader LP noise filters (2, 4 and 8 kHz) were shown to sensitize the DIN to detect hearing loss in the conventional frequencies (0.5 to 4 kHz) and HFs (4 to 12.5 kHz) (Motlagh Zadeh et al. 2020). A 2 kHz noise filter had a high correlation (r = 0.71) and steep slope to conventional PTA (0.5 to 4 kHz), but a higher, 4 kHz filter had the highest sensitivity and specificity (> 90%) to detect hearing loss in the HFs (Motlagh Zadeh et al. 2020).

6.5.4. Clinical implications

While HP DIN SRTs correlated moderately with PTA, using a combined LP and HP DIN approach to determine audiometric slope provided estimations with large variability. The same was found for a combination of BB and HP DIN. The correlation between LP DIN SRTs and PTA thresholds in the LF range was low (rs < 0.25), leading to inaccurate slope prediction. LP DIN thresholds were also more related to higher frequency PTA thresholds. One of the benefits of the DIN test is that digits are highly overlearned stimuli, thereby engaging more

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bottom-up processes to determine peripheral auditory processing (Smits et al. 2013). However, while there is a high reported correlation between the DIN SRT and PTA (Jansen et al. 2013; Potgieter et al. 2016; Potgieter et al. 2018; Smits et al. 2004; Smits et al. 2013), the DIN is considered to capture more of the real-life difficulty hearing in complex listening environments than pure tones. This is likely why PTA does not fully account for DIN SRT variance (Koole et al. 2016).

From a hearing aid fitting perspective, it would be useful to have an accessible method independent from advanced equipment and calibration requirements to estimate the degree of hearing loss and audiometric slope. This would be opportune given the progression toward alternative approaches to hearing care, for instance, over-the-counter hearing aids for which the act was recently passed into law in the United States. However, the results from this study suggest that a selective LF and HF approach was not as good as just a HF approach for detecting the range of hearing loss assessed here.

While both the DIN with LP filtered noise and HP filtered speech showed a stronger SRT-PTA relationship and improved sensitivity to hearing loss in the HFs than the BB DIN, some important clinical differences should be considered between these test procedures. LP noise maskers produce lower SRTs than those measured with the BB DIN (Vlaming et al. 2014). This is because speech becomes unmasked above the 1.5 kHz range, gaining around 15 dB (Vlaming et al. 2014). Listening to filtered speech presented in unfiltered background masking noise is arguably more cognitively demanding than unfiltered speech in filtered noise, requiring multiple auditory discrimination skills. This may account for the generally lower HP DIN SRTs compared to the BB DIN. Nonetheless, the HP DIN in this study improved the sensitivity and specificity across all PTA averages more than the BB DIN and is, therefore, a more effective measure for detecting hearing loss than the BB DIN, especially for HF hearing loss. Furthermore, due to the unintelligibility of certain digits in the different filtering methods, the scoring procedure was changed to reduce the SNR when two or three digits were recognized correctly and increase when no or one digit was correct.

Hearing loss caused by occupational noise typically presents with an increased pure tone threshold around 4 kHz (Jansen et al. 2014; Oxenham et al. 2003). The HP DIN, due to its high association with 2 and 4 kHz thresholds, may be applied as a measure to screen for hearing loss among people who are exposed to occupational noise. Our study further demonstrated better SRT-PTA correlation to EHFs (8 to 16 kHz) using the HP rather than LP DIN, contributing to the recent evidence that EHFs are important for recognizing speech-in-noise (Motlagh Zadeh et al. 2019; Polspoel et al. 2021; Motlagh Zadeh et al. 2020). Therefore, early evidence of hearing loss in the EHF range may be detected earlier using the HP DIN than the BB DIN.

BB DIN tests have already been widely implemented for hearing screening among the public using digital devices like computers and smartphones (Swanepoel et al. 2019). However, one potential issue to consider is the effect of headphone type. Potgieter et al. (2016) showed that the headphone type used in the BB DIN did not significantly influence the SRT (Potgieter et al. 2016). However, the HP speech filtering strategy proposed here, emphasizing higher frequencies, will be influenced by the frequency response of the headphones used. This study used a high-quality audiometric headphone (Sennheiser HDA 280), but a future study should determine HP DIN performance across a range of headphone types, including commercially available options that the public would likely use.

6.6. Conclusion

The HP DIN improved sensitivity and specificity to a conventional, HF-weighted hearing loss relative to a BB DIN, especially for HL between 2 and 4 kHz. Furthermore, the HP DIN SRT correlated more strongly than the BB DIN SRT with EHFs (8 to 16 kHz) for normally hearing ears (PTA ≤ 15 dB HL). These results add to growing evidence that EHFs play a role in recognizing speech in noise. The LP DIN had poor reliability and association with PTA. The results of this study show the dominant effects of hearing in the HFs on the DIN SRT.

6.7. References

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CHAPTER 7

GLOBAL USE AND OUTCOMES OF THE HEARWHO MHEALTH HEARING TEST APP

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7.1. Abstract

Background: The objective of this study was to examine the uptake, user characteristics and performance of the free WHO smartphone hearing screening test (hearWHO) as a global hearing health promotion initiative.

Methods: We retrospectively examined the data of 242 626 tests conducted by adults (> 18 years) on the *hearWHO* app between February 2019 and May 2021. Test uptake was evaluated by country, WHO world region, test date and demographics of age and gender.

Findings: The *hearWHO* test was completed in nearly every country globally (n = 179/195), with the greatest uptake seen in China and India. Uptake was greatest in the Western Pacific (32.9 %) and European (24.8 %) WHO regions. There was a high uptake of tests (44%) by young adults under the age of 30 years. Referral rates were typically higher for older age groups in most WHO regions, except for the African and Eastern Mediterranean regions, where overall *hearWHO* test uptake was lowest. Most testing (49%) took place in March (2019-2021), coinciding with World Hearing Day (3rd of March) each year.

Interpretation: Digital mhealth tools provide many benefits in healthcare, including health promotion, access to information and services for hearing loss. The *hearWHO* test was mainly reaching younger adults, positioning it as an important measure for public health advocacy to prevent hearing loss. Since hearing loss is primarily age-related, more targeted campaigns or community-based initiatives should be directed toward older adults.

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7.2. Introduction

Throughout the life course, hearing loss has pervasive effects. Besides the detriment to early childhood development [1], it is associated with factors central to the quality of life in adults, including increased risk of depression, loneliness [2], unemployment [3], and dementia [4]. Conservative estimates indicate that by 2050, nearly one in four people will have a certain degree of hearing loss and, for one in fourteen people, it will be of a moderate or higher degree [5]. There has been a drive to address hearing loss, leading to the report on the *Global cost of unaddressed hearing loss and cost-effectiveness of interventions* by the World Health Organization (WHO) in 2017 [6], the *Resolution and action plan for prevention of deafness and hearing loss* at the World Health Assembly in 2017 [7] and, most recently, the *World Report on Hearing* in 2021 [5]. The World Report calls for urgent investment in hearing loss prevention, considering that, in 2020, nearly 1 trillion international dollars was lost globally due to unaddressed hearing loss [8].

Lack of awareness and knowledge by the public and health care providers has contributed to insufficient prevention, early detection and treatment of hearing loss, with stigmatization largely unaddressed. Almost one billion young adults are at risk of preventable hearing loss due to unsafe listening practices [5]. Hearing promotion through screening is a strategy to promote awareness, early detection and timely treatment. Economic benefits of reducing the prevalence and severity of hearing loss show that a 5% reduction in prevalence could reduce the global monetary loss of hearing loss by, conservatively, around 50 billion dollars per annum [8]. The World Report on Hearing (2021) has recommended the use of innovative screening measures and telehealth to make hearing care more accessible [5].

Screening for hearing loss has been out of reach for most people with disabling hearing loss since more than 80% reside in low-and middle-income countries (LMICs) where ear and hearing care is often unavailable or limited [5]. This is due to the dearth of professionals, infrastructure and resources to provide services [9]. While this issue is challenging in LMICs, particularly for rural communities, it is also encountered in high-income countries where nearly three-quarters of people who could benefit from hearing aids do not have them [5, 10]. Utilizing digital platforms including mHealth tools is a scalable way to improve public awareness and access to hearing care. By the end of 2019, global mobile internet usage increased to 3.8 billion people, an increase of 250 million people in a single year, of which 90% were new users from LMICs [11]. As a result there has been a rapid increase in mHealth solutions for hearing loss in the past 10 years (Frisby et al. In Press), particularly for hearing screening [12]. One of the most widely used mHealth tools for hearing screening is the smartphone digits-in-noise test (DIN) that has become freely available to the general public as a self-screen for hearing

loss [13, 14]. On World Hearing Day 2019, WHO released an English version of the DIN test called *hearWHO*, followed by Spanish and Mandarin versions in 2021.

The DIN measures a person's ability to understand speech in noise by presenting spoken digit triplets (e.g., 3-4-7) in adaptive levels of background masking noise [15, 16]. The test tracks the level where 50% of triplets could be recognized, called the speech recognition threshold (SRT) [13]. The *hearWHO* app uses an antiphasic test paradigm, where the target speech is presented binaurally out-of-phase [17]. The antiphasic SRT has high sensitivity and specificity of more than 80% to detect different types of hearing loss and correlates strongly with clinical pure tone audiometry performed in sound-treated environments [17, 18]. Unlike traditional pure tone audiometry, which requires a trained test facilitator, calibrated equipment and soundproof booth, the test can be accurately conducted on many devices without device calibration. Groups of three successive digits are easily understood, remembered, and entered on a keypad, making it an undemanding task in terms of language and cognition. In addition, self-testing makes for a versatile, accurate and rapid (3-minute) screen.

Healthcare developments in mHealth like the *hearWHO* app are affordable and particularly suitable for hard-to-access communities. In addition to impaired communication, unaddressed hearing loss has a high general health cost, such as the increased risk of dementia, for which hearing loss treatment is the number one modifiable risk factor [4]. The *hearWHO* app is focused on raising awareness and motivating earlier rehabilitation steps in part to prevent a cascade of neurological and mental health problems.

hearWHO has been widely used and promoted by global health organizations, governments, and hearing health organizations. This paper reports *hearWHO* hearing screening uptake across world regions, user characteristics, and performance as a mHealth hearing health promotion tool.

7.3. Method

This study received ethical approval from the University of Pretoria Humanities Research Ethics Committee (Protocol Number: HUM025/0621).

Participants

We retrospectively examined the data of 259 894 tests conducted on the *hearWHO* app between February 2019 to May 2021. We excluded the data of 88 tests where either the birth date, digit language, or stimulus type was captured in an incorrect format rendering the data unavailable (technical issue). In addition, data of test users who indicated age under 18 years ($n = 17\,180$) were excluded from the analyses, as the test validation and cut-offs are currently based on adult normative data. There was a small group of test users ($n = 56$) who indicated

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age over 100 years that were kept in the analyses. Furthermore, 0.9% (*n* = 2192) of users reached a ceiling SRT test (17.7 dB SNR) possibly reflecting an unreliable test but their data were kept in the analyses to indicate actual test performance across test users. The *hearWHO* test was completed by downloading the application on an Android (*n* = 137 479) or iOS (*n* = 105 147) device. We did not include tests from the *hearWHO Pro* test version, used by health workers to screen people in their communities. Before completing the test, users were prompted to choose their preferred test language between English (*n* = 237 417), Mandarin (*n* = 3806) or Spanish (*n* = 1403). The Spanish and Mandarin versions were only released on the 3rd of March 2021, two years after the initial launch, with English as the only test option.

Procedures

Before the test, users were asked to select their birth year and native language and whether the test was completed as a self-test or with the help of a test facilitator. Thereafter, participants were instructed to connect headphones and select a comfortable volume while digit-triplets were presented without masking noise. Afterwards, 23 digit-triplets (e.g., 3-5-8) were randomly selected and presented using an antiphasic paradigm, where the digits had a 180° phase shift between the ears while keeping stationary masking noise in phase [19]. The antiphasic DIN has greater sensitivity to various hearing loss types than the original diotic DIN, including bilateral or unilateral sensorineural hearing loss and conductive hearing loss [17]. The exact construction of the masking noise and test procedure can be found in De Sousa et al. (2020) . The SRT was categorized, based on cut-offs, as either 'Good', 'OK' or 'Needs Help'.

7.4. Results

The mean age of users was 35.7 years (SD = 14.6 years). Most of the users conducted the test themselves (87.8 %, *n* = 213 097), and the rest with the help of a facilitator (12.2 %, *n* = 29 529). Most tests (51.3%) were conducted in the user's non-native language. Mean SRTs were comparable between native (-17.1 dB SNR) and non-native (-17.0 dB SNR) users who passed the English version (n = 106 689).

Across all WHO regions, test uptake was highest for younger adults between the ages of 18 to 30 years (44.4 %; Figure 7.1A). Referral rates were typically higher for older age groups in most WHO regions, except for the African and Eastern Mediterranean regions, where overall hearWHO test uptake was lowest and referral rate across age groups more even, notably in Africa (Figure 7.1B). The majority of tests globally were taken by males (56.7%; Figure 7.1 C), except in the Americas WHO region (Table 7.1). Age-related deterioration in SRTs was evident for both females and males (Figure 7.2), but there was a clear gender difference. Female SRTs were stable until about 50 years, while male SRTs deteriorated more continuously. Until about 40 years, males had better thresholds, but females over 40 had

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better thresholds. In general, there were increasing percentages of tests in the "Needs help" hearing status category with each advancing age group (Figure 1D).
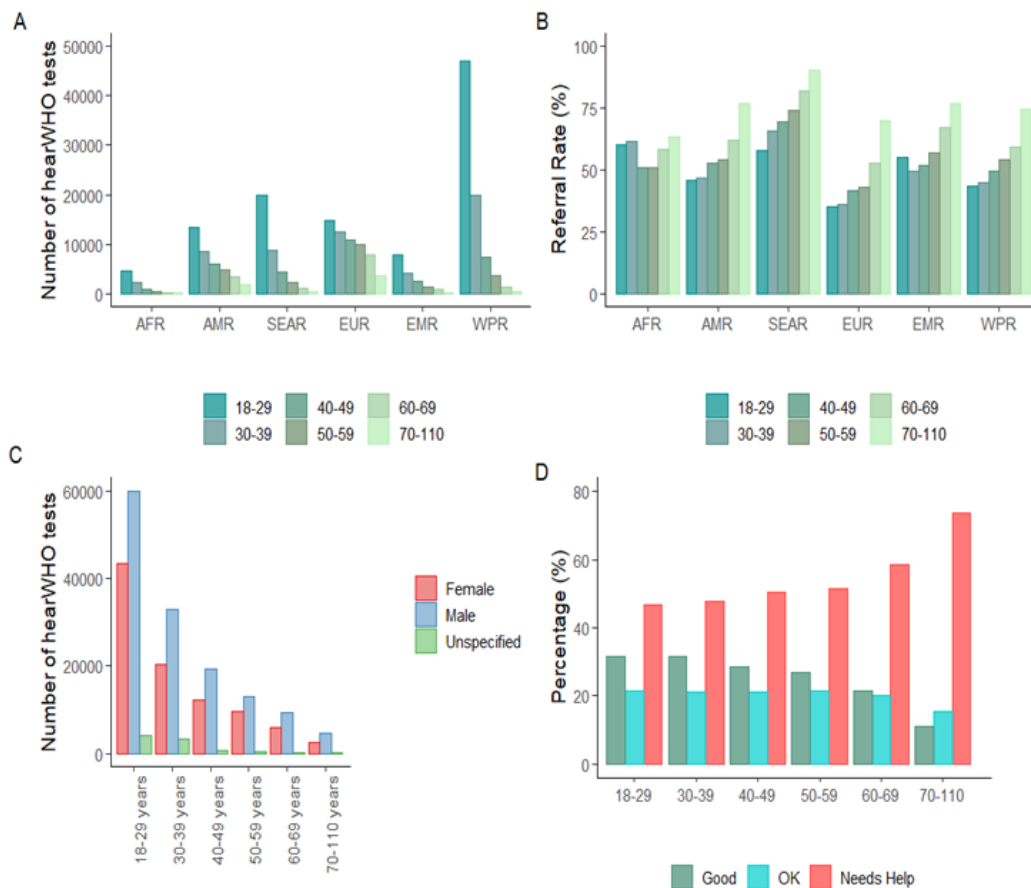
Figure 7.1. *hearWHO tests according to age group and WHO region taken between February 2019 and May 2021 (n = 242 234). (A) Number of hearWHO tests taken per WHO region and age group, (B) Referral rate per WHO region and age group, (C) Distribution of hearWHO tests across age groups between February 2019 and May 2021 (n = 242 626), (D) Percentage of tests in each WHO results category according to age group.*

Note. AFR indicates African Region, AMR; Region of the Americas, SEAR; South-East Asian Region, EUR; European Region, EMR; Eastern Mediterranean Region, WPR; Western Pacific Region.

The *hearWHO* test was completed in nearly every country globally (*n* = 179/195; Figure 7.3), with the greatest uptake seen in the Western Pacific (32.9 %) and European regions (24.8 %; Table 7.1; Figure 7.3). Test uptake per 100 000 people showed the highest uptake in Saint Lucia, Iceland, and Ireland (Figure 7.4A), while overall, the greatest number of tests were conducted in China, India and the United States (Figure 7.4B). Nearly half of all tests (49%) took place in March (2019-2021), coinciding with World Hearing Day held on the 3rd of March each year (Figure 7.5). Most of these tests were taken in 2019, and the overall rate of testing declined markedly in 2020, and again in 2021.

Table 7.1.

hearWHO test user (18 years of age and above) characteristics and referral rates across WHO regions (n = 242 234)

	African Region (AFR)	Region of the Americas (AMR)	South-East Asian Region (SEAR)	European Region (EUR)	Eastern Mediterranean Region (EMR)	Western Pacific Region (WPR)	Global
Tests taken							
n	9 218	38 562	37 256	60 091	17 317	79 790	242 234
%	3.8 %	15.9 %	15.4 %	24.8 %	7.1 %	32.9 %	100 %
Age in years							
Mean (IQR)	33.0 (14)	39.4 (25)	32.3 (15)	43.4 (26)	34.3 (20)	30.4 (11)	35.7 (20)
Gender							
Male %	61.0	45.8	67.3	56.3	58.6	59. 1	57.6
N	5 622	17 648	25 088	33 815	10 141	47 170	139 484
Female %	35.9	51.4	29.7	41.0	37.6	35.9	38.8
N	3 307	19 805	11 080	24 648	6 504	28 647	93 991
Unspec %	3.1	2.9	2.9	2.7	3.9	5.0	3.6
N	289	1 109	1 088	1 628	672	3 973	8 759
Median SRT in dB SNR (IQR)	-13.4 (6.4)	-14.2 (6.0)	-13 (6.0)	-15 (5.2)	-13.8 (5.8)	-14.8 (5.6)	-14.4 (6.0)
hearWHO result category							
Good %	23.3	28.6	17.0	35.7	23.0	33.1	29.5
OK %	17.7	20.2	19.7	22.0	22.4	21.6	21.1
Needs Help %	59.0	51.2	63.2	42.3	54.6	45.3	49.4

*Note. * For 392 users the IP country address could not be identified*
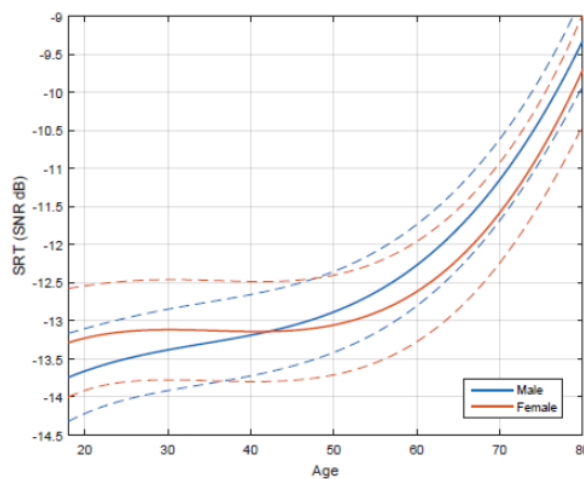
Figure 7.2. *Average hearWHO DIN SRTs fitted with third order polynomials across age for males and females (n = 233 844).*

Note. Dotted lines are 90% confidence intervals.

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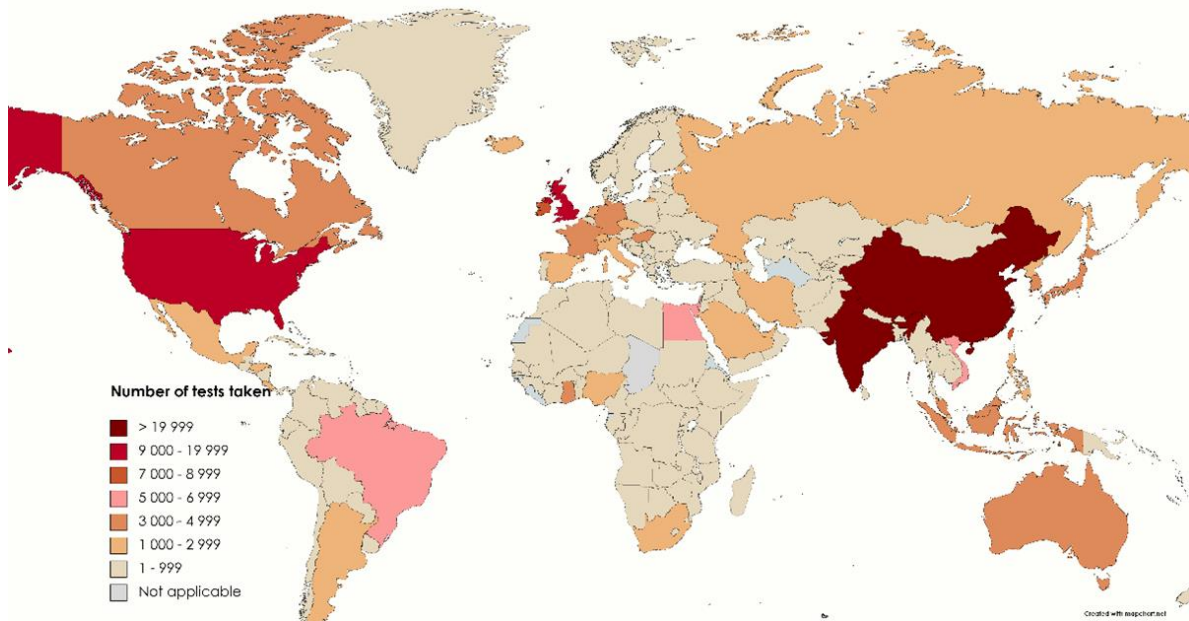
Figure 7.3. *Distribution of global hearWHO tests by country between February 2019 and May 2021 (n = 242 626).*

Note. Not applicable means that no tests were conducted in the specific region.
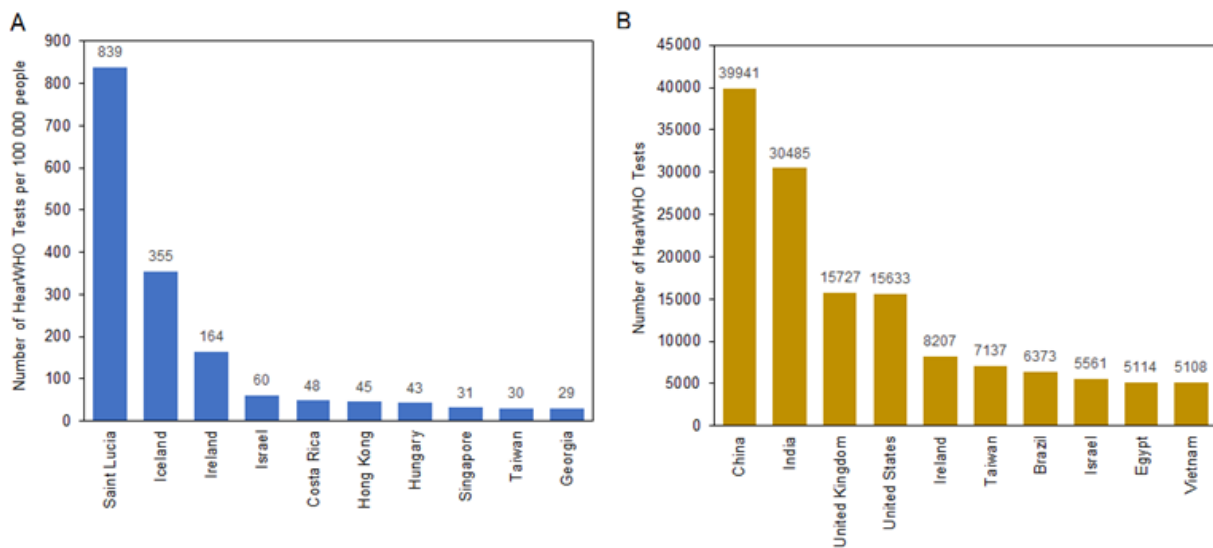
Figure 7.4. *HearWHO uptake across countries. (A) Number of hearWHO tests per 100 000 people for the top 10 countries, (B) Number of hearWHO tests for the top 10 countries.*

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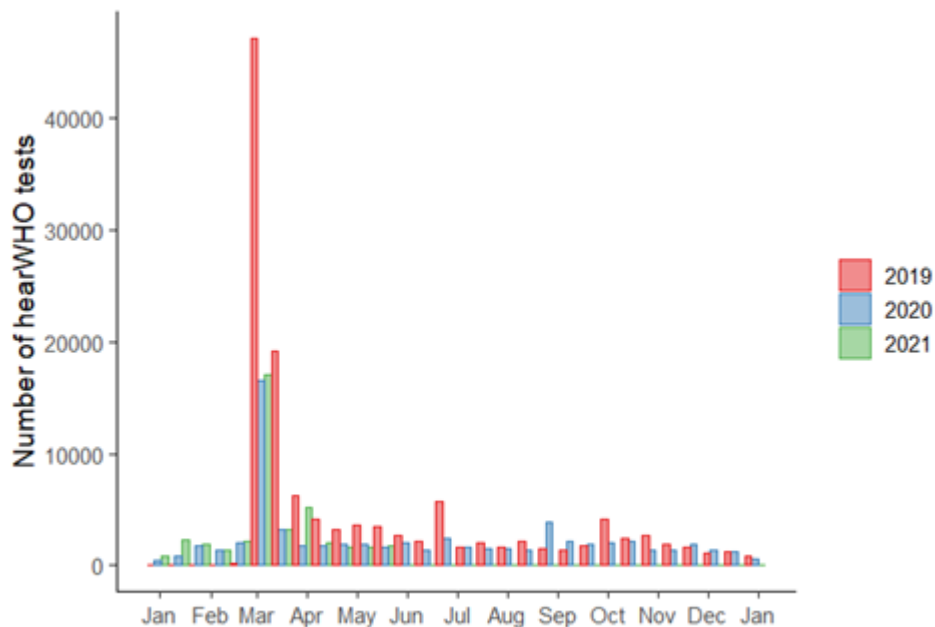
Figure 7.5. *HearWHO monthly test uptake from February 2019 to May 2021 (n = 242 626).*

7.5. Discussion

The *hearWHO* app was released as a global public health initiative to increase hearing health awareness and prevention through access to a free self-test for hearing screening. Digital mhealth technologies like *hearWHO* are becoming increasingly valuable as the world transitions into the information age, concomitant with the rapidly advancing ownership of mobile devices and internet connectivity [11]. To date, more than 250 000 *hearWHO* tests have been completed across the globe, most of which were completed in the Western Pacific and European Regions. Hearing loss prevalence is driven mainly by demographic changes and population ageing. In the coming years, the prevalence is predicted to rise in accordance with the population profile, of which the highest number of people in 2050 is expected to be in the Western Pacific.

Fewer tests were conducted in African and Eastern Mediterranean than in other regions. Unfortunately, rates of hearing loss are expected to double in these regions by 2050 [5]. Several factors could have contributed to the lower uptake. For instance, Sub-Saharan Africa had a notably lower smartphone adoption rate by the end of 2020 compared to other world regions [20]. Furthermore, health promotion initiatives in sub-Saharan Africa are sorely lacking, considering the population's generally low-health status [21]. As shown in Figure 7.5, health campaigns like World Hearing Day play a significant role in public awareness of available tools like the *hearWHO* app. Promotion efforts may be hampered in these regions due to a lack of

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adequate resources and knowledge among healthcare providers who play an important role in hearing health awareness [5]. While the digits-in-noise test is not a linguistically or cognitively demanding task, test uptake is very likely influenced by the test language offered. Currently, the *hearWHO* app is only available in English, Spanish and Mandarin. Releasing the test in other languages more widely spoken in the Eastern Mediterranean and African regions could improve the uptake and test accuracy, as the performance of the digits-in-noise test in a non-native language is known to be slightly lower than for native speakers [22]. Other language versions for the *hearWHO* app are currently under development.

Younger users under 30 years were a large proportion (44%) of all tests taken. Generally, hearing loss prevalence is higher among older adults due to age-related hearing degeneration [5]. The Global Burden of Disease study in 2019 indicated that 65% of adults over 60 years have hearing loss, of which 25% are moderate or higher degrees [23]. Another example is the analyses of the UK Biobank, which showed that the ability to hear speech in background noise, measured using the digits-in-noise, declines exponentially from the age of 50 years and is linked with declining cognitive processing ability [24]. In general, age related decline in this study was evident (Figure 7.2) and was in close parallel between women and men. However, there was a gender cross-over in terms of SRT performance. Younger men (< 40 years) had better SRTs than women, while the inverse was found for older test users (> 40 years), where women had better SRTs. Data from the UK Biobank reported a similar digits-in-noise performance trend between the sexes, although their sample only included older adults [24]. Potential reasons for the trend should be investigated in future.

The overall referral rate for the *hearWHO* test was 49.4%, and, as expected, referral rates increased for each advancing age group. However, the number of users failing the test was high across all ages, even for the younger cohort under 30 years (46.8%; Figure 7.

1D). It is possible that many users were already concerned about their hearing and subsequently took the test. Similarly, referral rates were high for a digits-in-noise test released over landline and cell phone in the United States, with a reported 81% referral rate [25]. A noteworthy number of tests in the Western Pacific (*n* = 46 884) were taken by younger adults. Since hearing loss in the Western Pacific is estimated to rise in the coming years, it can be considered beneficial that the *hearWHO* test is promoting awareness among an important younger demographic in this region. Reaching a younger population is an effective preventative strategy to ensure hearing health awareness among the youth. However, alternative strategies should be explored to reach the critical target population of people over 60 years.

Although there has been tremendous growth in smartphone and mobile internet usage, even among LMICs and previously marginalized groups, it is recognized that there is a so-called 'digital divide' among different populations, genders, age groups and countries, which likely influences the uptake of the *hearWHO* test. In general, smartphone ownership and digital literacy are lower among older adults [26, 27], which could partially account for the lower test uptake in people over 60 years. Another probable factor is the way in which the application was promoted to the elderly. Test uptake was also greatest for males across all the age groups (Figure 7.1).There is a notable gender gap in smartphone ownership, especially in LMICs, with women 7% less likely to own a mobile phone and 15% less likely to use mobile internet than their male counterparts [28]. Another plausible reason for higher test uptake among males is higher hearing loss prevalence rates in men than women [29, 30]. Therefore, it is possible that more males became aware of their hearing loss and subsequently completed the test.

Although the test is recommended and validated for adults, many tests (n = 17 180) were completed by people under 18 years, showing an interest in tools to screen younger children and adolescents' hearing. The digits-in-noise test can reliably be conducted in children as young as four years old [31], but may benefit from the help of an adult to facilitate the test [31, 32]. Furthermore, speech recognition in noise is a skill that matures with age [33]. For the antiphasic digits-in-noise test, maturation was seen for children up to 12 years [31, 34]. A future research priority could be to validate and establish normative criteria for children in each test language.

Many *hearWHO* tests were completed in 2019, coinciding with the app release and the year's theme for World Hearing Day, 'Check your hearing'. Furthermore, a notable spike in the number of tests seen each year in March (54.4%, 29.3% and 55.9% of all tests for 2019, 2020 and 2021, respectively) was anticipated due to hearing loss awareness campaigns steered for World Hearing Day [35, 36]. When looking at the proportion of tests with respect to population size, the best uptake was seen in Saint Lucia and Iceland, both smaller countries with an estimated population less than 400 000 people [37]. WHO activity reports indicate that Iceland launched marketing campaigns on World Hearing Day that leveraged social media, television and radio broadcasts [35, 36]. Marketing strategies are thus an effective way to increase uptake among the public, of which campaigns via digital media have proven to be valuable motivators to increase efficiency and uptake of services [38].

mHealth tools provide many benefits in healthcare, including health promotion, access to information and services for hearing loss [14]. The *hearWHO* app is a globally utilized public health tool for raising awareness and improving access to early detection for hearing loss. Currently, the test is mainly reaching younger adults positioning it as an important measure for public health advocacy to prevent hearing loss due to unsafe listening practices [39]. Hearing loss prevalence is usually higher later in life. As such, awareness campaigns especially

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targeting older people using more traditional marketing campaigns like local newspapers or magazines, television or radio broadcasts may be an effective strategy. Furthermore, targeted screening programs for older adults using trained health workers and the *hearWHO Pro* screening application may be a more suitable approach. As smartphone adoption and mobile internet connectivity continue to grow across the globe, the reach of the *hearWHO* test is expected to increase. Translation in other languages and validation for people under 18 years is also likely to further improve global uptake.

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7.6. References

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CHAPTER 8
DISCUSSION, CLINICAL IMPLICATIONS AND CONCLUSIONS

Over the last almost two decades, the digits-in-noise (DIN) test has predominantly been implemented as a screening measure for detecting hearing loss (Van den Borre et al., 2021). Owing to its robust nature and familiar stimuli that can be conducted accurately over analogue landline phones and more recently across digital technologies, the test has high face validity as an automated self-screen for public use (Potgieter et al., 2016; Van den Borre et al., 2021). Much research has been devoted to optimising DIN test procedures and stimuli to be as sensitive and efficient as possible (Van den Borre et al., 2021). However, beyond detecting hearing loss, there have been no DIN studies that could accurately classify or triage types of hearing loss. This is a shortcoming since there are concerns that people with complex ear disease may be missed, especially when using service delivery models with limited involvement from health professionals, e.g., the sale of over-the-counter (OTC) hearing aids, for which an act was just recently passed into law (US Food and Drug Administration, 2017). Advanced DIN procedures and applications could potentially support improved accuracy and directed referral for triaged types of hearing loss. These advances further support its widespread use through global initiatives like the World Health Organization's (WHO) *hearWHO* application. Therefore, this study evaluated advanced DIN approaches for improved detection and categorizing hearing loss.

8.1. Summary of research findings

Differentiating hearing loss based on DIN test results

Study I determined the ability of a sequential antiphasic and diotic DIN test to classify hearing loss based on the type of loss. This study was a novel contribution to existing DIN literature as a first attempt to investigate a classification method that could triage referrals as either requiring (i) medical intervention or (ii) audiological referral. Antiphasic speech recognition threshold (SRT) had a more significant distinction than diotic SRT between normal hearing listeners and listeners with any type of hearing loss. As a result, sensitivity and specificity to detect hearing loss were better for the antiphasic DIN. This was evident by the excellent area under the receiver operating characteristic (AUROC) curves (0.94 and 0.95) to detect hearing loss with pure tone average (PTA) greater than 25- and 40- decibel hearing levels (dB HL), respectively. As expected, the diotic DIN had lower test characteristics to detect hearing loss, especially for conductive hearing loss (CHL) and unilateral sensorineural hearing loss (SNHL), and had a lower AUROC (0.79 and 0.82) to detect PTA hearing loss more than 25- and 40- dB HL. AUROC was further investigated by factoring in the effect of age using binomial logistic

regression. The AUROC to detect hearing loss > 25 dB HL in the poorer ear was slightly higher in antiphasic and diotic conditions when considering both SRT and age in the prediction, rather than DIN SRT alone. However, the effect was negligible, implying that age-adjusted cut-offs for the antiphasic and diotic SRT were unnecessary.

The second objective of the study investigated two SRT cut-off methods to categorise hearing as (a) normal hearing, (b) unilateral or asymmetric SNHL or CHL, or (c) bilateral SNHL based on the combination of antiphasic and diotic SRT. This was done by plotting diotic SRT against antiphasic SRT. The first method used a fixed antiphasic SRT cut-off to distinguish normal hearing from participants with hearing loss. Furthermore, a diotic cut-off was used to separate unilateral or asymmetric SNHL or CHL from bilateral SNHL. This method could correctly classify 75% of all hearing categories but could not optimally discriminate all cases of bilateral SNHL (56.1% overall incorrect classification) from unilateral, asymmetric SNHL or CHL. Therefore, the second procedure used a fixed antiphasic and sloping diotic cut-off (varying slope and offset) to capture the maximum correctly classified participants. This procedure increased correct classification to 79%; however, it came at the cost of more normal hearing participants classified as having hearing loss (10.9%) and lower numbers of correctly identified unilateral or asymmetric SNHL or CHL (20.6%). The choice of cut-off method will likely be determined based on the target disorder. For example, the second method may not be the best choice for triaging if the goal is to identify the maximum proportion of unilateral SNHL or CHL cases.

Differentiating hearing loss based on air conduction DIN and pure tone audiometry

Traditionally, to determine SNHL from CHL or mixed hearing loss requires a comprehensive test battery, including pure tone air- and bone-conduction audiometry conducted in a soundproof booth (International Standards Organization, 2015). Study II investigated whether it could distinguish CHL from SNHL using a method that combined pure tone air conduction thresholds and a diotic DIN. The relationship of the diotic DIN between participants with CHL and SNHL was inspected per test frequency (0.5 to 4 kHz). Diotic SRTs were lower (better) for CHL than SNHL across all frequencies. Consequently, similar results were found for low-frequency PTA (LF PTA 0.5 & 1 kHz) and high-frequency PTA (HF PTA 2 & 4 kHz). Binomial logistic regressions were used to determine the likelihood of having CHL or bilateral SNHL. Models including LF PTA explained most of the variance in CHL, most accurate category prediction and showed the largest AUROC (0.94). Including age in the LF PTA model could differentiate CHL from bilateral SNHL with an overall accuracy of 93.7% and sensitivity and specificity of more than 93% (AUROC = 0.98). Positive and negative predictive values were modelled for various CHL prevalence rates. Negative predictive values remained constant,

while positive predictive values became higher as CHL prevalence was increased. These results indicated that CHL could be distinguished from bilateral SNHL with high accuracy using a combination of pure tone air conduction audiometry and a diotic DIN test.

Detecting hearing loss in low and high frequencies using DIN

Hearing loss type is an important consideration when screening for hearing loss since it will essentially guide the type of intervention. However, another critical factor, especially when considering hearing aid fitting in SNHL, is hearing loss defined in both LFs and high frequencies (HFs), thus the audiometric slope. Study III developed a low-pass (LP) and high-pass (HP) DIN by filtering speech at 1.5 LF and HF band. The first phase determined the recognition probability of each digit across a range of signal-to-noise ratios (SNRs). The goal was to use the data to equalise the material by applying level corrections to each digit. Due to an error in the script, equalisation was not precise, resulting in heterogeneous material. Since the average level corrections equalled 0 dB, the measured SRTs in this study's validation phase were still expected to be correct. However, the equalisation error will have affected test reliability (i.e., measurement error).

While the correlation between all the DIN tests (BB, LP and HP) and pure tone thresholds was relatively high, the strongest correlations and intra-subject spread of SRTs were found for the HP filtered version. This indicated greater sensitivity of the HP DIN to detect hearing loss across all the PTA frequency averages. In fact, AUROC analysis showed that the HP DIN had better sensitivity and specificity to detect hearing loss (PTA > 25- and 40-dB HL) than the BB or LP DIN. The BB DIN correlated better to the LF thresholds (0.5 & 1 kHz) than the LP DIN. The relationship of SRT and extended high frequencies (EHFs; 8 to 16 kHz) and SRT were further investigated by looking at the DIN performance of ears with normal hearing (PTA 0.5 to 4 kHz ≤ 15 dB HL). BB and HP DIN SRT had a significant ($p < 0.01$) moderate, positive correlation to EHF PTA (8 to 16 kHz), suggesting that EHFs affect the SRT performance. However, the HP DIN SRT had a stronger correlation (rs = 0.61) and steeper regression fit to EHF PTA$_{8-16kHz}$ than the BB DIN SRT correlation (rs = 0.51) and regression fit.

The slope of the pure tone audiogram was estimated by subtracting the LF PTA (0.5 & 1 kHz) from HF PTA (2 & 4 kHz), thereby a higher value indicating a steeper HF audiometric slope. Furthermore, the difference between the HP and LP DIN SRT (HP- LP DIN) was used to predict the audiometric slope. While ears with hearing loss had a moderate correlation (rs= 0.41, $p < 0.01$) between the audiometric slope and HP-LP DIN predictors, multiple linear regression showed that only the HP DIN significantly ($p < 0.05$) contributed to the prediction. The model showed limited ability to predict the PTA slope from the LP and HP DIN (adjusted $R^2 = 0.26$). The same results were found when using a HP- BB DIN slope to predict the PTA

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slope. Overall, these findings demonstrated better sensitivity and specificity to detect hearing loss using a HP rather than BB or LP DIN. HP DIN sensitivity was especially high for hearing loss occurring in the 2 and 4 kHz range. Furthermore, the HP DIN correlated more strongly to EHFs (8 to 16 kHz) for ears with normal hearing (PTA ≤ 15 dB HL), suggesting that EHFs play a role in speech recognition in noise.

Global DIN uptake and outcomes with hearWHO app

Study IV investigated the global use and outcomes of the *hearWHO* smartphone hearing test application (app) to provide insight into the DIN's effectiveness as a digital screening and health promotion tool. The app uses the antiphasic DIN test paradigm and procedure developed by De Sousa et al. (2020) since it is more sensitive across a range of hearing losses (De Sousa et al., 2020). The *hearWHO* test was completed globally in almost all countries (n = 179/195), with the most significant uptake in the Western Pacific (32.9%) and European regions (24.8%). Test uptake was highest across all WHO world regions (44.1%) for young users under 30 years. As expected, referral rates were higher for older age groups, with the exception of the African and Eastern Mediterranean region, where *hearWHO* test uptake was lowest. Age-associated deterioration in SRTs was seen for both females and males. However, there was an apparent gender disparity. Female SRTs remained relatively constant until approximately 50 years, while male SRTs deteriorated more continuously. Until about 40 years, males had lower SRTs (i.e., better SRTs), but females over 40 had better thresholds. Nearly half of all tests (49%) took place in March (2019-2021), coinciding with World Hearing Day held annually on the 3rd of March. The descriptive analysis provided here indicates that the *hearWHO* test was primarily used by the younger population of adults and thus positions it as an approach for public health advocacy to prevent hearing loss.

8.2. Clinical and theoretical implications

Alternative clinical approaches to clinic-based audiological service delivery models are necessary and becoming increasingly common to overcome the global access challenges (Wasmann et al., 2021). Computational augmentation refers to supplementing clinical work through digital tools. This exention of clinical work through the different tools is an applied tactic to deal with the lack of human resource to provide hearing care, as well as the mounting numbers of underserved people with hearing loss (Wasmann et al., 2021). Due to the increasing availability of mobile devices and the internet (GSMA, 2020b), access to hearing loss and ear disease assessment can dramatically and cost-effectively be improved using digital modes. A major driving force for the adoption of digital tools to augment clinical work has been the COVID-19 pandemic (Madden et al., 2020; Saunders & Roughley, 2021; Tortajada-Goitia et al., 2020; Yellowlees et al., 2020). The acceptance and further

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development of these telehealth models and digital tools implemented into routine clinical practice could benefit millions of people for whom traditional care has been out of reach (World Health Organization, 2021). However, it is critical to establish the complexity of a person's hearing-related disorder and their level of confidence to use digital technology, which will direct the degree of professional involvement and assistance (Swanepoel & Hall, 2020; Wasmann et al., 2021). For instance, large proportions of people with mild and moderate hearing loss (usually bilateral SNHL) may be served using simplified models and digital devices that apply self-assessment (Swanepoel & Hall, 2020). Hearing loss together with complexities like ear disease typically requires more professional involvement and medical care (AAO-HNS, 2014; Swanepoel & Hall, 2020). Being able to triage patients using tools with remote and decentralised reach can increase access and support efficiencies in hearing health delivery. This study provides empirical evidence of DIN methods that can support improved detection and classification of different hearing loss types. These advances contribute to burgeoning research to optimise the DIN test efficiency and sensitivity as a screening and potential triaging tool. Furthermore, these classification methods can provide simple, applied solutions that support alternative service delivery models like over-the-counte (OTC) r or direct-to-consumer (DTC) pathways.

Study I confirmed that the antiphasic DIN has improved test characteristics compared to previously used monaural and diotic DIN versions to detect bilateral SNHL, unilateral SNHL and CHL in a single 3-minute binaural test. Furthermore, the addition of a diotic test could categorise hearing loss with an accuracy of between 75 and 79% as either (i) normal hearing, (ii) bilateral SNHL or (iii) unilateral SNHL or CHL. As a triage procedure, persons with bilateral SNHL could be eligible for a direct referral to a hearing aid provider (e.g., audiologist) or alternative DTC or OTC service models. In contrast, people with unilateral SNHL, mixed hearing loss or CHL should be refered for full audiological and medical assessment) due to the potential accompanying ear disease (AAO-HNS, 2014). For example, cholesteatoma, otitis media or acoustic neuroma are severe ear- and hearing-related disorders that could have adverse effects without professional involvement and surveillance (Osma et al., 2000; Spilsbury et al., 2010; Suzuki et al., 2010). As emphasized earlier, the COVID-19 pandemic placed significant strain on traditional clinical care due to the sudden enforcement of national lockdowns and requirements for physical distancing (Keesara et al., 2020). The triage method described here, provided as a digital tool to prospective patients, could prioritize people on a case by case basis. Suspected unilateral SNHL or CHL should proceed with an in-person comprehensive test battery, with precautions to prevent infection, while bilateral SNHL could be served using low- (minimal physical contact) or no-touch (no-physical contact) models.

Study II further demonstrated how the DIN could support these alternative care models. Bone conduction audiometry is the gold-standard procedure to define a conductive component but is limited in its use as a self-administered procedure due to variability and calibration standard errors, even in meticulous experimental setups (Margolis et al., 2013). Moreover, the accuracy of bone conduction thresholds outside a soundproof booth is expected to be lower, with unoccluded bone conduction testing being the main reason for soundproof booths. Study II developed a predictive model that could accurately distinguish CHL from bilateral SNHL with high accuracy using a diotic DIN and pure tone air conduction audiometry. Where traditional sound-booth audiometry cannot be conducted, this prediction model could identify people with suspected CHL needing a more comprehensive examination. In fact, the prevalence of CHL in adults is typically very low compared to SNHL (Hoff et al., 2020). Therefore, most patients with hearing loss could benefit from simplified and alternative low-touch models. This approach could also be applicable in resource-constrained settings. For example, low- and middle-income countries (LMICs) have limited access to professionals and equipment to allow sound-booth audiometry but have the most significant incidence of hearing loss (World Health Organization, 2021). Therefore, novel procedures like these described here might be more feasible alternatives to sound-booth audiometry that can be used for mobile health or community-delivered hearing care.

Whilst determining type of hearing loss is important to triage referrals and direct the model of care, early detection is just as critical. The results from Study III showed that HP DIN is more sensitive than the BB DIN to SNHL hearing loss across PTAs (conventional, LF and HF) but was especially sensitive to hearing loss occurring in the higher frequencies (> 2 kHz). Due to the low association with LP DIN SRTs to LF PTA, a combined LP/HP approach is not precise enough to estimate an audiometric configuration. The HP DIN had a closer relationship with EHF PTA (8 to 16 kHz) than the BB DIN. More recent evidence shows that EHFs play an essential role in speech recognition in noise (Monson et al., 2019; Motlagh Zadeh et al., 2019; Polspoel et al., 2021; Motlagh Zadeh et al., 2020). The results of this study contribute to the mounting evidence demonstrating the importance of EHFs in speech recognition in noise. It has implications for clinicians, highlighting a need to assess patients more comprehensively by including EHFs in the standard audiometric test battery. Furthermore, as a clinical tool, HP DIN could further be applied to screen for hearing loss in EHFs, encouraging earlier detection, monitoring and prevention.

Study I to III demonstrated how different DIN stimuli, test paradigms, and procedures could classify hearing loss based on type. However, it does not provide information on the real-world implementation of DIN tests and their use among the public. Study IV provides valuable information on the use and reach of a global, free antiphasic DIN test (*hearWHO*), and makes

a case for further developments. One of the most noteworthy, practical implications highlighted by this study was that test uptake is higher amongst younger adults when applied as a digital screening and health promotion tool. This underlines the strengths and weaknesses of this approach. First, promoting awareness and healthy hearing habits through self-reliance, such as regular screening among the youth, is a huge benefit. Early detection is imperative to circumvent the associated health and personal risk of hearing loss. Furthermore, fostering awareness of hearing loss and its associated risks can facilitate prevention through strategic, targeted information and education provided to at-risk groups (World Health Organization, 2021). However, as shown in this and other studies, older adults are most at risk for having hearing loss (Davis et al., 2016; DeStefano et al., 2003; Jayakody et al., 2018; Yamasoba et al., 2013) and have a significantly higher prevalence rate (Haile et al., 2021). Unfortunately, test reach and uptake were lower for people over 40 years. Therefore, other alternatives should be considered for older populations to increase access to hearing care, for example, community-based initiatives. Nevertheless, screening programs are important and effective, with evidence showing a higher hearing aid uptake rate for a screened population of older adults compared to unscreened populations (Yueh et al., 2010).

8.3. Proposed DIN assessment model to categorise and classify hearing loss

8.3.1. Hearing loss classification using the DIN

Based on this research project's findings and clinical implications, a conceptual model to classify hearing loss based on the DIN is proposed in Figure 8.1. The proposed model is designed and motivated as follows:

The first test (step 1 in conceptual model; Figure 8.1) is an antiphasici DN test, selected based on its high sensitivity and sensitivity of more than 85% to detect different types of hearing loss, including bilateral SNHL, CHL or unilateral SNHL (De Sousa et al., 2020). Since the test uses a binaural test paradigm, the approximate test time is three minutes. This project developed normative cut-off criteria in a large sample of participants using a conventional four frequency PTA (0.5 to 4 kHz). The different cut-offs with their respective sensitivity and specificity are presented in Study I, with findings suggesting that age-corrected cut-off criteria are not required. WHO grades of hearing impairment (Olusanya et al., 2019) for detecting slight hearing loss or worse (PTA ≤ 25 dB HL) or moderate hearing loss or worse (PTA ≤ 40 dB HL) was used to decide the SRT cut-offs. The choice of hearing loss criterion will depend on the acceptable positive and negative predictive rates for the target population.

Normal hearing in the conventional frequency range (0.5 to 4 kHz) is assumed if the antiphasic DIN test is below (better) than the normative cut-off. However, as described above in Study III, recent evidence shows that hearing in EHFs also affects speech recognition in noise.

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Therefore, determining the level of hearing in EHFs could serve to identify the early risk of developing hearing loss in conventional frequencies. A second screening test (step 2 in conceptual model; Figure 8.1), either employing the HP speech filtered DIN test described in Study III, or LP noise filtered DIN test used in earlier studies (Denys et al., 2019; Jansen et al., 2014; Vercammen et al., 2018; Vlaming et al., 2014) is recommended to detect possible hearing loss in the EHF range (8 to 16 kHz). A binaural test paradigm is proposed, which will likely reflect the performance of the better hearing ear (De Sousa et al., 2021; De Sousa et al., 2020); however, it is practical to ensure an overall time-efficient model.

If the second DIN (employing a filtering method to sensitise the test to high frequencies) is lower (better) than the SRT cut-off, normal hearing across the 0.5 to 16 kHz range is assumed. The recommendation is, therefore, to monitor for surveillance. Target information can be communicated via a digital app-based interface (e.g., preventing hearing loss, safe listening etc.). These health promotion initiatives provide the benefit of reaching hard-to-access populations rather than employing resource-intensive methods in formal clinical care. If the second filtered DIN test is higher (poorer) than the SRT cut-off, hearing deterioration in the EHFs is a potential risk. In this case, age criteria can be considered. Hearing deterioration in younger adults under 35 years could be considered a high-risk category. Therefore, greater emphasis could be placed on increasing awareness and regular screening. For e.g., in-app notifications can be sent as a reminder to re-screening annually or bi-annually. More than one billion young adults are at risk of hearing loss due to recreational noise (World Health Organization, 2021). Thus target information for this at-risk age group could include the World Health Organization and International Telecommunication Union (WHO-ITU) standards (World Health Organization, 2019), communicating information to improve listening practices for exposure to music or sound through personal audio devices.

If the first antiphasic DIN SRT (step 1 of the conceptual model, Figure 8.1) is higher (poorer) than the cut-off, hearing loss in conventional frequencies (0.5 to 4 kHz) can be suspected. A second, diotic DIN test (binaural test) is proposed to differentiate (i) unilateral SNHL or CHL from (ii) bilateral SNHL. Unilateral SNHL or CHL is suspected when the second diotic DIN is lower or equal to SRT cut-off, and medical referral is recommended. It may also be possible to differentiate CHL from unilateral SNHL further using risk-based case history questions (e.g. consumer ear disease risk questionnaire; CEDRA) (Klyn et al., 2019) that factor into the recommendation. For example, a history of ear infections or current discharge from ear signals possible CHL due to otitis media and can, therefore, be referred to a physician. Sudden onset hearing loss in one ear accompanied by tinnitus, on the other hand, could warrant more comprehensive audiological referral. Bilateral SNHL is suspected when the second diotic DIN SRT is higher than the SRT cut-off. Direct referral to an audiologist is a possible route.

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However, people with bilateral SNHL could potentially also be served using alternative care models, like low- (minimal physical contact) or no-touch (no physical contact) consumer care, like OTC or DTC hearing aids.

Study I proposed two cut-off methods to categorise hearing loss based on the DIN. It could be more beneficial to use the first fixed method since it had the most accurate classification of unilateral SNHL or CHL, even though more bilateral SNHL was shown to be referred along this path. Still, less than 10% of people with hearing loss were identified as having normal hearing.
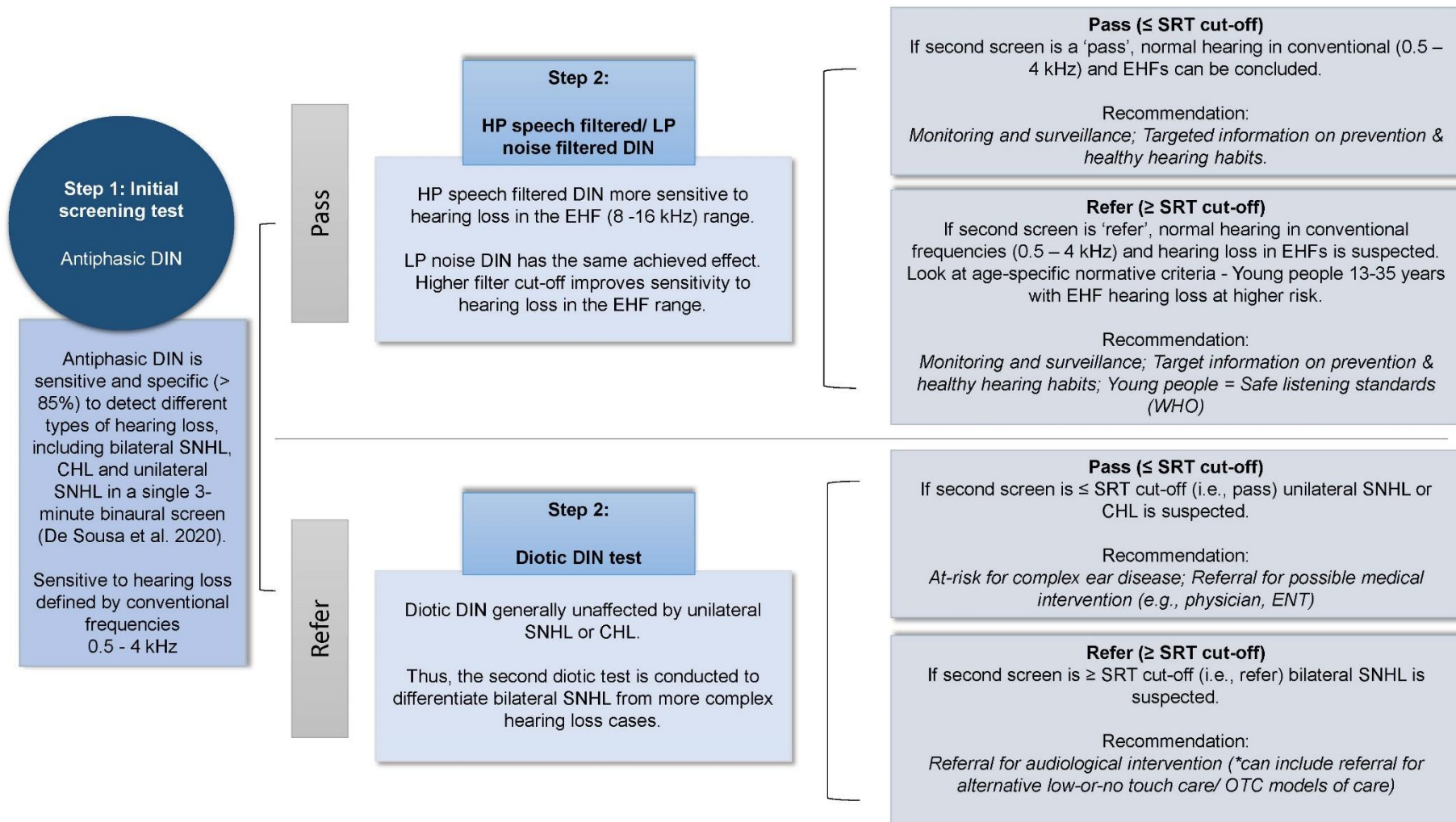
Figure 8.1. *Conceptual online DIN test screening model to classify hearing loss and triage referral.*

8.3.2. DIN test hearing loss classification to support alternative modes of care

For many years, audiological care has been a service that requires several face-to-face appointments to diagnose hearing loss, complete hearing aid fittings and conduct follow-ups for troubleshooting and counselling (Swanepoel & Hall, 2020). Advances in technology have allowed many of these services to be integrated and provided on mobile devices (Bright & Pallawela, 2016). These advances can support several different models of care. However, as highlighted above, patient profiles need to be at the centre of deciding on a potential service delivery model. Based on this project's findings and newly emerging research propositioning alternative care, the DIN test could support different methods to formal clinic-based care. A proposed conceptual model for how hearing loss classification using the DIN test can support alternative service delivery models is presented in Figure 8.2.

The DIN test hearing loss classification method presented in Study I could assist audiological practices to identify prospective patients who can be served using a teleaudiology approach (e.g., bilateral SNHL) versus cases requiring face-to-face, clinic-based diagnostics (e.g., unilateral SNHL, mixed hearing loss or CHL). A combined antiphasic and diotic DIN provided fully online could help identify risk for more complex ear diseases (see step 2 for people who fail an antiphasic DIN test in the conceptual model presented in Figure 8.1). For instance, CHL or unilateral SNHL would require diagnostics, including bone conduction audiometry, which will most accurately be completed using a double-walled soundbooth (International Standards Organization, 2015). On the other hand, prospective patients with likely bilateral SNHL could be served using low- or no-touch methods. Swanepoel and Hall (2020) present examples of how potential models like these could work (Swanepoel & Hall, 2020). In summary, it would entail home-based or counter-side self-testing or facilitated testing with real-time online support from an audiologist. Of course, these hybrid models of care would not solely rely on the type of hearing but also the level of self-efficacy to utilise these technologies for self-testing. One could consider adding a computer proficiency questionnaire (e.g., the Computer Proficiency Questionnaire-12) together with the hearing loss classification method to determine who may be able to benefit from a low- or no-touch model.

Due to the pending OTC regulations, the DIN hearing loss classification methods proposed here could also assist in more accountable provision of hearing care. Allowing the sale of OTC hearing aids will allow people with self-perceived hearing loss to procure hearing aids without assessment or counselling from a hearing care professional (Willink et al., 2021). As a self-administered test, the combination of the antiphasic and diotic DIN could be provided to prospective consumers to self-assess risk for more complex ear diseases. Retail clinics could, for instance, provide free-standing mobile devices which people with suspected hearing loss could use to self-assess their hearing. Since these devices can be calibrated to the

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audiometric headphone, the method described in Study II could be used to predict the risk of CHL (unilateral or bilateral) using a combination of pure tone air conduction audiometric frequencies and a diotic DIN.

A more regulated assessment with professional involvement would be recommended in either of these approaches in the conceptual model, where risk of complex ear disease or hearing loss is detected.

DIN applied in practice for low-or no-touch audiology

Combined Antiphasic & Diotic DIN screen

Prospective patients can complete an online combined antiphasic and diotic DIN to classify hearing loss as either (i) unilateral SNHL/ CHL or (ii) bilateral SNHL

Complex HL (unilateral SNHL or CHL)

Clinic-based diagnostics and intervention
In person, clinic-based appointment
Full audiometric test battery (otoscopy, acoustic immittance, pure-tone air- and bone-conduction audiometry, speech audiometry to ascertain type and degree of hearing loss)

Bilateral SNHL

Low- or no-touch audiological services
Models suggested by Swanepoel & Hall (2020)
Home-based and counter-side services with self-testing and facilitated assessment on digital devices (can be shipped to and picked up from patients) - Step-by-step guidance/ real-time audiological support
Pure-tone air conduction and diotic DIN risk algorithm to re-confirm absence of CHL

DIN applied in DTC or OTC models

Combined antiphasic/ diotic DIN OR CHL risk algorithm

Prospective patients can complete an online combined antiphasic and diotic DIN to classify hearing loss as either (i) unilateral SNHL/ CHL or (ii) bilateral SNHL

Freestanding devices in stores can measure pure tones and diotic DIN on calibrated devices = CHL risk algorithm

Complex HL (unilateral SNHL or CHL)

Recommendation for standard in-person diagnostics and intervention
In person, clinic-based appointment (physician or audiologist)
Full audiometric test battery (otoscopy, acoustic immittance, pure-tone air- and bone-conduction audiometry, speech audiometry to ascertain type and degree of hearing loss)
Following medical clearance, proceed with OTC or DTC intervention options.

Bilateral SNHL

OTC or DTC intervention options (counter-based fittings)
OTC or DTC hearing aid provision- Pure-tone results from CHL risk algorithm can be used to fit hearing aids (DTC or OTC).
If people want to order pre-set hearing aids online, the combined antiphasic/diotic approach could assist in more accountable provision of hearing care

Figure 8.2. *DIN hearing loss classification to support alternative models of care.*

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8.4. Study strengths and limitations

A critical evaluation of this research project was conducted to evaluate its strengths and limitations.

Study strengths

Except for our work on developing the antiphasic DIN (De Sousa et al., 2020), previous DIN research has primarily been devoted to increasing sensitivity to different forms of SNHL (Van den Borre et al., 2021). This study was the first of its kind to not only detect but classify hearing loss based on DIN test results. The models proposed in this study demonstrate the potential of a comprehensive assessment method to screen for hearing loss and streamline referral of hearing loss cases. Furthermore, the findings of this study demonstrate how these classification methods can be applied to support low- or no touch service delivery. This is a timely, contextual response to the COVID-19 pandemic, which dramatically altered audiological care globally (Saunders & Roughley, 2021).

Various methodological strengths can be highlighted. Firstly, Study I to III include large samples and a wide range of hearing loss types and degrees. Previous DIN research has mainly restricted samples to include SNHL. However, due to the representativeness of the range and degrees of hearing loss included in the studies, the findings can be generalised to a larger population. Furthermore, purposive sampling, and the quantitative, experimental and correlational research design allowed for precise data analyses to understand the complex relationships between the type of hearing loss and DIN SRT. In Study III, presentation between ears and LP and HP DIN was counterbalanced, allowing the researcher to isolate the main effects of the filtering strategy associations with PTA due to control of order sequence effects.

Study IV used an implementation research approach to understand work within real-world environments (Peters et al., 2013). Therefore, the study design has high ecological validity. The type of design (retrospective, descriptive design) and selection (randomised) enabled the ability to determine reach, performance and indications for the DIN test used as a global digital hearing screening and health promotion tool. Furthermore, the implementation research approach is important for global and public health since it allows the researchers to determine the gaps in the test as implemented in a real-world setting (Theobald et al., 2018).

Limitations

Although Study I was the first successful attempt to discriminate bilateral SNHL from CHL or unilateral SNHL, it should be kept in mind that the CHL and unilateral SNHL samples were small relative to the normal hearing and bilateral SNHL samples. Ideally, the validity of the DIN diotic-antiphasic classification method should have been evaluated in a larger cohort of

listeners with CHL and unilateral SNHL. However, bilateral SNHL is generally more common in adults than other types of hearing loss (Dubno et al., 2013; Hoff et al., 2020). Furthermore, Study II, developing a CHL hearing loss risk algorithm, showed very high sensitivity and specificity (>90%) to discriminate CHL from bilateral SNHL. However, the study did not assess the accuracy of the procedure for people with mixed hearing loss, who could also be considered risk cases in need of medical or more comprehensive evaluation. This should be done in a future study.

Study III, developing and evaluating a LP and HP DIN included a large sample (125 participant; 249 ears). Due to an error in software script discovered after the study, equalisation could not be achieved. Therefore, the material used in the validation phase of the study was heterogeneous. However, the level correction average was 0 dB. Therefore, it was not expected that the material used in Phase II would be different when using equalized digits as the shallow slopes of the LP and HP filtered digit recognition functions (~7-8 %/dB), and the heterogeneity of the recognition functions were likely to only have a small effect on the measurement error (see Figure 6 in Smits and Houtgast, 2006) (Smits et al. 2006).The equalization could have influenced measurement error. Furthermore, test-retest reliability was only assessed in a small sub-group of normal-hearing participants that is not representative of the entire sample. Based on the findings of previous DIN studies (Vlaming et al., 2014). It is expected that the variability would be slightly larger for participants with hearing loss.

8.5. Recommendations for future work

The findings from Study I demonstrated high accuracy to classify hearing loss based on type, which can be fully conducted on digital devices, like smartphones. As the DIN is a suprathreshold measure of SNR, absolute calibration of headphones is not required as demonstrated in Potgieter et al. (2016). . The normative data provided for this study was specifically developed for adults (≥ 18 years). However, data from Study IV, which had more than 17 000 tests conducted for people under 18 years, support the potential need and use of the DIN to screen children. CHL prevalence due to otitis media is generally higher in younger children, meaning that childhood screening programs have a lot to gain from this classification approach. Koopmans et al. (2018) already demonstrated that the DIN could be used reliably in children as young up to four years, with the help of a test facilitator (Koopmans et al., 2018). As a result, the DIN test has successfully been used to screen school-aged children (Denys et al., 2018). Wolmarans et al. (2021) collected normative data on the antiphasic and diotic DIN test, which demonstrated a maturational effect of the DIN SRTs until approximately ten years (Wolmarans et al., 2021). Future studies should validate the proposed classification method for younger children, considering the age-contingent normative criteria. The same

need for validation in children can be said for Study II's predictive hearing loss algorithm. School-screening programs, especially in resource-constrained settings, could benefit from simple approaches that can discriminate CHL from bilateral SNHL with as little equipment as possible. Therefore, a future implementation project should determine the feasibility and accuracy of the algorithm in the field.

Both Study I and II did not include mixed hearing loss as part of the classification method. It is unclear what the interaction between this hearing loss type and diotic and antiphasic SRT would be. The hypothesis is that mixed hearing loss with larger ABGs are likely to mimic CHL results, whereas more severe mixed hearing loss with more affected bone conduction thresholds would replicate SNHL. A future study should validate the hearing loss classification approaches in mixed hearing loss samples. Furthermore, CHL could be simulated to represent different types and degrees of hearing loss to determine the effect of laterality (unilateral, asymmetric versus bilateral) and interaural attenuation on the proposed methods in Study I and II.

The findings in Study III show greater sensitivity to SNHL using a HP DIN compared to a BB DIN. Furthermore, this study suggests greater sensitivity to hearing loss in the EHF range. Monaural, diotic and antiphasic BB DIN tests have already been implemented as digital hearing screening tests among the public (Swanepoel et al., 2019). The effect of headphone type was explored and showed to have a slight, non-significant difference when using high-quality audiometric headphones versus lower quality commercially available earbuds or headphones (Potgieter et al., 2016). However, the HP speech filtering strategy proposed here, emphasising higher frequencies, is likely to be affected by the frequency response of the headphones used. Study III used high-quality audiometric headphones (Sennheiser HDA 280), but a future study should determine HP DIN performance across a range of headphone types, including commercially available options that would be used as an applied screening among the public.

Study IV evaluated the performance and uptake of the *hearWHO* test provided in English, Spanish and Mandarin. While the DIN test is not a linguistically or cognitively demanding task, test uptake as a public hearing screening and health promotion tool, is highly likely to be affected by the language offered. Releasing the test in other languages more widely spoken in the Eastern Mediterranean and African regions could improve the uptake and test accuracy, as the performance of the DIN test in a non-native language is known to be slightly lower than for native speakers. This would involve a development, equalization and validation process for each language.

This chapter conceptualised a model (Figure 8.1) to screen and triage hearing loss. Two sequential DIN tests were proposed (antiphasic and LP/HP filtered DIN or antiphasic and diotic DIN). Test time is expected to be approximately 6 minutes for the entire test procedure. While 6 minutes is arguably not long, shorter test times are crucial to increase reliability and reduce test dropout as in a self-test consumer model. Future work should focus on optimising the test procedure to ensure the entire proposed model can be completed in less time.

8.6. Conclusion

This research project was the first to use the DIN test to classify types of hearing loss. The methods described here demonstrated high sensitivity and specificity to detect hearing loss, increasing the test's utility as a hearing screening tool. A combined antiphasic and diotic DIN approach could classify hearing loss according to type with high accuracy. Furthermore, a method using both pure tone audiometry and diotic DIN could identify the risk of CHL. Optimised care pathways could be assisted by signalling cases requiring a medical referral from cases that can be managed audiologically or using non-traditional models like OTC hearing aids. Furthermore, filtering the speech to represent hearing in the separate LF and HF bandwidths showed a higher association of the HP DIN to higher frequencies. However, the LP DIN had a low association with LF hearing loss. The HP DIN sensitised the DIN test for SNHL occurring above the 2 kHz range, and had higher associations with EHFs (8 to 16 kHz), demonstrating its potential to be used as a screening tool to identify the early risk of hearing loss. The classification system proposed here could further support alternative service delivery models with accountability, as complex hearing loss cases needing comprehensive services can be identified and classified with high accuracy.

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APPENDICES

Appendix A: Sustainability Publication Confirmation

From:	Yonina Wang/MDPI
To:	sustainability@mdpi.com; karina.swanepoel@up.ac.za; david.moore2@cchmc.org; c.smits@amsterdamumc.nl; dewet.swanepoel@up.ac.za
Cc:	billing@mdpi.com; website@mdpi.com
Subject:	Re: [Sustainability] Manuscript ID: sustainability-1327784; online version check, paper will be released on 24 September
Date:	Friday, 10 September 2021 03:58:11
Attachments:	Paper Promotion Tips.pdf

Dear Authors,

We are pleased to inform you that your article (sustainability-1327784) has been published in Sustainability and is available online. This issue will be released on **24 September 2021** (DATE, Beijing time). Articles cannot be changed once released, so please could you carefully check yours again and let me know within **48 h** if you have any questions.

Abstract: https://www.mdpi.com/2071-1050/13/18/10124
HTML Version: https://www.mdpi.com/2071-1050/13/18/10124/htm
PDF Version: https://www.mdpi.com/2071-1050/13/18/10124/pdf

Please carefully verify that the following information is correct:
1. Surname and first name spelling for every author;
2. Affiliations(Department, Postcode);
3. Funding number;
4. Formula;
5. All the references (References Title, Authors name abbreviation and newly added information);
6. The citation of your paper announced online.

Please note that the authorship and contents of the paper are not allowed to be changed at this stage.

We also encourage you to promote your paper and make it more visible to the research community, the promotion tips have been attached herewith.

Best regards,
Yonina Wang
Assistant Editor

News:

Sustainability receives its 8th Impact Factor, 3.251 (2020)

To edit a Special Issue in Sustainability, please send your proposal via
https://www.mdpi.com/journalproposal/sendproposalspecialissue/sustainability

Sustainability joins Twitter now, follow us at @Sus_MDPI and be part of our scientific community
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The 9th World Sustainability Forum will be held from 13-15 September 2021. Registration is FREE and open until 12 September! Looking forward to you joining us!

Conference Webpage: https://wsf-9.sciforum.net/

Special Issue in Sustainability:

Appendix B Ethical clearance

11 February 2020

Dear Mrs KC De Sousa

Project Title:	A smartphone digits-in-noise test: Improving access, efficiency and audiogram prediction
Researcher:	Mrs KC De Sousa
Supervisor:	Prof DCDW Swanepoel
Department:	Speech Language Path and Aud
Reference number:	12006280 (HUM003/0120)
Degree:	Doctoral

I have pleasure in informing you that the above application was **approved** by the Research Ethics Committee on 30 January 2020. Data collection may therefore commence.

Please note that this approval is based on the assumption that the research will be carried out along the lines laid out in the proposal. Should the actual research depart significantly from the proposed research, it will be necessary to apply for a new research approval and ethical clearance.

We wish you success with the project.

Sincerely

Prof Maxi Schoeman
Deputy Dean: Postgraduate and Research Ethics
Faculty of Humanities
UNIVERSITY OF PRETORIA
e-mail: PGHumanities@up.ac.za

Fakulteit Geesteswetenskappe
Lefapha la Bomotho

Research Ethics Committee Members: **Prof MME Schoeman (Deputy Dean)**; Prof KL Harris; Mr A Bizos; Dr L Blokland; Dr K Booyens; Dr A-M de Beer; Ms A dos Santos; Dr R Fasselt; Ms KT Govinder Andrew; Dr E Johnson; Dr W Kelleher; Mr A Mohamed; Dr C Puttergill; Dr D Reyburn; Dr M Soer; Prof E Taliard; Prof V Thebe; Ms B Tsebe; Ms D Mokalapa

Faculty of Humanities

Fakulteit Geesteswetenskappe
Lefapha la Bomotho

29 June 2021

Dear Prof DCDW Swanepoel

Project Title:	Online hearing assessment using the hearWHO app
Researcher:	Prof DCDW Swanepoel
Supervisor(s):	
Department:	Speech Language Path and Aud
Reference number:	02606623 (HUM025/0621)
Degree:	Staff Research / Non Degree

Thank you for the application that was submitted for ethical consideration.

The Research Ethics Committee notes that this is a literature-based study and no human subjects are involved.

The application has been **approved** on 27 May 2021 with the assumption that the document(s) are in the public domain. Data collection may therefore commence, along these guidelines.

Please note that this approval is based on the assumption that the research will be carried out along the lines laid out in the proposal. However, should the actual research depart significantly from the proposed research, a new research proposal and application for ethical clearance will have to be submitted for approval.

We wish you success with the project.

Sincerely,

Prof Karen Harris
Acting Chair: Research Ethics Committee
Faculty of Humanities
UNIVERSITY OF PRETORIA
e-mail: PGHumanities@up.ac.za

Fakulteit Geesteswetenskappe
Lefapha la Bomotho

Research Ethics Committee Members: Prof I Pikirayi (Deputy Dean); Prof KL Harris; Mr A Bizos; Dr A-M de Beer; Dr A dos Santos; Ms KT Govinder Andrew; Dr P Guture; Dr E Johnson; Prof D Marae; Mr A Mohamed; Dr I Noomé; Dr C Puttergill; Prof D Reyburn; Prof M Soer; Prof E Taljard; Prof V Thebe; Ms B Tsebe; Ms D Mokalapa

Appendix C: Permission from the Ear Institute

UNIVERSITEIT VAN PRETORIA
UNIVERSITY OF PRETORIA
YUNIBESITHI YA PRETORIA

Faculty of Humanities
Department of Speech-Language Pathology and Audiology

2 July 2019

Att: Anita van der Merwe
The Ear Institute

Dear Ms van der Merwe

RE: PRACTICE PARTICIPATION IN A RESEARCH STUDY

We are two audiologists from the Department of Speech-Language Pathology and Audiology at the University of Pretoria. We are currently undertaking a series of research studies under the supervision of Prof. De Wet Swanepoel, Dr. David Moore (USA) and Dr. Cas Smits (Netherlands), to increase the effectiveness of smartphone technologies in hearing loss detection, support and intervention. We would like to request your assistance in the first of these research studies.

Title: The dichotic DIN hearing test by smartphones: Determining normative scores
Researchers: Karina de Sousa and Renate le Roux
Study Leaders: Prof. De Wet Swanepoel, Dr. David Moore (USA) and Dr. Cas Smits (Netherlands)
Design and Procedures: This study will employ a quantitative cross-sectional research design. During the study, 600 adults aged 18 years and older will have their hearing tested using a smartphone-based dichotic digits-in-noise (DIN) hearing test, in addition to conventional audiometric testing. This data will be used to establish normative values for this test. Furthermore, the effect of age and English language competence on hearing test results will be analysed. Participants will be stratified according to their age and self-reported English language competence.
Ethical Considerations: All identifiable patient information will be handled with strict

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Room 3-4, Level 3, Building Communication Pathology

University of Pretoria, Private Bag X20

Hatfield 0028, South Africa

Fakulteit Geesteswetenskappe
Departement Spraak-Taalpatologie en Oudiologie
Lefapha la Bomotho
Kgoro ya Phatholotši ya Polelo-Maleme le Go kwa

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Faculty of Humanities
Department of Speech-Language Pathology and Audiology

confidentiality. Informed consent will be obtained from each participant prior to conducting the test.

Risks: There are no risks associated with this study and anonymity will be guaranteed at all times. In order to conduct this study, collaboration from audiologists working in private practice is desired. During the study, should permission be granted by the audiologist in that particular private practice, each audiologist will be equipped with a smartphone with the DIN hearing test application, data collection sheets and informed consent letters. The audiologists would then conduct a short DIN hearing test on the patients that come into their practice, in addition to the conventional pure-tone audiometric tests. We, as researchers, will be available for on- and off-site support and will collect the data collection sheets and informed consent letters at regular intervals.

If you would like to collaborate with us, kindly complete the practice consent form below and return it to us. If you would like further information on the research study, please contact us on:

Karina de Sousa *Researcher*	082 556 5431
Renate le Roux *Researcher*	074 996 9692
Prof. De Wet Swanepoel *Study Leader*	(012) 420 4280

We look forward to collaborating with you!
Yours Sincerely,

Prof. De Wet Swanepoel
Study Leader

Karina Swanepoel
Audiologist/Researcher

Room 3-4, Level 3, Building Communication Pathology

University of Pretoria, Private Bag X20

Hatfield 0028, South Africa

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Departement Spraak-Taalpatologie en Oudiologie
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CONSENT TO PARTICIPATE IN RESEARCH STUDY

I, ___Anita. V.d. Merwe___ , ~~audiologist~~ / owner of the following audiology practice, ___A v. d. Merwe Inc.___ , practice number ___5002508___ , hereby consent to participate in the study entitled *The dichotic DIN hearing test by smartphones: Determining normative scores.* I understand that I will be equipped with the necessary hard- and software to conduct the data collection for the study myself, and will assume responsibility for this equipment.

Signature: _____   Date: ___23 . 1 . 2018___ .

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Appendix D: Permission from Jeani-Marie Potgieter Practice

Faculty of Humanities
Department of Speech-Language Pathology and Audiology

29 Jan 2019

Att: Ms. Jenni-Mari Potgieter
Jenni-Mari Potgieter Audiologist & Speech Therapist

Dear Ms. Potgieter,

RE: PRACTICE PARTICIPATION IN A RESEARCH STUDY

We are two audiologists from the Department of Speech-Language Pathology and Audiology at the University of Pretoria. We are currently undertaking a series of research studies under the supervision of Prof. De Wet Swanepoel, Dr. David Moore (USA) and Dr. Cas Smits (Netherlands), to increase the effectiveness of smartphone technologies in hearing loss detection, support and intervention. We would like to request your assistance in the first of these research studies.

Title: The dichotic DIN hearing test by smartphones: Determining normative scores
Researchers: Karina de Sousa and Renate le Roux
Study Leaders: Prof. De Wet Swanepoel, Dr. David Moore (USA) and Dr. Cas Smits (Netherlands)
Design and Procedures: This study will employ a quantitative cross-sectional research design. During the study, 600 adults aged 18 years and older will have their hearing tested using a smartphone-based dichotic digits-in-noise (DIN) hearing test, in addition to conventional audiometric testing. This data will be used to establish normative values for this test. Furthermore, the effect of age and English language competence on hearing test results will be analysed. Participants will be stratified according to their age and self-reported English language competence.
Ethical Considerations: All identifiable patient information will be handled with strict confidentiality. Informed consent will be obtained from each participant prior to conducting the test.
Risks: There are no risks associated with this study and anonymity will be guaranteed at all times. In order to conduct this study, collaboration from audiologists working in private practice is desired. During the study, should permission be granted by the audiologist in that particular

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private practice, each audiologist will be equipped with a smartphone with the DIN hearing test application, data collection sheets and informed consent letters. The audiologists would then conduct a short DIN hearing test on the patients that come into their practice, in addition to the conventional pure-tone audiometric tests. We, as researchers, will be available for on- and off-site support and will collect the data collection sheets and informed consent letters at regular intervals.

If you would like to collaborate with us, kindly complete the practice consent form below and return it to us. If you would like further information on the research study, please contact us on:

Karina de Sousa	082 556 5431
Researcher	karina.swanepoel@up.ac.za
Renate le Roux	074 996 9692
Researcher	renate.leroux@up.ac.za
Prof. De Wet Swanepoel	(012) 420 4280
Study Leader	dewet.swanepoel@up.ac.za

We look forward to collaborating with you!
Yours Sincerely,

Prof. De Wet Swanepoel
Study Leader

Karina Swanepoel
Audiologist/Researcher

Renate le Roux
Audiologist/Researcher

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CONSENT TO PARTICIPATE IN RESEARCH STUDY

I, _Jenni-Marí Potgieter_ , audiologist / owner of the following audiology practice, _Jenni-Marí Potgieter Audiologist & Speech Therapist_ practice number _0525405_ , hereby consent to participate in the study entitled *The dichotic DIN hearing test by smartphones: Determining normative scores*. I understand that I will be equipped with the necessary hard- and software to conduct the data collection for the study myself, and will assume responsibility for this equipment.

Signature: _JMPotgieter_ Date: _3 April 2019_

Appendix E: Permission from hearX Group

Faculty of Humanities
Department of Speech-Language Pathology and Audiology

WHO Collaborating Centre for Prevention of Deafness and Hearing Loss

10 June 2021

TO: Mr Nic Klopper, CEO (HearX Group)
RE: Permission to Use Anonymized Dataset for the hearWHO Application for Research

Dear Mr Nic Klopper,

In partnership with the World Health Organization we are planning to conduct a research project describing the results of the World Health Organization's hearing screening application (hearWHO) developed and hosted by hearX. Herewith we are requesting permission to use an anonymized data set on the global hearWHO application usage statistics.

The project is entitled, *Online detection of hearing loss using the hearWHO app.* As you may know, the our department at the University of Pretoria is a collaborating centre for the World Health Organization on the prevention of deafness and hearing loss. The proposed research project aims to determine the uptake and performance per country and as well as characteristics of test users (in terms of age, gender and home language). Furthermore we will explore error patterns in presented digit-triplets at different signal-to-noise ratio's in conjunction with user response times and describe potential relationships with test results.

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Kgoro ya Phatholotši ya Polelo-Maleme le Go kwa

We appreciate the ongoing partnership. Should you require any additional information, do not hesitate to contact me at 012 420 4280.

Sincerely,

Professor De Wet Swanepoel
Researcher

PERMISSION TO ACCESS DATA OF THE HEARWHO APPLICATION
FOR A RESEARCH PROJECT

Herewith, I, **Nic Klopper,** give permission on behalf of the hearX Group to Prof De Wet Swanepoel from the University of Pretoria to use the anonymied hearWHO test data for his project entitled: *"Online detection of hearing loss using the hearWHO app".* We will provide you with an anonymous datasheet with test results dating back from March 2019 to June 2021.

Nic Klopper
Chief Executive Officer: hearX Group

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Appendix F: Study I and II Informed consent

5 September 2019

INVITATION TO PARTICIPATE IN A RESEARCH STUDY

I, Karina De Sousa, am conducting my doctoral degree in Audiology at the University of Pretoria. In completion of my degree, I am required to conduct several research studies. I would kindly like to invite you to participate in a research study conducted under the supervision of Professor De Wet Swanepoel. The purpose of the study is to determine normative scores for a digits-in-noise (DIN) hearing test, which is a hearing test that measures a person's ability to accurate hear speech-in-noise using simple digits presented in background noise. This letter will help you decide if you want to participate in this study research study.

The purpose of the study
Approximately 360 million people worldwide suffer from disabling hearing loss, with the majority residing in low- and middle-income countries. However, only a small portion of people are detected and receive treatment. A new method of testing using a digits-in-noise test was introduced in 2016, to improve access to hearing care. Although very accurate to detect certain types of sensorineural hearing loss, the previous test was not sensitive enough to detect hearing loss occurring only in one ear (unilateral hearing loss) or hearing loss due to pathology in the middle ear (conductive hearing loss). Recently, a new stimulus highly improved the sensitivity of the test to all types of hearing loss, however, new normative data is required to fully implement the new test version.

What will I need to do if I agree to participate?

All tests will be non-invasive, without charge and results will be made available to you. Should you agree to participate in this study the following procedures will be followed:

- Otoscopy
  For this test, you will be required to be seated upright while I visually inspect your ear canal by using an otoscope (ear-light).

- Middle ear test
  For this test, you will be required to be seated upright while a soft plastic probe is inserted into your ear canal in order to test the middle ear pressure and movement.

- Hearing test
  For this test, you will wear earphones on your ears. You will be asked to respond to a soft sound (at different pitches) by pressing a button. This will be done in order to measure your hearing

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Email dewet.swanepoel@up.ac.za
www.up.ac.za

Faculty of Humanities
Fakulteit Geesteswetenskappe
Lefapha la Bomotho

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sensitivity. Thereafter, you will be expected to wear headphones and repeat a list of words that you heard.

- Digits in Noise test
  For this test, you will be expected to listen to a list of digits e.g. 2-5-1 in the presence of noise and enter the numbers that you heard on a keypad.

All the above-mentioned testing should not exceed more than 60 minutes.

Are there any risks or benefits for me if I participate in this study?
Participants will not be exposed to any risk or experience any discomfort during this test. There are no direct benefits of participating in this study and no reimbursements will be given to participants. However, information obtained from this study will assist in increasing the effectiveness of smartphone technologies in hearing loss detection, support and intervention.
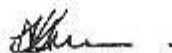
What are your rights as a participant?
Your participation in this study is entirely voluntary. You may decline to participate or stop at any time during the examination. This will have no effect on any current services or treatment you are receiving at the Audiology practice or the Department of Speech-Language Pathology and Audiology at the University of Pretoria.

Confidentiality
All your information will be kept confidential. Once the data sheet has been completed by me, a number will be allocated to your data sheet. Your name will not appear on any document. Research articles in scientific journals will not include any information that could identify you. All of the data collection sheets from this study will be stored for a period of 15 years in both hard copies and scanned electronic versions that will be stored on a CD and/or USB stick at the Department of Speech-Language Pathology and Audiology for future research by other researchers. However, before any further research will be done on the data, a proposal will be submitted to the Research Ethics Committee of the Faculty of Humanities, University of Pretoria.

Before you agree to take part, you should fully understand what is involved. If you have any questions that this letter does not fully explain, please do not hesitate to ask me either in person or by telephone on 082 556 5431. Alternatively, you can contact my supervisor, Prof De Wet Swanepoel at dewet.swanepoel@up.ac.za.

Kind Regards,

Karina De Sousa
Audiologist & Ph.D. Student

De Wet Swanepoel
Professor of Audiology

CONSENT TO PARTICIPATION IN A RESEARCH STUDY

I, _____, hereby consent to participate in the research study entitled *The antiphasic digits-in-noise hearing test by smartphone: Determining normative scores*. I have read the and understood the consent letter and have been given the opportunity to ask questions, and I am satisfied that they have been answered satisfactorily. I understand that I will not be reimbursed for participating in this research study. I am aware that I may withdraw from the research study at any point, should I wish to do so. I understand that every effort will be made to ensure that I am not harmed in this research study. I consent that my results may be used anonymously in research publications from this study.

Signature: _____
Date: _____

AFFIRMATION OF INFORMED CONSENT BY AN ILLITERATE PARTICIPANT
(if suitable)

I, the undersigned, …………………………………………., have read and have explained fully to the participant, named …………………………… , the informed consent document, which describes the nature and purpose of the study in which I have asked the him/her to participate. The explanation I have given has mentioned both the possible risks and benefits of the study. The participant indicated that he/she understands that he/she will be free to withdraw from the study at any time for any reason and without jeopardizing the his/her standard care.
I hereby certify that the patient has agreed to participate in this study.

_____   _____
Participant's name (Please print)   Date

_____   _____
Participant's signature   Date

_____   _____
Investigator's Name (Please print)   Date

_____   _____
Investigator's Signature   Date

_____   _____
Name of the person who witnessed
the informed consent (Please print)   Date

_____   _____
Signature of the Witness   Date

Appendix G: Data collection sheet Study I and II

Data Collection Sheet

Participant Demographics

Gender: _____

Race: _____

D.O.B: _____

English Competence: How well do you <u>understand</u> spoken English?

Excellent	
Good	
Poor	
Not at all	

hearDigits DIN:

Binaural Out-of-Phase SNR	
Binaural In-Phase SNR	

Pure-Tone Audiometry:

Left: AC						Right: AC					
0.25 kHz	0.5 kHz	1 kHz	2 kHz	4 kHz	8 kHz	0.25 kHz	0.5 kHz	1 kHz	2 kHz	4 kHz	8 kHz

Left: BC						Right: BC					
0.25 kHz	0.5 kHz	1 kHz	2 kHz	4 kHz	8 kHz	0.25 kHz	0.5 kHz	1 kHz	2 kHz	4 kHz	8 kHz

If not completed, audiogram attached? **Yes / No**

Appendix H: Study III Informed consent

5 September 2019

INVITATION TO PARTICIPATE IN A RESEARCH STUDY

I, Karina De Sousa, am conducting my doctoral degree in Audiology at the University of Pretoria. In completion of my degree, I am required to conduct several research studies. I would kindly like to invite you to participate in a research study conducted under the supervision of Professor De Wet Swanepoel. The purpose of the study is to improve the efficiency of a smartphone-based digits-in-noise (DIN) hearing test, which is a hearing test that measures a person's ability to accurate hear speech-in-noise using simple digits presented in background noise. This letter will help you decide if you want to participate in this study research study.

The purpose of the study
Approximately 360 million people worldwide suffer from disabling hearing loss, with the majority residing in low- and middle-income countries. However, only a small portion of people are detected and receive treatment. A new method of testing using a digits-in-noise test was introduced in 2016, to improve access to hearing care. The test is downloaded as a free smartphone app, on Android or iOS operated smartphones. Using sensitive antiphasic stimuli, the test assesses both ears at the same time and is very accurate to determine various types and severity of hearing loss (occurring in either one or both ears). Currently the test can be completed within three minutes. However, some people may still decide to terminate the test due to long test duration. Also, when testing children test duration should be kept as short as possible to prevent inaccurate results due to loss of attention. The purpose of this study is, therefore, to compare various digits-in-noise test procedures to the shorten test duration, while keeping the test as accurate as possible.

What will I need to do if I agree to participate?

All tests will be non-invasive, without charge and results will be made available to you. Should you agree to participate in this study the following procedures will be followed:

- Otoscopy
  For this test, you will be required to be seated upright while I visually inspect your ear canal by using an otoscope (ear-light).

- Middle ear test
  For this test, you will be required to be seated upright while a soft plastic probe is inserted into your ear canal in order to test the middle ear pressure and movement.

- Hearing test
  For this test, you will wear earphones on your ears. You will be asked to respond to a soft sound (at different pitches) by pressing a button. This will be done in order to measure your hearing sensitivity. Thereafter, you will be expected to wear headphones and repeat a list of words that you heard.
- Digits in Noise test
  For this test, you will be asked to complete five short digits-in-noise tests. You will be asked to listen to a list of digits e.g. 2-5-1 in the presence of noise and enter the numbers that you heard on a keypad.

All the above-mentioned testing should not exceed more than 60 minutes.

Are there any risks or benefits for me if I participate in this study?

Participants will not be exposed to any risk or experience any discomfort during this test. There are no direct benefits of participating in this study and no reimbursements will be given to participants. However, information obtained from this study will assist in increasing the effectiveness of smartphone technologies in hearing loss detection, support and intervention.
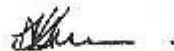
What are your rights as a participant?

Your participation in this study is entirely voluntary. You may decline to participate or stop at any time during the examination. This will have no effect on any current services or treatment you are receiving at the Audiology practice or the Department of Speech-Language Pathology and Audiology at the University of Pretoria.

Confidentiality

All your information will be kept confidential. Once the data sheet has been completed by me, a number will be allocated to your data sheet. Your name will not appear on any document. Research articles in scientific journals will not include any information that could identify you. All of the data collection sheets from this study will be stored for a period of 15 years in both hard copies and scanned electronic versions that will be stored on a CD and/or USB stick at the Department of Speech-Language Pathology and Audiology for future research by other researchers. However, before any further research will be done on the data, a proposal will be submitted to the Research Ethics Committee of the Faculty of Humanities, University of Pretoria.

Before you agree to take part, you should fully understand what is involved. If you have any questions that this letter does not fully explain, please do not hesitate to ask me either in person or by telephone on 082 556 5431. Alternatively, you can contact my supervisor, Prof De Wet Swanepoel at dewet.swanepoel@up.ac.za.

Kind Regards,

Karina De Sousa
Audiologist & Ph.D. Student

De Wet Swanepoel
Professor of Audiology

CONSENT TO PARTICIPATION IN A RESEARCH STUDY

I, _____, hereby consent to participate in the research study entitled *Improving efficiency of the antiphasic digits-in-noise test*. I have read the and understood the consent letter and have been given the opportunity to ask questions, and I am satisfied that they have been answered satisfactorily. I understand that I will not be reimbursed for participating in this research study. I am aware that I may withdraw from the research study at any point, should I wish to do so. I understand that every effort will be made to ensure that I am not harmed in this research study. I consent that my results may be used anonymously in research publications from this study.

Signature: _____
Date: _____

Appendix I: Permission from *Ons Tuis* retirement facility

25 November 2019

Att: Caretha Bronkhorst
Ons Tuis Retirement Village

Dear Elize van der Westhuizen,

<u>**RE: INVITATION TO PARTICIPATE IN A RESEARCH STUDY**</u>

I, Karina De Sousa, am a doctoral student in audiology at the Department of Speech-Language Pathology and Audiology, University of Pretoria. In completion of my degree, I am undertaking a research study under the supervision of Prof. De Wet Swanepoel, Dr Herman Myburgh and Dr. Cas Smits (Netherlands), to determine if a conventional audiogram can be predicted from a simple digits-in-noise test. We would like to request your permission to recruit participants from *Ons Tuis*. The project details are as follows:

Title: Audiogram prediction from a digits-in-noise test.
Background and purpose: Hearing loss is among the most prevalent health conditions globally with nearly half a billion people estimated to have a hearing loss of a disabling degree. There is an abundance of evidence that links hearing loss to depression, risk for hospitalization and cognitive decline and dementia. Early detection and intervention are essential to reduce the consequences of hearing loss, yet many cases are undetected. Typical assessment of hearing involves pure tone audiometry, which requires expensive calibrated equipment to measure a persons' ability to hear soft tones and different frequencies. In order to improve access to hearing healthcare, a digits-in-noise test was developed that can be conducted over an inexpensive smartphone. The test measures one's ability to accurately hear speech-in-noise and is currently being used to screen for hearing loss. The purpose of this study, however, is to see when different types of noise are used, if the digits-in-noise test can be used to predict conventional tone-based audiograms.
Design and procedures: This study will employ a quantitative cross-sectional research design. During the study 250 adults will be asked to participate. Those who consented, will be asked to complete a diagnostic pure tone hearing assessment, where after they will be asked to complete four digits-in-noise tests over a smartphone. The data will be used to determine the accuracy of a digits-in-noise test to predict a conventional audiogram.
Ethical considerations: All identifiable participant information will be handled with strict confidentiality. Informed consent will be obtained from each participant prior to conducting the test battery. All testing will be done at *Ons Tuis*, at no cost to the participant, should permission be provided.
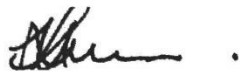
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Risks: There are no risks associated with this study. Participant will be informed of their rights, including the right to withdraw at any time, without any consequences. Participants identified with hearing loss will be referred for further management to an audiologist of their choosing.

Should you provide us with permission to recruit participants from *Ons Tuis*, kindly complete the consent form and return to us. If you would like any additional information on the research study, please feel free to contact me, Karina De Sousa telephonically on 082 556 5431 or via email (karina.swanepoel@up.ac.za). Alternatively, you can contact my study supervisor via email (dewet.swanepoel@up.ac.za).

We look forward to working with you.

Kind Regards,

Karina De Sousa
Audiologist and PhD Student

Professor De Wet Swanepoel
Student Supervisor

Faculty of Humanities
Fakulteit Geesteswetenskappe
Lefapha la Bomotho

Page 2 of 3

CONSENT TO PARTICIPATE IN A RESEARCH STUDY

I, _Elize v.d. Westhuizen_, matron/ manager at Ons Tuis Retirement
Village, provide permission to Karina De Sousa to recruit participants at Ons Tuis for a research
project entitled *Audiogram prediction from a digits-in-noise test.*

Evdwesthuzen   _3/12/19_
Signature   Date

Ons Tuis (Riviera)
Tak van Ons Tuis Groep
Soutpansbergweg / Road 180
Tel: 012 329 3623
Fax: 012 329 3626

Faculty of Humanities
Fakulteit Geesteswetenskappe
Lefapha la Bomotho

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Appendix J: Ear and Hearing Acceptance

From:	em.eandh.0.762e7b.27bee3f9@editorialmanager.com on behalf of Ear and Hearing
To:	Karina Cecilia De Sousa
Subject:	EANDH Decision
Date:	Thursday, 23 September 2021 05:16:59

CC: jan.wouters@med.kuleuven.be, "Cas Smits" c.smits@amsterdamumc.nl, "David Moore" david.moore2@cchmc.org, "Hermanus Myburgh" herman.myburgh@up.ac.za, "De Wet Swanepoel" dewet.swanepoel@up.ac.za

RE: EANDH-D-21-00058R2
"Diotic and antiphasic digits-in-noise testing as a hearing screening and triage tool to classify type of hearing loss"

Dear Ms De Sousa,

I am pleased to inform you that your work has now been accepted for publication in Ear and Hearing. All manuscript materials will be forwarded immediately to the production staff. In general, articles are published-ahead-of-print (PAP) within 8-10 weeks of acceptance. This can vary depending on the level of corrections required during the author's proof stage. You may view articles as they are posted ahead of print, and sign up for PAP alerts, on the EANDH journal website: https://journals.lww.com/ear-hearing/toc/publishahead

Thank you for choosing Ear and Hearing as the venue for your important work. Your contribution as an author is critically important to the Journal, our readers and the field. Your involvement in future peer review is just as vital to the continued excellence of our Journal. That is why it is so important that you consider accepting the offer to review papers for Ear and Hearing if asked. Finding authors with subject matter expertise is a critical part of the peer review process and your help in this area is most appreciated. Thank you for considering these potential future requests.

OPEN ACCESS

** Ear and Hearing has recently transitioned to a new Open Access payment platform. If your manuscript was submitted prior to **March 5, 2021**, please contact the Ear and Hearing Editorial Office, emily.hurd@wolterskluwer.com. If your manuscript was submitted after **March 5, 2021**, please disregard this message. **

If you indicated in the revision stage that you would like your submission, if accepted, to be made open access, please go directly to step 2 only if you have not already submitted a signed License to Publish. If you have not yet indicated that you would like your accepted article to be open access, please follow the steps below to complete the process:
1. Notify the journal office via email that you would like this article to be available open access (emily.hurd@wolterskluwer.com). Please include your article title and manuscript number.
2. A License to Publish (LTP) form must be completed for your submission to be made available open access. Please download the form from http://links.lww.com/LWW-ES/A49, sign it, and Email the completed form to the journal office.
3. You will be receiving an Open Access Publication Charge letter from the Journal's Publisher, Wolters Kluwer, with instructions on how to submit any open access charges. The email will be from publicationservices@copyright.com with the subject line 'Please Submit Your Open Access Article Publication Charge(s)'. **Please complete payment of the Open Access charges within 48 hours of receipt.**

Thank you for submitting your interesting and important work to the journal.

With Kind Regards,
Brenda
Brenda Ryals, PhD
Editor-in-Chief
Ear and Hearing

****

Jan Wouters

Guest Editor

https://www.editorialmanager.com/eandh/

Your username is: Karina De Sousa-722
click here to reset your password

Appendix K: Proof of Acceptance International Journal of Audiology

From:	International Journal of Audiology
To:	karina.swanepoel@up.ac.za
Cc:	jclark@utdallas.edu
Subject:	International Journal of Audiology - Decision on Manuscript ID TIJA-2020-05-0227.R2
Date:	Wednesday, 10 June 2020 20:40:03

MS: "Pure-tone audiometry without bone conduction thresholds: Using the digits-in-noise test to detect conductive hearing loss"
MS#: TIJA-2020-05-0227.R2

Dear Mrs. De Sousa:

Thank you for submitting your above listed revised manuscript. Based on the recommendation received, it is a pleasure to accept it for publication within the International Journal of Audiology.

At this time, your manuscript will be sent to the publisher for the final production processes. The journal issue in which your article will be assigned requires at least 4-5 months to reach formal electronic publication. Page proofs and copyright release websites will be sent to you via email during part of the production phases. Please be sure to check your inbox and SPAM/Junk Mail (in case the email lands in the wrong place). It is very important that you read your page proofs carefully and return them promptly to production so that your manuscript can be published on schedule. After you review your page proofs your article will be finalized to make it available to those interested by navigating to the Taylor & Francis Early Online publication website with email announcements distributed globally. You and others will be able to view your article, along with the newest International Journal of Audiology online manuscripts at the website. Please keep in mind that the early online (electronic) publication of your article is considered formal publication with a unique assigned DOI.

We want to increase the impact of your article, and we work with authors to ensure your work reaches the widest possible (and most appropriate) audiences. Please consider discovering some simple yet effective ways to highlight your research at https://authorservices.taylorandfrancis.com/ensuring-your-research-makes-an-impact/.

Thank you for your fine contribution. On behalf of the Editors of the International Journal of Audiology, we look forward to your continued contributions to the Journal. Of particular importance is that you consider accepting the offer to review papers for IJA if/when asked. Finding seasoned authors to review papers is a critically important component of the peer review process and your assistance in the future within this area would be most appreciated.

Sincerely,

De Wet Swanepoel, PhD
Editor-in-Chief
International Journal of Audiology
dewet.swanepoel@up.ac.za

Cc: Prof. Jackie Clark
IJA Managing Editor

Appendix L: Proof of submission to Ear and Hearing

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From:	em.eandh.0.77e01f.be8ec988@editorialmanager.com on behalf of Ear and Hearing
To:	Karina Cecilia De Sousa
Subject:	EANDH Submission Confirmation for Low and high-pass digits-in-noise test development and associations with pure tone audiometry
Date:	Thursday, 09 December 2021 08:29:46

Dear Ms De Sousa,

Your submission entitled "Low and high-pass digits-in-noise test development and associations with pure tone audiometry" has been received by the Ear and Hearing editorial office.

You will be able to check on the progress of your paper by logging on to Editorial Manager as an author.

https://www.editorialmanager.com/eandh/

username: Karina De Sousa-722
password: click here to reset your password

Your manuscript will be given a reference number once an Editor has been assigned.

Thank you for submitting your work to EANDH.

Kind Regards,

Ear and Hearing

In compliance with data protection regulations, you may request that we remove your personal registration details at any time. (Remove my information/details). Please contact the publication office if you have any questions.

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Appendix M: Digital Health Submission Notification

From:	Digital Health
To:	karina.swanepoel@up.ac.za; c.smits@amsterdamumc.nl; David.Moore2@cchmc.org; chadhas@who.int; herman.myburgh@up.ac.za; dewet.swanepoel@up.ac.za
Subject:	Digital Health DHJ-21-0386
Date:	Thursday, 09 December 2021 11:06:01

09-Dec-2021

Dear Ms. De Sousa:

Your manuscript entitled "Global use and outcomes of the hearWHO mHealth hearing test" has been successfully submitted online and is presently being given full consideration for publication in Digital Health.

Your manuscript ID is DHJ-21-0386.

You have listed the following individuals as authors of this manuscript:
De Sousa, Karina; Smits, Cas; Moore, David; Chadha, Shelly; Myburgh, Herman; Swanepoel, De Wet

Please mention the above manuscript ID in all future correspondence or when calling the office for questions. If there are any changes in your street address or e-mail address, please log in to ScholarOne Manuscripts at https://mc.manuscriptcentral.com/dhj and edit your user information as appropriate.

You can also view the status of your manuscript at any time by checking your Author Center after logging in to https://mc.manuscriptcentral.com/dhj.

As part of our commitment to ensuring an ethical, transparent and fair peer review process SAGE is a supporting member of ORCID, the Open Researcher and Contributor ID (https://orcid.org/). We encourage all authors and co-authors to use ORCID iDs during the peer review process. If you have not already logged in to your account on this journal's ScholarOne Manuscripts submission site in order to update your account information and provide your ORCID identifier, we recommend that you do so at this time by logging in and editing your account information. In the event that your manuscript is accepted, only ORCID iDs validated within your account prior to acceptance will be considered for publication alongside your name in the published paper as we cannot add ORCID iDs during the Production steps. If you do not already have an ORCID iD you may login to your ScholarOne account to create your unique identifier and automatically add it to your profile.

Thank you for submitting your manuscript to Digital Health.

Sincerely,
Simran Kaur
Digital Health
digitalhealth@sagepub.co.uk

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