

# **Hearing Screening with a Digits-in-Noise Test: Evaluating a National Test and New Stimulus Approach**

by

**Karina Swanepoel**

**(12006280)**

---

Dissertation submitted in fulfillment of the requirements for the degree MA  
(Audiology) in the Department of Speech-Language Pathology and Audiology.

**UNIVERSITY OF PRETORIA**

**FACULTY OF HUMANITIES**

**Supervisor: Prof De Wet Swanepoel**

**Co-supervisors: Dr Cas Smits**

**October 2018**



## UNIVERSITY OF PRETORIA

The Department of **Speech-Language Pathology and Audiology** places great emphasis upon integrity and ethical conduct in the preparation of all written work submitted for academic evaluation.

While academic staff teach you about referencing techniques and how to avoid plagiarism, you too have a responsibility in this regard. If you are at any stage uncertain as to what is required, you should speak to your lecturer before any written work is submitted.

You are guilty of plagiarism if you copy something from another author's work (eg a book, an article or a website) without acknowledging the source and pass it off as your own. In effect you are stealing something that belongs to someone else. This is not only the case when you copy work word-for-word (verbatim), but also when you submit someone else's work in a slightly altered form (paraphrase) or use a line of argument without acknowledging it. You are not allowed to use work previously produced by another student. You are also not allowed to let anybody copy your work with the intention of passing it off as his/her work.

Students who commit plagiarism will not be given any credit for plagiarised work. The matter may also be referred to the Disciplinary Committee (Students) for a ruling. Plagiarism is regarded as a serious contravention of the University's rules and can lead to expulsion from the University.

The declaration which follows must accompany all written work submitted while you are a student of the Department of **Speech-Language Pathology and Audiology**. No written work will be accepted unless the declaration has been completed and attached.


Full names of student: **Karina Swanepoel**

Student number: **12006280**

Topic of work: **Hearing Screening with a Digits-in-Noise Test: Evaluating a National Test and New Stimulus Approach**

### Declaration

1. I understand what plagiarism is and am aware of the University's policy in this regard.
2. I declare that this **dissertation** is my own original work. Where other people's work has been used (either from a printed source, Internet or any other source), this has been properly acknowledged and referenced in accordance with departmental requirements.
3. I have not used work previously produced by another student or any other person to hand in as my own.
4. I have not allowed, and will not allow, anyone to copy my work with the intention of passing it off as his or her own work.

SIGNATURE :  .

DATE: 4 September 2018

## **ACKNOWLEDGEMENTS**

- Colossians 3:17. “And whatever you do, whether in word or deed, do it all in the name of the Lord Jesus, giving thanks to God the Father through him”. I dedicate this research to my Heavenly Father who has blessed this work during in ways I could never think possible.
- Alex De Sousa, you encouraged and supported me to do this project at a time of great uncertainty. Without you I would not have been able to take on this degree.
- Professor De Wet Swanepoel and Dr Cas Smits, my supervisors, mentors and idols. Thank you for your solid and unprecedented guidance.
- Professor David Moore, thank you for your never-ending support and for keeping my humble during this process.

## Table of Contents

ABSTRACT.....	8
1. INTRODUCTION .....	9
2. METHODOLOGY.....	13
2.1. Research Aims .....	13
2.2. Research Design .....	13
2.3. Ethical considerations .....	14
2.4. Phase One: Characteristics and test performance of listeners who completed the SA English DIN test on the hearZA App. ....	16
2.4.1. Participants .....	16
2.4.2. Procedures .....	16
2.4.3. Data processing procedure .....	17
2.4.4. Data analysis procedure .....	17
2.5. Phase Two: Evaluating a new stimulus approach of the SA English DIN test... 18	
2.5.1. Participants .....	18
2.5.2. Materials and apparatus .....	18
2.5.3. Research Procedures .....	19
2.5.4. Data processing procedure .....	21
2.5.5. Data analysis procedure .....	21
2.6. Reliability and Validity .....	22
3. A SMARTPHONE NATIONAL HEARING TEST: PERFORMANCE AND CHARACTERISTICS OF USERS .....	23
3.1. Abstract .....	23
3.2. Introduction .....	24
3.3. Method.....	26
3.4. Results.....	28
3.5. Discussion .....	30
3.6. References .....	33
4. IMPROVING ACCESS TO GLOBAL HEARING CARE USING A NOVEL mHEALTH APPROACH.....	37
4.1. Abstract .....	37
4.2. Introduction .....	38
4.3. Method.....	39
4.4. Results.....	41
4.5. Discussion .....	45

4.6. References .....	47
5. DISCUSSION AND CONCLUSION .....	51
5.1. Discussion of Results .....	51
5.2. Clinical Implications .....	55
5.3. Critical Evaluation .....	57
5.4. Future Research .....	58
5.5. Conclusion .....	58
6. REFERENCES .....	60
7. APPENDICES .....	68
Appendix A: Faculty of Humanities Ethical Clearance .....	68
Appendix B: Faculty of Health Sciences Ethical Clearance .....	69
Appendix C: Consent for anonymized data from the hearX Group .....	71
Appendix D: Consent from the CEO at Steve Biko Academic Hospital .....	73
Appendix E: Consent from the Dean of Student Affairs .....	74
Appendix F: Participant informed consent letter .....	76

## **TABLES**

- Table 1. Equipment .....
- Table 2. Analysis of variance statistics for the effect of test presentation, repetition and symmetry of hearing loss on the SRT .....
- Table 3. Diotic and Dichotic SRT for listeners with normal hearing, symmetric and asymmetric hearing loss according to PTA (0.5, 1, 2 & 4 kHz) hearing loss categories.....

## **LIST OF ABBREVIATIONS**

DIN:	Digits-in-noise
ITD:	Interaural time difference
LMIC:	Low and middle-income country
MLD:	Masking level difference
N:	Native
NN:	Non-native
PTA:	Pure tone average
SA:	South African
SIN:	Speech in noise
SRM:	Spatial release from masking
SRT:	Speech reception threshold

## **FORMATTING**

APA referencing style was used in this dissertation.

## ABSTRACT

The prevalence of hearing loss is high, affecting 1.3 billion people globally. Most persons with disabling hearing loss reside in low-and-middle-income countries (LMICs) where current hearing healthcare systems are insufficient to meet the need for services. To decentralise hearing loss detection the digits-in-noise (DIN) test was released in South Africa as a smartphone application, called *hearZA*. The test corresponds well with pure tone audiometric thresholds with high sensitivity and specificity. However, in a binaural test setup designed to make the test more efficient, the DIN is not sensitive to detect unilateral or severely asymmetric hearing loss. Sequential testing of each ear would double test time and possibly reduce test uptake by consumers. The study retrospectively analysed 24072 DIN tests, completed between March 2016 and August 2017, to determine characteristics of *hearZA* App users and predictors of test performance. Furthermore, in a comparative within-subjects research design, the study determined if dichotic speech could improve the sensitivity of the DIN test compared to conventional diotic speech. Adults with normal hearing ( $n=51$ ; pure tone average thresholds (PTA)  $\leq 25$  dB HL in both ears), symmetric sensorineural hearing loss ( $n=47$ ; PTA  $\geq 26$  dB HL) and asymmetric sensorineural hearing loss ( $n=24$ ; PTA  $\geq 26$  dB HL in the poorer ear) were recruited. Overall referral rate of the *hearZA* DIN test was 22.4%, and 37% of these reported a known hearing difficulty. Age distributions showed that 33.2% of listeners were 30 years and younger, 40.5% were between 31 and 50 years, and 26.4% were older than 50 years. Age, self-reported English-speaking competence and self-reported hearing difficulty were significant predictors of the SRT. Furthermore, dichotic digit presentation markedly improved sensitivity of the DIN test to unilateral, asymmetric and symmetric sensorineural hearing loss. Dichotic testing Receiver Operating Characteristic area under the curve (0.94), and linear regression slope (0.18) and correlation (0.84) with SRT were higher than diotic (0.84, 0.08 and 0.79 respectively). High test uptake, particularly among younger users and high overall referral rate indicates that the *hearZA* App addresses a public health need. Furthermore, accurate detection of hearing loss is possible using a dichotic test paradigm. Population-wide access to the dichotic DIN test provides a promising prospect to address undetected hearing loss by making detection accessible and affordable.

**Keywords:** digits-in-noise, dichotic, diotic, hearing loss detection, hearing screening



## 1. INTRODUCTION

Hearing loss is a growing global health concern as the 4<sup>th</sup> leading contributor to years lived with disability, affecting close to 1.3 billion people annually (Wilson, Tucci, Merson, & O'Donoghue, 2017). The consequences of unaddressed hearing loss are well-known, including impaired communication (Hallam, Ashton, Sherbourne, & Gailey, 2008; Mick, Kawachi, & Lin, 2014) and psychosocial well-being (Fellinger, Holzinger, & Pollard, 2012). Close links to dementia have also been found, with hearing loss as one of the primary modifiable risk factors (Lin et al., 2011; Livingston et al., 2017). Furthermore, the global monetary cost associated with hearing loss is 750 billion dollars annually (World Health Organisation [WHO], 2017). Despite severe detriments, hearing loss continues to be an invisible epidemic with limited public health support (Mackenzie & Smith, 2009), especially in low-and-middle-income countries (LMICs) where the incidence is high, but services are largely unavailable (Stevens et al., 2011). A survey completed in 2009 aimed to determine the state of ENT, audiology and speech therapy services in 18 sub-Saharan Africa countries. Results indicated that availability of services was poor, the distribution of services was unbalanced, and that training opportunity was few (Fagan & Jacobs, 2009). The survey was recently repeated, indicating little progress. Although the number of professionals had increased, due to rapid population growth, the ratio to the population only marginally improved in some countries while declining in others (Mulwafu, Ensink, Kuper & Fagan, 2017).

The World Health Organisation (WHO) estimates that close to 50% of hearing loss can be prevented and that most of the remainder can be treated efficiently (WHO, 2017). A lack of adequate resources, therefore, means that people are affected by hearing loss that could have been prevented and are currently untreated, leaving them subject to adverse consequences. The growing importance of this issue led to a recent hearing loss prevention resolution adopted by the World Health Assembly (WHA) in 2017 (World Health Assembly [WHA], 2017). This resolution calls on hearing healthcare stakeholders to develop and implement strategies for improved service provision, especially in LMICs (Chadha, Cieza, & Krug 2018; WHA, 2017).

Secondary prevention strategies such as early detection of hearing loss is an essential and cost-effective method to reduce the significant and increasing burden of hearing

loss (WHO, 2012; Wilson et al., 2017). Typically, standard practice for hearing screening is pure tone air conduction testing. Unfortunately, this method is resource intensive, requiring calibrated headphones, soundproof booth and trained screening personnel (Mulwafu et al., 2017). More recently the focus has shifted to suprathreshold means of screening using speech-in-noise (SIN) tests. SIN tests measure the signal-to-noise (SNR) where a listener can recognise 50% of the words or sentences correctly (i.e. speech reception threshold; SRT). These measures vary regarding the type of speech stimulus, masking noise and test procedure. As the most common complaint of hearing loss is the inability to understand speech in noise (Vermiglio, Soli, Freed, & Fisher, 2012), SIN tests have the advantage of better representing the functional handicap produced by hearing loss compared to pure tone detection (Grant & Walden, 2013; Moore et al., 2014). Furthermore, SIN tests do not require calibrated equipment and are less sensitive to ambient noise and transducer type (Jansen, Luts, Wagener, Frachet, & Wouters, 2010).

Many high-income countries have resorted to digits-in-noise (DIN) hearing screening. The DIN test is a type of SIN test that measures the SRT where a listener can correctly identify 50% of digit triplets (e.g. 3-2-7) presented in speech masking noise. SIN tests using sentence-stimuli are considered more representative of daily life conversations. However, not all listeners can follow and understand complete sentences either due to the severity of their hearing loss or limited linguistic skills (Koole et al., 2016; Smits, Goverts, & Festen, 2013). In contrast, English digits are easily understood, even in multilingual populations, making it less dependent on linguistic competence and suitable for a wide range of users (Smits et al., 2013). To rapidly provide access to a DIN hearing screen, the first DIN test was released in the Netherlands as a telephone-based test (Smits, Kapteyn, & Houtgast, 2004). Two and a half years after launching, 60 000 tests were taken and 50% of those who failed, went for diagnostic assessments (Smits, Merkus, & Houtgast, 2006). Several other telephone and online versions of the DIN test were released over the past ten years in countries like the United Kingdom, United States of America, Australia, Germany, Switzerland, Poland and France (Folmer et al., 2017; Jansen et al., 2010; Smits et al., 2006; Watson, Kidd, Miller, Smits, & Humes 2012; Zokoll, Wagener, Brand, Buschermöhle, & Kollmeier, 2012).

A barrier to the use of a telephone-based DIN test in LMICs is the poor penetration of landline phones. Another alternative may be the increasing penetration of smartphones globally, estimated to be 80% at the end of 2020 (The Economist, 2015). A National Household Survey in South Africa indicated that 79.5% of the population had access to a mobile phone compared to the 13% with access to a landline telephone (Statistics South Africa, 2013). Smartphone technology is vital in modern day living with health applications becoming popular and central due to their monitoring abilities (Swanepoel, 2017). Health surveillance utilising smartphones has taken a significant foothold with estimates of 1.7 billion downloads by 2017 and global revenues of \$21.5 billion in 2018 (The Economist, 2016). Therefore, a modern approach would be offering the DIN test as a downloadable smartphone application. Although accessible globally, capitalising on the dispersion of low-cost smartphones, widespread uptake of hearing screening across various socio-economic classes is possible (Potgieter et al., 2016). The first smartphone DIN test was, therefore, released as South Africa's national hearing test in 2016, called *hearZA* (Potgieter, Swanepoel, Myburgh, Hopper, & Smits, 2016; Potgieter, Swanepoel, Myburgh, & Smits, 2017).

Typically, the South African (SA) English DIN is completed binaurally in under three minutes, is validated against pure tone audiometry with sensitivity and specificity more than 90%, suitable for population-based screening (Potgieter et al., 2016; Potgieter et al., 2017). In the current binaural test setup of this national smartphone test, digits are presented diotically (i.e. the same phase signal presented to each ear simultaneously; SoNo), without the possibility of testing ears monaurally. A listener with unilateral or asymmetric hearing loss may, therefore, still pass the screen since they can adequately hear the signal presented to the better ear. Sequential testing of each ear would double test time and may reduce test uptake as a result. This study explored a novel test development that could yield increased sensitivity and time efficiency for unilateral and asymmetric using speech that had a 180° phase shift between the two ears (i.e. dichotic; SπNo).

Dichotic listening involves central auditory processing and improves speech intelligibility in binaural conditions, also referred to as binaural unmasking. This phenomenon was first described by Hirsh (1948) and Licklider (1948) when they observed that masked thresholds varied with changes in phase relationships between

the masker and the signal. The SRT difference between diotic and dichotic conditions is referred to as masking level difference (MLD). Before the widespread use of auditory brainstem response, MLD was a tool to evaluate brainstem lesions and differentiate between types of hearing loss (Olsen & Noffsinger, 1976; Wilson, Moncrieff, Townsend, & Pillion, 2003). This research indicated that MLD was lower for listeners with hearing loss than for normal hearing controls (Olsen et al., 1976; Wilson et al., 2003). Smits et al. (2016) investigated SRTs in different listening conditions for the Dutch and American English DIN test for normal hearing listeners. Results indicated the threshold advantage over monotic presentation provided by the currently used diotic (SoNo) presentation is small ( $\cong 1$  dB). However, the use of interaural phase-reversed (dichotic) digits (S $\pi$ No) provided a further  $\cong 5$  dB SRT advantage. Listeners with a unilateral and asymmetric hearing loss would not be predicted to obtain this dichotic advantage since they will only adequately hear the one phase signal presented to the better ear. These exploratory findings support the idea that interaural phase-reversed dichotic listening can be a tool to sensitise the DIN for unilateral and asymmetrical HL using a time-efficient binaural test paradigm.

Analysis of large-scale hearing screening programs, like the *hearZA* national hearing test, can provide indications for test-use, considerations for interpretation and measures of reach. The purpose of this study, was, therefore, two-fold. First, it aimed to determine characteristics and test performance of individuals that completed the diotic SA English DIN test with the *hearZA* App. Secondly, this study aimed to determine whether improved sensitivity to unilateral and asymmetrical hearing loss was possible using phase reversed (dichotic) digits in the SA English DIN test.

## **2. METHODOLOGY**

### **2.1. Research Aims**

This study had two main aims:

#### **Study aim #1**

To determine the characteristics and test performance of listeners who completed the diotic SA English DIN test using the *hearZA* App.

#### *Secondary Aims*

- To determine predictors of the diotic SRT of the SA English DIN test.

#### **Study aim #2**

To determine whether improved sensitivity of the SA English DIN test to unilateral and asymmetrical hearing loss is possible using dichotic stimuli.

#### *Secondary Aims*

- To compare the SRTs of the SA English DIN test when presented in the current diotic listening condition to the dichotic listening condition in normal-hearing listeners.
- To compare the sensitivity of the diotic and dichotic SRTs in listeners with various levels of bilateral symmetric sensorineural hearing loss.
- To compare the sensitivity of the diotic and dichotic SRTs in listeners with varying degrees of unilateral and asymmetric sensorineural hearing loss.

### **2.2. Research Design**

The study was completed in two phases. Phase one (Aim #1) used a retrospective research design with quantitative data to determine characteristics and test performance of listeners who completed the SA English DIN test using the *hearZA* App. The first phase was retrospective since it used the *hearZA* database to obtain DIN test information, that had been collected for reasons other than research (Hess, 2004).

Phase two (Aim #2) of the study was completed using a comparative within-subjects research design applying quantitative measures (Leedy & Ormrod, 2015) to compare SRTs when the SA English DIN test was presented in the diotic- compared to dichotic

listening condition. Furthermore, phase two used a repeated measures design where the same participant was measured on more than one independent variable (Beins, 2009) using diotic and dichotic test conditions to compare SRT results. The repeat-measures design employed a balanced Latin square to counterbalance the test conditions and to prevent first-order carryover effects.

The time dimension of this study was cross-sectional, assembling a sample of participants at one point to assess the predictor and outcome variables simultaneously and determine any associations (Haynes & Johnson, 2009). In the case of this study, to describe *hearZA* user characteristics and test performance, as well as establish the effect of the dichotic presentation on the SRT of the DIN hearing test within a fixed period.

### **2.3. Ethical considerations**

Ethical approval for this study was granted by the Faculty of Humanities Research Ethics Committee (Appendix A) and Faculty of Health Sciences Research Ethics Committee, University of Pretoria (Appendix B) before data collection commenced.

#### *Permission*

The CEO at *HearX Group*, Pretoria, South Africa gave permission to obtain anonymized SA English DIN test results from the *hearZA* database (Appendix C). In addition, the CEO at *Steve Biko Academic Hospital*, Pretoria, South Africa (Appendix D) provided permission to conduct data collection on the premises and to provide patients of the hospital with information, allowing the opportunity to volunteer for phase two of the study. Permission was also granted by the Dean of Student Affairs at the University of Pretoria (Appendix E) to permit the recruitment of students from the Department of Speech-Language Therapy and Audiology for participation in the study.

#### *Informed Consent*

Informed consent (Appendix F) letters explaining the procedure, risks and benefits of participation was compiled and provided. The letters were easy to understand, distinctly stated the title and objective of the study and provided a clear description of the participant's rights (Maxwell & Satake, 1997). After an explanation of the research, participants were required to provide both verbal and written informed consent before assessment.

### *Confidentiality and Anonymity*

An essential requirement of research is to protect the anonymity and confidentiality of research participants by ensuring that no identifying characteristics in the data would reveal their identity (Beins, 2009). For phase one of the study, data was anonymized by the *hearX Group* before providing it to the researchers, thereby ensuring complete anonymity. For phase two, participants were ensured that all their information would be kept strictly confidential and that only research clinicians would analyse the data. The identity of participants was only known to the research clinician conducting the assessment. Subsequently, a unique alphanumerical code was assigned to all data, and no characteristic data was captured to ensure complete anonymity.

### *Protection from harm, risk and discomfort*

Ethical research conduct stresses that experimental research should avoid all unnecessary physical and mental discomfort to the participant. If the potential risk outweighs the potential benefit, the research is deemed inappropriate (Beins, 2009). The study contained no known associated medical risks or discomfort, as explained to the participant. Rest periods during the assessment were provided on request of the participant if they became fatigued.

### *Benefits*

Participants were informed that there are no direct benefits to him or her by partaking in the study, but that the results of this research may provide evidence of improved sensitivity for the SA English DIN test using dichotic antiphasic stimuli. Participants who were identified with hearing loss were referred for on-going intervention services at their closest hearing healthcare provider.

### *Release of findings*

Participants were informed that the results of this study might be published in professional journals or presented at professional conferences.

### *Plagiarism*

The close imitation of another author's original work without proper recognition to the author is considered as plagiarism (Leedy & Ormrod, 2015). All sources used in this study were appropriately cited in the text as well as in the reference list.

## **2.4. Phase One: Characteristics and test performance of listeners who completed the SA English DIN test on the hearZA App.**

### **2.4.1. Participants**

A total of 30321 DIN tests completed on the *hearZA* smartphone App between March 2016 and August 2017 were retrospectively analysed. There were 297 listeners who indicated ages of 100 years and older, of which 283 incorrectly indicated ages of 2017 or 2018 years. The remaining 14 subjects had ages 100 up to 117 years. Their data, together with listeners who kept the application's default setting of 27 years, were excluded as incorrect data entries ( $n=2175$ ). Furthermore, the data of listeners who completed the test without headphones or earbuds ( $n=4075$ ) were excluded to prevent confounding variables. After all exclusionary criteria were applied, 24072 tests were left for analysis. The ages of the remaining sample ranged between 5 to 99 years (average of 39 years;  $SD=16.6$  years;  $n=24072$ ). Listeners were further divided into two groups based on their self-rated level of English-speaking competence. English speaking competence is rated on a non-standardized visual analogue scale of 1 to 10, a lower score indicating poorer competence and a higher score, better competence. The two groups were 1) native (N) and non-native (NN)  $\geq 6$  and 2) NN  $\leq 5$  (Potgieter et al., 2017). Pass and fail criteria were based on that of Potgieter et al. (2017), N and NN  $\geq 6$  with a cut-off of -9.5 dB and N  $\leq 5$  with a cut-off of -7.5 dB.

### **2.4.2. Procedures**

The *hearZA* application stores a list of 120 different digit triplets which are randomly selected for presentation at the beginning of each test (Smits et al., 2013, Potgieter et al., 2016). The digit triplets are constructed out of SA English mono-and bisyllabic numerals between 0 and 9. The program presents the triplets with 500 ms silent intervals at the beginning and end of each digit triplet. The successive digits are presented with 200 ms of silence with 100 ms of jitter in between (Potgieter et al., 2016). Speech-weighted masking noise was produced by shaping white noise to match the long-term average speech spectrum of the digits without any silences (Smits et al., 2013; Potgieter et al., 2016). A fixed noise level (70dB SPL) and altering speech level are used when triplets with negative SNRs are presented. However, to prevent clipping of the signal, the speech level becomes fixed, and the noise level varies once



the SNRs become positive (Potgieter et al., 2016). The digits together with masking noise were presented in a binaural diotic (SoNo) condition.

Listeners completed the SA English DIN test by downloading the *hearZA* application on an Android or iOS operated smartphone. People were made aware of the application due to marketing campaigns on social media, television or word-of-mouth recommendations. Before the test, listeners were indicated to complete the test with either earbuds or headphones. Earlier versions of the App did not prevent test execution when earbuds or headphones were not plugged in, which was subsequently changed. The application requires listeners to provide their date of birth, home language and to rate their English-speaking competence on a non-standardized scale of 1-10. Users were required to indicate whether they experience hearing difficulty by selecting “Yes” or “No” on the application. After that, listeners self-select a comfortable listening intensity. Based on the comfort level selected, the application uses a fixed masking level with adaptive speech signal presentation (see Potgieter et al. 2016 for details). Listeners are expected to enter the digits heard on the smartphone, where a correct response will prompt the application to present the next digit at 2 dB lower signal-to-noise ratio (SNR). Where the listener is uncertain of the digits heard, they are instructed guess. When the response is incorrect, the application presents the next triplet at 2 dB higher SNR. The result is calculated by averaging the last 19 SNRs (Potgieter et al., 2016; Potgieter et al., 2018).

#### **2.4.3. Data processing procedure**

Data processing involves the logical organisation, categorisation and integration of data from various sources (Babbie & Mouton, 2001). Data preparation involves coding and cleaning of data in a quantifiable way (Terre Blanche, Durrheim, & Painter, 2006). Data was extracted from the *hearZA* cloud-based server and prepared in Microsoft Excel (Microsoft Inc, Redmond, USA). Data were imported into the Statistic Package for the Social Sciences Version 25 (IBM SPSS v25.0, Chicago, Illinois) for analysis.

#### **2.4.4. Data analysis procedure**

Descriptive and inferential statistics were used to describe and analyse quantitative data. Results were analysed using one-way analysis of variance (ANOVA) and Analysis of Covariance (ANCOVA). *Post hoc* comparisons were made using the Bonferroni adjustment. A *p*-value of  $\leq 0.05$  was used to indicate significance. Multiple

regression was performed for continuous and categorical variables to determine predictors of the SRT. The relationships between percentile SRTs and age were determined by following the procedure as described in Smits et al. (2013). Percentile values were calculated for 11-year age groups. These age groups were shifted in 1-year steps from 20 to 94 years. The percentile values were calculated for each age group, and a group-size weighted fit to an exponential growth function was performed.

## **2.5. Phase Two: Evaluating a new stimulus approach of the SA English DIN test**

### **2.5.1. Participants**

Power calculations were conducted to determine a medium effect size (Cohen  $f=0.25$ ) with 80% statistical power at a two-sided significance level of 0.05. Based on these calculations, a sample size of 122 participants were recruited using non-purposive sampling, including 51 participants with normal hearing (PTA<sub>0.5,1,2,4</sub> kHz < 25 dB HL); 47 with symmetric sensorineural hearing loss (PTA<sub>0.5,1,2,4</sub> kHz ≥ 26 dB HL) and 24 with asymmetric sensorineural hearing loss (PTA<sub>0.5,1,2,4</sub> kHz ≥ 26 dB HL). Chronic otitis media in both children and adults has been linked to reduced performance in MLD (Ferguson et al., 1998; Moore et al., 2001). Therefore, participants with a history of chronic otitis media and any other middle ear pathology were excluded from the study. Participants were adults ranging from 18 to 84 years (average of 54 years; SD=21 years) and were recruited from the University of Pretoria or hospital and private Audiology practices in the Gauteng Province of South Africa. Asymmetric hearing loss was defined as an interaural difference > 10 dB (PTA). Participants were further divided into hearing sensitivity categories based on the poorer ear PTA and categorised as excellent (0-15 dB HL), good (16-25 dB HL), mild (26-40 dB HL), moderate (41-55 dB HL) and severe-to-profound (56-120 dB HL). Listeners had various levels of English-speaking competence. Non-native English speakers self-reported their level of competence on a non-standardized scale from 1-10, a higher score indicating better competence.

### **2.5.2. Materials and apparatus**

Table 1 summarises the materials and apparatus used for data collection of the study.

**Table 1. Equipment**

<b>Equipment</b>	<b>Description</b>
Welch Allyn Pocketscope™ with reusable specula	An otoscope was used to inspect the tympanic membrane and external ear canal visually.
GSI Tymptstar - Comprehensive Middle Ear Tympanometry	This device was used to measure middle-ear functioning. Tympanometry was conducted to determine ear canal volume, middle-ear pressure and compliance.
GSI 61 - Two Channel Clinical Audiometer coupled with TDH 39 audiometric headphones	This audiometer was calibrated according to ISO 389-1(1998) and 389-2 (1994) standards and used in combination with an ISO 6189 (1993) compliant booth. Participants underwent conventional pure tone air, and bone conduction audiometry and thresholds were established at 250, 500, 1000, 2000, 4000 and 8000Hz.
Samsung SM-G313H Trend Neo smartphone run by OS version 4.4 connected to manufacturer supplied earbuds.	The SA English DIN ( <i>hearZA</i> ) test application was loaded onto the Samsung SM-G313H Trend Neo smartphone. Participants self-administered the SA English DIN application and completed testing by entering their responses onto the smartphone.

**2.5.3. Research Procedures***Programming application changes to the DIN test for dichotic stimuli*

The study entailed the programming application changes to the SA English DIN test for dichotic presentation, completed by mobile software developers. The application changes were designed in Android Studio version 2.3.0 and written in Java version 1.8.0.

*Stimuli*

As in phase one, the Android application stores a list of 120 different digit triplets (compiled from digits 0 to 9), randomly selected for presentation at the beginning of each test (Smits et al., 2013, Potgieter et al., 2016). The program presents the triplets with 500 ms silent intervals at the beginning and end of each digit triplet. The successive digits are presented with 200 ms of silence with 100 ms of jitter in between (Potgieter et al., 2016). For dichotic stimulation, the broadband masking noise was

delivered diotically (SoNo), while presenting the speech signal with a 180° phase shift between the two ears (SπNo).

#### *Masking noise and test procedure*

As in phase one, speech masking noise was produced by shaping white noise to match the long-term average speech spectrum of the digit triplets without any silences (Smits et al., 2013; Potgieter et al., 2016). A fixed noise level (70 dB SPL) and altering speech level are used when triplets with negative SNRs are presented. However, to prevent clipping of the signal, the speech level becomes fixed, and the noise level varies once the SNRs become positive (Potgieter et al., 2016). As part of the new test development, masking noise was randomised by generating a long noise file, with the noise beginning at random offset within the first 5 seconds. Also, the previous diotic version of the SA English DIN application comprised a list of 23 digit triplets, which together with the masking noise, presented in a fixed order of -2 dB SNR steps (Smits et al., 2004, Potgieter et al., 2016). Due to the improved SRTs in the dichotic listening condition, to avoid floor and ceiling effects, the first three presentations in this version were presented in 4-dB steps, after that continuing in 2-dB steps.

The test procedure was programmed as follows:

- Before the test, the listener is instructed to select a comfortable listening intensity.
- The first digit-triplet is presented at 0 dB SNR based on self-selected listening intensity.
- When the response is entered, the next triplet is submitted at a 4 dB lower SNR for a correct response and a 2 dB higher SNR for an incorrect response.
- The first three presentations continue in 4 dB lower SNRs for correct responses after that, continuing in 2-dB SNR steps for correct responses.
- A triplet is considered correct only when all the digits are entered correctly.
- The SRT is calculated by averaging the last 19 SNRs.

#### *Informed consent*

Permission was obtained from the Dean of Students (Appendix B), the CEO of Steve Biko Academic Hospital (Appendix C), private Audiology practices in Pretoria (Appendix E) to recruit and assess participants on the premises. For all the candidates; the research clinician verbally explained the nature of the study and the testing

protocol. Only once the participant understood the process, and after signing an informed consent letter (Appendix D), did data collection start.

#### *Audiometric Test Battery*

For many of the participants, pure tone results, not older than one week, was already available. For the remaining participants, diagnostic air and bone conduction thresholds were established using the ISO shortened ascending method (ISO 8253-1, 2010) to determine the participant's type and degree of hearing loss. Participants with normal bilateral hearing, bilateral symmetric or asymmetric sensorineural hearing loss were included. Participants with conductive or mixed hearing loss were excluded from the study.

#### *Digits-in-Noise testing*

DIN testing was carried out on a Samsung SM-G313H Trend Neo smartphone coupled with manufacturer supplied earbuds, alternating between three dichotic and two diotic tests. The test order was counterbalanced using a balanced Latin square to counteract test order bias. The SA English DIN application provided test instructions on a separate page, but additionally, the research clinician explained the procedure before testing. Participants were instructed to select a comfortable listening intensity, after that, to listen to digit triplets (e.g. 4-2-7) and to enter the perceived triplets on the smartphone. Whenever participants were uncertain, they were instructed to guess. The response was only considered correct by the application if all the digits were entered correctly. Depending on the response entered, the application would adjust the SNR on the next digit triplet presentation until the final averaged SRT score was provided.

#### **2.5.4. Data processing procedure**

Data was extracted from the Samsung Trend Neo Smartphone and data collection sheets and prepared in Microsoft Excel (Microsoft Inc, Redmond, USA). Data was imported into the Statistic Package for the Social Sciences Version 25 (IBM SPSS v25.0, Chicago, Illinois) for analysis.

#### **2.5.5. Data analysis procedure**

Descriptive and inferential statistics were employed to describe and analyse quantitative data. The effect of test method, symmetry of hearing loss and repetition

number on the SRT was assessed using separate repeated-measures analysis of variance (ANOVA). Post hoc comparisons used Bonferroni adjustment for multiple comparisons. In cases where sphericity was violated, Greenhouse-Geisser corrections were applied. Analysis of covariance (ANCOVA) was run to determine the effect of age and English-speaking competence on the dichotic SRT. General linear regression was used to test whether the slope of the relation between PTA and SRT differs between dichotic and diotic testing. Intraclass correlation coefficients (ICC) were calculated for the test and retest measurements for dichotic and diotic presentations and were based on a mean rating ( $k=2$ ), absolute agreement and a two-way mixed effects model. All subsequent analysis was conducted by averaging the test-retest SRT values for the diotic and dichotic test method. Associations between poorer ear PTA and SRT were examined using Pearson's correlation. Results in three hearing categories and five PTA hearing sensitivity categories were assessed using ANOVA. Receiver Operating Characteristics (ROC) curves were calculated to determine sensitivity and specificity of the DIN tests to detect mild hearing loss and worse (PTA > 25 dB HL) and moderate hearing loss and worse (PTA > 40 dB HL).

## **2.6. Reliability and Validity**

Reliability refers to the accuracy and consistency of results, whereas validity refers to the extent to which a tool measures what it is intended to measure (Leedy & Ormrod, 2010). Reliability and validity measures were employed in the design of this study. First, the SA English DIN test is an accurate and valid tool, proved to correlate well to pure tone audiometric results with high sensitivity and specificity (Potgieter et al., 2016; Potgieter et al., 2017). Furthermore, in phase two of the study the accuracy and consistency of pure tone audiometric results were ensured by only testing on equipment calibrated in accordance with international standards and using the same testing procedure for each participant (ISO shortened ascending method [ISO 8253-1, 2010]). To further ensure accuracy, this study employed a repeated measures design for both diotic and dichotic versions of the DIN test. Intraclass correlation coefficients between test-retest measures were also conducted to prove an agreement between the tests.

### 3. A SMARTPHONE NATIONAL HEARING TEST: PERFORMANCE AND CHARACTERISTICS OF USERS

Authors: Karina C. De Sousa, De Wet Swanepoel, David R. Moore, Cas Smits

Journal: American Journal of Audiology<sup>1</sup>

Submitted: 15 January 2018

Accepted: 30 April 2018

#### 3.1. Abstract

**Purpose:** The smartphone digits-in-noise (DIN) hearing test, called *hearZA* was made available as a self-test in South Africa in March 2016. This study determined characteristics and test performance of the listeners who took the test.

**Method:** A retrospective analysis of 24072 persons who completed a test between March 2016 to August 2017 was conducted. User characteristics, including age, English-speaking competence and self-reported hearing difficulty were analyzed. Regression analyses were conducted to determine predictors of the speech reception threshold (SRT).

**Results:** Overall referral rate of the *hearZA* test was 22.4%, and 37% of these reported a known hearing difficulty. Age distributions showed that 33.2% of listeners were 30 years and younger, 40.5% were between 31 and 50 years, and 26.4% were older than 50 years. Age, self-reported English-speaking competence and self-reported hearing difficulty were significant predictors of the SRT.

**Conclusions:** High test uptake, particularly among younger users and high overall referral rate indicates that the *hearZA* App addresses a public health need. The test also reaches target audiences including those with self-reported hearing difficulty and those with normal hearing who should monitor their hearing ability.

**Keywords:** digits-in-noise; hearing screening; early detection; hearing loss; smartphone hearing screening; national hearing test

---

<sup>1</sup> This article was edited in accordance with the editorial specifications required by the journal and may differ from the editorial style of the rest of this document.

### **3.2. Introduction**

The global burden of hearing loss has been increasing steadily with close to half a billion people estimated to suffer from permanent disabling hearing loss (Vos et al., 2015; Hay et al., 2017; Wilson et al., 2017). The rise in recreational noise exposure further places an estimated 1.1 billion young people between the ages of 12 to 35 years at risk of acquiring hearing loss (WHO, 2017). Regardless of high prevalence rates and significant consequences, hearing loss continues to be an undetected and untreated disability that is not adequately positioned or prioritized within many healthcare systems (Mackenzie & Smith, 2013). This is especially true in low-and-middle-income countries (LMICs) where hearing health care is scarce or often unavailable due to the lack of resources and poor awareness amongst the lay public and health professionals (Mackenzie & Smith, 2013). Consequences of unaddressed hearing loss are far-reaching, affecting social participation (Hallam et al., 2008), psychological well-being (Fellinger et al., 2012), cognitive function (Livingston et al., 2017) and employment opportunity (Tucci, Merson & Wilson, 2010; WHO, 2017). With high proportions of occupations dependant on spoken communication (Ruben, 2015), the cumulative effects of hearing loss can have significant economic implications for the individual and society. Recent WHO estimates of the global estimated costs associated with hearing loss equaled 750 billion (WHO, 2017). Emphasis on prevention and treatment of hearing loss is, therefore, important on a global scale with particular focus on LMICs (Wilson et al., 2017).

Although it is well established that timely identification and management could substantially reduce the functional impairment of hearing loss (Cacciatore et al., 1999), most cases remain undiagnosed and untreated, especially in older adults (Pronk et al., 2011). Hearing screening programmes have a critical role in monitoring hearing and early detection of hearing difficulty (WHO, 2017). However, implementation and success of these programmes are reliant on specific human and technological resources like trained screening personnel, audiological equipment, and optimal quiet test environments. Also, within LMICs, individuals may be required to travel substantial distances for hearing screening as health care providers are severely limited and unequally distributed (Mulwafu et al., 2017). The high costs involved and limited access to population-based hearing screening has led to various initiatives to use telephone and internet based speech in noise (SIN) screening tests (Smits et al., 2004;



Jansen et al., 2010; Watson et al., 2012; Paglialonga et al., 2014; Vlaming et al., 2014; Sheik Rashid et al., 2017; Folmer et al., 2017). Although all these tests measure speech recognition in noise, they vary in terms of speech stimuli, type of background noise and test procedure. Compared to conventional pure tone audiometry, SIN tests do not require calibrated equipment and also have the advantage of being less sensitive to ambient noise and transducer type (Jansen et al., 2010). Furthermore, SIN tests measure the functional deficits related to hearing loss as opposed to hearing sensitivity (Smits & Houtgast, 2005). The digits-in-noise (DIN) test is a type of SIN test that measures the speech reception threshold (SRT) where a listener can correctly identify 50% of digit triplets (e.g., 3-2-7) presented in speech noise. Compared to SIN tests that use sentences, English digits are easily understood, even in multilingual populations making it less dependent on the listener's linguistic skills and suitable for a wide range of users (Smits et al., 2013). The DIN was first developed for landline telephone use as Netherland's national hearing test in 2004 (Smits et al., 2004). Several telephone and online versions after that arose in countries like the USA, Australia, Germany, France and Poland (Folmer et al., 2017; Jansen et al. 2010; Smits et al. 2006a; Watson et al. 2012; Zokoll et al. 2012). A challenge related to telephone DIN tests, however, is insufficient landline coverage in LMICs. In South Africa for example, only 13.9 % of people have access to a landline telephone (STATSSA, 2013). Capitalizing on rapid dispersal of low-cost smartphones with estimated 80% worldwide access by the year 2020 (The Economist, 2015), offering the DIN test as a smartphone application was a suitable alternative to landline testing. The first smartphone DIN test was made available in 2016 as South Africa's national hearing test, called *hearZA* (Potgieter et al., 2016; Potgieter et al., 2017). The application can be completed within 3 minutes, correlates highly with pure tone average (0.5,1,2,4 kHz) and has sensitivity and specificity over 90%, sufficient for population-based screening (Potgieter et al., 2016; Potgieter et al., 2017).

As a free downloadable application on Android and iOS app stores *hearZA* has been marketed through sponsorships and endorsements by South African celebrities serving as hearing health ambassadors. The *hearZA* campaign and platform are utilized for several different purposes, of which hearing screening is only one. These purposes include serving as a 1) strategic public awareness tool for hearing health; 2) screening tool for hearing loss; 3) providing a personal hearing profile for tracking

hearing health; 4) decision support tool encouraging action on hearing loss developed in collaboration with the Ida Institute; 5) location-based referral system to connect persons to their closest hearing health providers in partnership with national audiological societies (Swanepoel, 2017).

Analysis of large-scale hearing screening programs, like the *hearZA* National Hearing Test, can provide indications for test-use, considerations for interpretation and measures of reach. The purpose of the study was therefore to determine characteristics and test performance of individuals that have tested themselves with the *hearZA* national hearing test App.

### **3.3. Method**

The study was reviewed and received ethical approval from the Faculty of Humanities Research Ethics Committee, University of Pretoria.

#### *Participants*

A retrospective analysis of 30321 DIN tests completed from March 2016 to August 2017 was conducted. There were 297 listeners who indicated ages of 100 years and older, of which 283 incorrectly indicated ages of 2017 or 2018 years. The remaining 14 subjects had ages 100 up to 117 years. Their data, together with listeners who kept the application's default setting of 27 years, were excluded as incorrect data entries ( $n=2175$ ). Furthermore, 4075 listeners who completed the test without headphones or earbuds were excluded to prevent confounding variables. This resulted in a total of 24072 tests for analysis. The ages of the remaining sample ranged between 5 to 99 years (*Average*: 39 years; *SD*: 16.6 years;  $n=24072$ ). Listeners were further divided into two groups based on their self-rated level of English-speaking competence. English speaking competence is rated on a non-standardized visual analogue scale of 1 to 10, a lower score indicating poorer competence and a higher score, better competence. The two groups were 1) native (N) and non-native (NN)  $\geq 6$  and 2) NN  $\leq 5$  (Potgieter et al., 2017). Pass and fail criteria were based on that of Potgieter et al. (2017), N and NN  $\geq 6$  with a cut-off of -9.55 dB and N  $\leq 5$  with a cut-off of -7.5 dB.

#### *Procedures*

Listeners completed the DIN test by downloading the application on an Android or iOS operated smartphone. Individuals were made aware of the App due to marketing

campaigns or word-of-mouth recommendations. Before the test, listeners were indicated to complete the test with either earbuds or headphones. Earlier versions of the App did not prevent test execution when earbuds or headphones are not plugged in, which was subsequently changed. The application requires listeners to provide their date of birth, home language and to rate their English speaking competence on a non-standardized scale of 1-10. Users were required to indicate whether they experience hearing difficulty by selecting “Yes” or “No” on the application. After that, listeners self-select a comfortable listening intensity. Based on the comfort level selected, the application uses a fixed overall level with an adaptive signal-to-noise ratio (SNR) (see Potgieter et al. 2016 for details). Masking noise is formed to match the long-term average speech spectrum of the digits. Speech signals are presented diotically. Listeners are expected to enter the digits heard on the smartphone, where a correct response will prompt the application to present the next digit at 2 dB lower SNR. Where the listener is uncertain of the digits heard, they are instructed to guess. When the response is incorrect, the application presents the next triplet at 2 dB higher SNR. The result is calculated by averaging the last 19 SNRs (Potgieter et al., 2016; Potgieter et al., 2017).

### *Statistics*

Data analysis was completed using Statistical Package of the Social Sciences (SPSS v23.0). Results were analyzed using one-way analysis of variance (ANOVA) and Analysis of Covariance (ANCOVA). *Post hoc* comparisons were made using the Bonferroni adjustment. A *p*-value of 0.05 was used to indicate significance. Multiple regression was performed for continuous and categorical variables to determine predictors of the SRT result. The relationships between percentile SRTs and age were determined by following the procedure as described in Smits et al. (2013). Briefly, percentile values were calculated for 11-year age groups. These age groups were shifted in 1-year steps from 20 to 94 years. The percentile values were calculated for each age group and a group-size weighted fit to an exponential growth function was performed.

### 3.4. Results

Approximately one in four persons (22.4%) who took the *hearZA* test ( $n=24072$ ) failed based on normative data by Potgieter et al. (2017). Of persons for whom self-report of hearing status was available ( $n=17611$ ), 37% reported a hearing difficulty of which 30.2% failed the test. Of those who did not self-report a hearing difficulty, 19.7% failed. The age distribution of persons taking the *hearZA* test (Figure 1) indicated that 33.2% were 30 years of age and younger, 40.5% were between 31 and 50 years of age while 26.4% were older than 50 years of age. Over 56 years, SRTs became worse and referral rates rapidly increased (Figure 2).

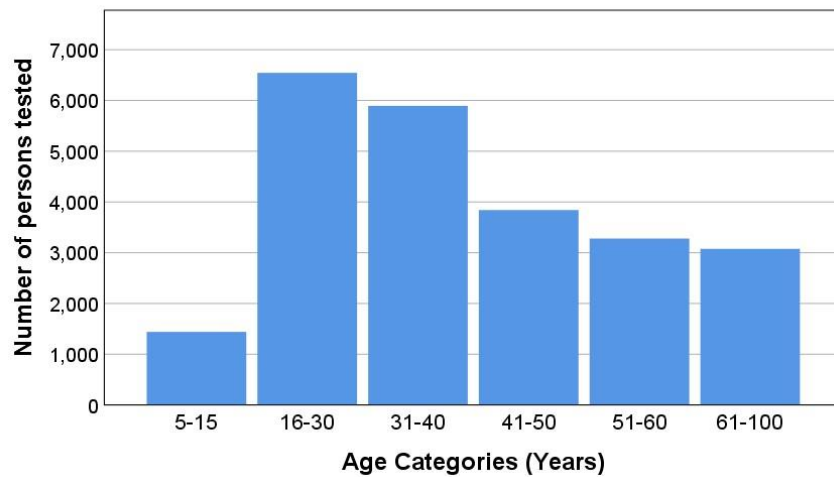


Figure 1. Age distribution of persons taking the *hearZA* test ( $n=24072$ )

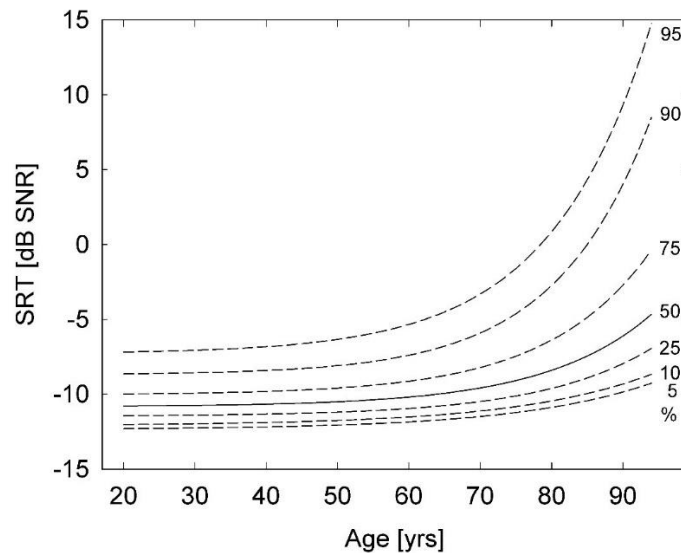


Figure 2. The SRT against age group. Percentiles are shown. SRT; speech reception threshold, dB; decibel, SNR; signal-to-noise ratio

A one way ANOVA indicated a significant effect of age groups on the SRT results ( $F[5,24066]=182$ ;  $p<0.001$ ). Listeners were further evaluated according to their level of English-speaking competence ( $n=24072$ ). Most listeners selected English as their first language ( $n=17832$ ). When divided into N & NN  $\geq 6$  ( $n=22737$ ) and NN  $\leq 5$  ( $n=1335$ ) groups based on the categories used by Potgieter et al. (2017), significant mean SRT differences between the two groups were found. NN $\leq 5$  listeners performed significantly worse than N & NN $\geq 6$  listeners (95% CI, 1.1 to 1.6;  $t[1410.9]= -11.3$ ;  $p<0.001$ ). Referral rate according to cut-off criteria by Potgieter et al. (2017) increased with age group, the highest referral rates in the 51-60 and 61-99-year groups (Table 1). After adjustment for age and level of English-speaking competence, there was a statistically significant difference ( $F[2,24067]=132.89$ ;  $p<0.001$ ; partial  $\eta^2 =0.011$ ) in SRTs between listeners without self-reported hearing difficulty ( $n=11089$ ) and with a self-reported hearing difficulty ( $n=6522$ ). SRTs in listeners with a self-reported hearing difficulty were significantly higher ( $-9.5 \pm 0.04$  dB SNR) than in listeners without a reported hearing difficulty ( $-10.2 \pm 0.02$  dB SNR), with a mean difference of 0.7 (95% CI, 0.6 to 0.8) dB SNR,  $p<0.001$ .

**Table 1. Mean SRTs and referral rates of N&NN  $\geq 6$  and NN  $\leq 5$  English speakers according to age (referral according to Potgieter et al. In Press norms)**

Age Category in years (n)	Group mean SRT in dB SNR (SD)	Number of N/ NN English Listeners	Mean SRT in dB SNR (SD)	Referral Rate (n)
5-15 (1441)	-8.5 (4.6)	N & NN $\geq 6$ : 1275 NN $\leq 5$ : 166	-8.7 (4.4) -7.2 (5.4)	No Norms
16-30 (6543)	-10.2 (2.9)	N & NN $\geq 6$ : 6217 NN $\leq 5$ : 326	-10.3 (2.8) -9 (4)	17.3% (1076) 30.7% (100)
31-40 (5893)	-10 (2.8)	N & NN $\geq 6$ : 5629 NN $\leq 5$ : 264	-10.2 (2.8) -9.1 (3.8)	18.3% (1030) 31.8% (84)
41-50 (3840)	-9.8 (2.8)	N & NN $\geq 6$ : 3662 NN $\leq 5$ : 178	-10.1 (2.7) -9.0 (4.4)	19.9% (729) 30.9% (55)
51-60 (3279)	-9.8 (2.8)	N & NN $\geq 6$ : 3082 NN $\leq 5$ : 197	-9.8 (2.7) -8.9 (3.4)	26.4% (814) 40.6% (80)
61-99 (3670)	-8.7 (3.7)	N & NN $\geq 6$ : 2872 NN $\leq 5$ : 204	-8.8 (3.6) -7.1 (5)	45.6% (1309) 57.4% (117)

*N; native, NN; non-native SRT; speech reception threshold, SD; standard deviation*

Multiple regression was conducted to determine if English speaking competence, self-reported hearing difficulty, and age were significant predictors of the SRT result. Data of 6461 listeners who did not select whether they had a known hearing problem were excluded. In the remaining sample ( $n=17611$ ), all the variables contributed significantly to the prediction ( $F[3,17067]=219.55$ ,  $p<0.001$ ); adj.  $R^2=0.04$ ). Linear regression analysis for  $N \& NN \geq 6$  ( $n=19430$ ) and  $NN \leq 5$  ( $n=1413$ ) listeners were conducted for the same variables. For  $N$  and  $NN \geq 6$  listeners, the model was significant  $F(3,16705)=146.79$ ,  $p<0.001$ ; adj.  $R^2=.02$ , with age ( $B=0.02$ ; 95% CI [0.016 to 0.021];  $p<.001$ ) and self-reported hearing difficulty ( $B=-0.53$ ; 95% CI [-0.62 to -0.44];  $p<.001$ ) contributing significantly to the prediction. Overall, the model was also significant for  $NN \leq 5$  listeners,  $F(3.898)=13.66$ ;  $p<.001$ ; adj.  $R^2=.04$ , with age ( $B=0.02$ ; 95% CI [0.01 to 0.03];  $p<.001$ ), self-reported English-speaking competence rating ( $B=-0.47$ ; 95% CI [-0.67 to -0.28];  $p<.001$ ), and self-reported hearing difficulty ( $B=-0.91$ ; 95% CI [-1.46 to -0.35]) contributing significantly to the prediction.

### **3.5. Discussion**

The *hearZA* national hearing test App had 30321 persons tested from 3 March 2016 to 14 August 2017. Overall the test had a referral rate of 22.4%. Compared to the 81% referral rate of the US national hearing test (Watson et al., 2015), the referral rate of *hearZA* was low. It is possible that *hearZA* targets a younger population group, where the prevalence of hearing loss is still low, explaining the overall low SRTs across age groups. From the tests for which self-report of a hearing problem was available, 37% reported a known hearing difficulty. Most persons who took the test (40.5%) were between 31 and 50 years of age, and 27.2% were 30 years of age and younger. The median age of the listeners was 37 years. Compared to the Dutch national hearing test (Smits et al., 2006a), the median age in this analysis was lower than both internet (40 years) and telephone version (54 years) of the test, suggesting the *hearZA* App is reaching a younger population. Over 50 years of age, test uptake dropped with less than a third (26.4%) of the sample in this category. The same pattern was seen for the Dutch National Hearing Test (Smits et al., 2006a). A study by Moore et al. (2015) linked poorer computer literacy with age among the elderly population. Although computer literacy does not necessarily relate to smartphone use, it reflects general digital literacy and limited ability and perhaps willingness to take self-testing using internet technology. Physical restrictions such as visual impairment and limited upper

extremity dexterity, typical in the aging population, were also suggested contributors to limited use of Internet-based health provision (Or et al., 2011; Moore et al., 2015). Of course, the *hearZA* marketing efforts, mostly on digital media, also biases the sample to younger populations.

Referral rates remained constant for native and non-native English-speaking listeners between the ages of 16-50 years. Over the age of 50 years, however, hearing deteriorates quickly (Smits et al., 2006b) and referral rates rapidly increase. In South Africa, a multilingual country with 11 official languages, native English speakers comprise only 9.6% of the population (STATSSA 2011). It was therefore interesting that the majority of listeners in this analysis selected English as their first language. One apparent reason for the high rate of listeners designated as native English speakers in the data set is the fact that it was the default setting on the *hearZA* App (changed subsequently). Mantonakis et al. (2009) investigated how the order of choices affects selection and found that most individuals are likely to select the first option in a sequence. Another possibility could be attributed to the fact that the test is reaching mostly native English speakers because marketing campaigns were conducted and distributed in an English medium. In line with the study of Potgieter et al. (2017), self-rated English-speaking competence was a significant predictor of the SRT. Even though some listeners may have kept the default selection of English as first language, native and non-native listeners with English speaking competence equal or better than 6 still performed significantly better than non-native listeners with ratings equal or lower than 5. The self-reported English-speaking competence rating was also a significant predictor in non-native listeners with English speaking competence  $\leq 5$ , poorer scores showing poorer SRTs

The high test uptake, especially amongst younger population groups, and the high overall referral rate (22.4%) indicates that the *hearZA* App is addressing a public health need. Although developed for adult users, there was a substantial sample ( $n=1275$ ) of listeners under 15 years of age. The ability to understand speech in noise is an intrinsic attribute of the auditory system that matures with age (Talarico et al., 2007). Koopmans et al. (2018) demonstrated the effect of age on the Dutch DIN test SRT for a group of more than 100 normal hearing children. It will, therefore, be essential to determine age-specific norms of the test for the users between the ages of 5-15 years since it is clear that parents want to use it for this purpose. Age, self-reported English-

speaking competence and hearing difficulty were all significant factors influencing test outcomes. A limitation of this analysis, however, was that results assumed that listeners correctly entered personal information such as date of birth, self-reported hearing problem, native language, non-native language English speaking competence rating, over which researchers had no control. Furthermore, between the two groups with and without self-reported listening difficulty, although statistically different, the difference was small (0.7 dB). Large distributions of SRTs in both groups likely shifted the means of the two groups, another limitation of field testing. Moreover, Pronk, Deeg and Kramer (2018) found that self-report of hearing disability is influenced by other factors such as demographics, personality, mood and social situation, causing discrepancies between self-report and DIN test results. This could also possibly account for the small difference between the two groups. Lastly, considering the effect of self-reported English-speaking competence, the SRT cut-off criteria set out for native and non-native speakers in Potgieter et al. (2017) are appropriate.

Overall, this study demonstrated widespread uptake of the *hearZA* App across age groups with a substantial number of persons self-reporting hearing problems (37%) and failing the test (22.4%). This means it is reaching an important target audience, those who think they have hearing loss. Conversely, it also reaches a high proportion of persons not yet presenting with a clear hearing problem but having taken the test are aware of their hearing status and can then track it through the App's personal profile (Swanepoel, 2017). Users are also reminded annually (via in-app notifications) to conduct follow-up tests allowing for longitudinal tracking and the possibility of early detection of hearing problems. A failed DIN test result has demonstrated positive influence on uptake of interventions (Smits et al., 2005; Watson et al., 2015). This method of self-testing should therefore, promote increased self-efficacy and accessible hearing health behaviors among users.



### 3.6. References

- 1 Cacciatore, F., Napoli, C., Abete, P., Marciano, E., Triassi, M., & Rengo, F. (1999). Quality of life determinants and hearing function in an elderly population: Osservatorio Geriatrico Campano Study Group. *Gerontology*, *45*(6), 323-328.
- 2 Ericsson. (2016). *Sub-Saharan Africa: Ericsson Mobility Report*. Retrieved from <https://www.ericsson.com/assets/local/mobility-report/documents/2016/ericsson-mobility-report-november-2016-rssa.pdf>
- 3 Fellinger, J., Holzinger, D., & Pollard, R. (2012). Mental health of deaf people. *The Lancet*, *379*(9820), 1037-1044.
- 4 Folmer, R. L., Vachhani, J., McMillan, G. P., Watson, C., Kidd, G. R., & Feeney, M. P. (2017). Validation of a Computer-Administered Version of the Digits-in-Noise Test for Hearing Screening in the United States. *Journal of the American Academy of Audiology*, *28*(2), 161-169.
- 5 Hallam, R., Ashton, P., Sherbourne, K., & Gailey, L. (2008). Persons with acquired profound hearing loss (APHL): how do they and their families adapt to the challenge?. *Health*: *12*(3), 369-388.
- 6 Hay, S. I., Jayaraman, S. P., Truelsen, T., Sorensen, R. J., Milllear, A., Giussani, G., & Beghi, E. (2017). GBD 2015 Disease and Injury Incidence and Prevalence Collaborators. Global, regional, and national incidence, prevalence, and years lived with disability for 310 diseases and injuries, 1990-2015: a systematic analysis for the Global Burden of Disease Study 2015 (vol 388, pg 1545, 2016). *Lancet*, *389*(10064), E1-E1.
- 7 Jansen, S., Luts, H., Wagener, K. C., Frachet, B., & Wouters, J. (2010). The French digit triplet test: A hearing screening tool for speech intelligibility in noise. *International Journal of Audiology*, *49*(5), 378-387.
- 8 Koopmans, W. J., Goverts, S. T., & Smits, C. (2018). Speech Recognition Abilities in Normal-Hearing Children 4 to 12 Years of Age in Stationary and Interrupted Noise. *Ear and hearing*.
- 9 Mackenzie, I., & Smith, A. (2009). Deafness—the neglected and hidden disability. *Annals of Tropical Medicine & Parasitology*, *103*(7), 565-571.

- 10 Mantonakis, A., Rodero, P., Lesschaeve, I., & Hastie, R. (2009). Order in choice: Effects of serial position on preferences. *Psychological Science*, *20*(11), 1309-1312.
- 11 Moore, A. N., Rothpletz, A. M., & Preminger, J. E. (2015). The effect of chronological age on the Acceptance of Internet-Based Hearing Health Care. *American Journal of Audiology*, *24*(3), 280-283.
- 12 Or, C. K., Karsh, B. T., Severtson, D. J., Burke, L. J., Brown, R. L., & Brennan, P. F. (2011). Factors affecting home care patients' acceptance of a web-based interactive self-management technology. *Journal of the American Medical Informatics Association*, *18*(1), 51-59.
- 13 Paglialonga, A., Tognola, G., & Grandori, F. (2014). A user-operated test of suprathreshold acuity in noise for adult hearing screening: the SUN (Speech Understanding in Noise) test. *Computers in biology and medicine*, *52*, 66-72.
- 14 Potgieter, J. M., Swanepoel, D. W., Myburgh, H. C., Hopper, T. C., & Smits, C. (2016). Development and validation of a smartphone-based digits-in-noise hearing test in South African English. *International Journal of Audiology*, *55*, 405–411.
- 15 Potgieter, J.M., Swanepoel, D.W., Myburgh, H.C. & Smits, C. (2017). The South African English Smartphone Digits-in-Noise Hearing Test: Effect of Age, Hearing Loss and Speaking Competence. *Ear and Hearing*.
- 16 Pronk, M., Kramer, S. E., Davis, A. C., Stephens, D., Smith, P. A., Thodi, C., ... & Grandori, F. (2011). Interventions following hearing screening in adults: a systematic descriptive review. *International Journal of Audiology*, *50*(9), 594-609.
- 17 Pronk, M., Deeg, D., Versfeld, N.J., Heymans, M.W., Naylor, G. & Kramer, S.E. (2016). Predictors of help-seeking and hearing-aid uptake in older persons with hearing loss. *The Gerontologist*, *56*(13), 303.
- 18 Pronk, M., Deeg, D. J., & Kramer, S. E. (2018). Explaining Discrepancies Between the Digit Triplet Speech-in-Noise Test Score and Self-Reported Hearing Problems in Older Adults. *Journal of Speech, Language, and Hearing Research*, 1-14.
- 19 Ruben, R. J. (2015). How did otolaryngology-head & neck surgery become an essential medical discipline for the 21st century? *International Journal of Pediatric Otorhinolaryngology*, *79*(6), 783-785.

- 20 Sheikh Rashid, M., Leensen, M. C., de Laat, J. A., & Dreschler, W. A. (2017). Laboratory evaluation of an optimised internet-based speech-in-noise test for occupational high-frequency hearing loss screening: Occupational Earcheck. *International journal of audiology*, 56(11), 844-853.
- 21 Smits, C., Kapteyn, T. S., & Houtgast, T. (2004). Development and validation of an automatic speech-in-noise screening test by telephone. *International Journal of Audiology*, 43(1), 15-28.
- 22 Smits, C., & Houtgast, T. (2005). Results from the Dutch speech-in-noise screening test by telephone. *Ear and hearing*, 26(1), 89-95.
- 23 Smits, C., Merkus, P. & Houtgast, T. (2006a). How we do it: The Dutch functional hearing–screening tests by telephone and internet. *Clinical Otolaryngology*, 31(5), 436-440.
- 24 Smits, C., Kramer, S.E., Houtgast, T. (2006b) Speech reception thresholds in noise and self-reported hearing disability in a general adult population. *Ear and Hearing*; 27(5): 538-49.
- 25 Smits, C., Theo Goverts, S., & Festen, J. M. (2013). The digits-in-noise test: assessing auditory speech recognition abilities in noise. *The Journal of the Acoustical Society of America*, 133(3), 1693-1706.
- 26 Statistics South Africa (STATSSA). (2011). *Census in brief, South Africa*. Retrieved from <http://www.statssa.gov.za/publications/P03014/P030142011.pdf>
- 27 Statistics South Africa (STATSSA). (2013). *General Household Survey*. Retrieved from: <http://www.statssa.gov.za/publications/P0318/P03182013.pdf>
- 28 Swanepoel, D. W. (2017). Smartphone-based National Hearing Test Launched in South Africa. *The Hearing Journal*, 70(1), 14-16.
- 29 Talarico, M., Abdilla, G., Aliferis, M., Balazic, I., Giaprakis, I., Stefanakis, T., ... & Paolini, A. G. (2007). Effect of age and cognition on childhood speech in noise perception abilities. *Audiology and Neurotology*, 12(1), 13-19.
- 30 The Economist. (2015). *Planet of the phones*. Retrieved from <http://www.economist.com/news/leaders/21645180-smartphone-ubiquitous-addictive-and-transformative-planet-phones>

- 31 Tucci, D. L., Merson, M. H., & Wilson, B. S. (2010). A summary of the literature on global hearing impairment: current status and priorities for action. *Otology & Neurotology*, 31(1), 31-41.
- 32 Vlaming, M. S., MacKinnon, R. C., Jansen, M., & Moore, D. R. (2014). Automated screening for high-frequency hearing loss. *Ear and hearing*, 35(6), 667.
- 33 Vos, T., Barber, R. M., Bell, B., Bertozzi-Villa, A., Biryukov, S., Bolliger, I., ... & Dicker, D. (2015). Global Burden of Disease Study 2013 Collaborators. Global, regional, and national incidence, prevalence, and years lived with disability for 301 acute and chronic diseases and injuries in 188 countries, 1990-2013: a systematic analysis for the Global Burden of Disease Study 2013. *Lancet*, 386(9995), 743-800.
- 34 Watson, C. S., Kidd, G. R., Miller, J. D., Smits, C., & Humes, L. E. (2012). Telephone screening tests for functionally impaired hearing: Current use in seven countries and development of a US version. *Journal of the American Academy of Audiology*, 23(10), 757-767.
- 35 Watson, C. S., Kidd, G. R., Preminger, J. E., Miller, J. D., Maki, D. P., & Crowley, A. (2015). Benefits of a telephone-administered national screening test. *Audiology Online*, 27(6), 1-8.
- 36 Wilson, B. S., Tucci, D. L., Merson, M. H., & O'Donoghue, G. M. (2017). Global hearing health care: new findings and perspectives. *The Lancet*.
- 37 World Health Organisation. (2017). *Deafness and Hearing Loss Factsheet*. Retrieved from <http://www.who.int/mediacentre/factsheets/fs300/en/>
- 38 Zokoll, M. A., Wagener, K. C., Brand, T., Buschermöhle, M., & Kollmeier, B. (2012). Internationally comparable screening tests for listening in noise in several European languages: The German digit triplet test as an optimization prototype. *International Journal of Audiology*, 51(9), 697-707.

## 4. IMPROVING ACCESS TO GLOBAL HEARING CARE USING A NOVEL mHEALTH APPROACH

Authors: Karina C. De Sousa, De Wet Swanepoel, Cas Smits, David R. Moore

Journal: Bulletin of the World Health Organization<sup>2</sup>

Submitted: 13 June 2018

### 4.1. Abstract

**Background:** Hearing loss is a growing global health concern affecting close to 1.3 billion people annually. Functional impairment of hearing loss can be significantly reduced through detection and treatment, but most cases remain undiagnosed. We assessed a method for a self-administered smartphone hearing test that can increase sensitivity and breadth of detection to all major forms of hearing loss.

**Methods:** We did a cross-sectional study, recruiting adult listeners with normal hearing ( $n=51$ ; pure tone average thresholds (PTA)  $\leq 25$  dB HL in both ears), symmetric sensorineural hearing loss ( $n=47$ ; PTA  $\geq 26$  dB HL) and asymmetric sensorineural hearing loss ( $n=24$ ; PTA  $\geq 26$  dB HL in the poorer ear). We compared the new, dichotic (binaural, antiphase speech) digits-in-noise (DIN) test with a conventional diotic (in-phase) test of speech reception threshold (SRT) using a repeated measure balanced Latin square design.

**Findings:** Dichotic testing was more sensitive and specific than diotic testing to both symmetric and asymmetric hearing loss. Dichotic area under Receiver Operating Characteristic curve (0.94), and linear regression slope (0.18) and correlation (0.84) with SRT were higher than diotic (0.84, 0.08 and 0.79 respectively). The extent of asymmetric hearing loss (poorer ear PTA) was unrelated to SRT.

**Conclusion:** The new dichotic test provides an accurate test that is sensitive to all major forms of hearing loss. Using a simple, self-administered smartphone application for this test can scale accurate detection at a fraction of current costs. Population-wide access to early detection can improve the capacity to prevent and address undetected hearing loss globally.

---

<sup>2</sup> This article was edited in accordance with the editorial specifications required by the journal and may differ from the editorial style of the rest of this document.

## 4.2. Introduction

Hearing loss is a growing global health concern as the 4<sup>th</sup> leading contributor to years lived with disability, affecting close to 1.3 billion people annually.<sup>1</sup> The global economic cost associated with hearing loss is estimated at 750 billion dollars annually.<sup>2</sup> Even so, hearing loss continues to be an invisible epidemic, with limited public health support, especially in low-and-middle-income countries (LMICs) where incidence is high<sup>3</sup> and resources are scarce and unequally distributed.<sup>3-6</sup> Consequences of unaddressed hearing loss include impaired communication<sup>7,8</sup> and psychosocial well-being.<sup>9</sup> Close links to dementia have also been found, with hearing loss as one of the primary modifiable risk factors.<sup>10,11</sup> WHO estimates that close to 50% of hearing loss can be prevented and that most of the remainder can be treated efficiently.<sup>2</sup> Although the functional impairment of hearing loss can be significantly reduced through early detection and treatment, a high proportion of cases remains undiagnosed.<sup>4,5</sup> The growing importance of this issue led to the adoption of a hearing loss prevention resolution by the World Health Assembly (WHA) in 2017.<sup>12</sup> This resolution calls on hearing healthcare stakeholders to develop and implement strategies for improved service provision, especially in LMICs.<sup>12,13</sup>

Capitalising on advances in mobile phone penetration, mHealth solutions provide a unique opportunity for innovative hearing health service-delivery models that can dramatically improve access to and uptake of care.<sup>14</sup> By the year 2020, access to smartphones is estimated to be 80% globally.<sup>15</sup> While applicable worldwide, using a mobile platform can specifically address the major gap in hearing healthcare resources affecting LMICs. In sub-Saharan Africa for instance, there is only one audiologist to every million people.<sup>6</sup> The recent innovation of a smartphone hearing test that uses digits presented in background noise provides a rapid self-test consumer solution for population-based screening.<sup>16,17</sup> Typically, hearing loss is assessed by pure tone audiometry and expressed in decibels hearing level (dB HL). However, these measurements are reliant on some sound booth, specific calibrated audiometric equipment and trained personnel. The Digits-in-Noise (DIN) test uses recorded digit triplets (e.g. 4-2-7) presented in background noise to determine the level of the digits relative to the noise level (signal-to-noise ratio, SNR) where a person can identify 50% of the digit triplets correctly (speech reception threshold, SRT). DIN test assessment of sensorineural hearing loss correlates highly with conventional audiometric test

assessment and eliminates the need for a sound booth, calibrated equipment, and a test administrator.<sup>16,17</sup> However, presentation of identical signals to both ears simultaneously (diotic stimulation) in the standard DIN test does not detect unilateral or conductive hearing loss. Listeners with asymmetric hearing loss may pass diotic DIN test because performance is primarily based on the better ear. Sequential testing of each ear would double test time and may reduce test uptake as a result.

In this study, we assessed the use of a novel test method of the DIN smartphone hearing test using speech that had a 180° phase shift between the ears (dichotic presentation). A dichotic DIN test could allow dramatically increased sensitivity and breadth of detection across all major forms of hearing loss, without increasing test duration. The objective of this study was to determine whether this new test method improves test characteristics for (1) detecting symmetric sensorineural hearing loss and (2) detecting asymmetric sensorineural hearing loss. This technology has the potential to make accurate population-based hearing screening affordable and accessible in LMICs, with additional supporting functions possible for location-based referrals and interventions. Furthermore, as a preventative strategy, self-administered, population-wide hearing screening can play a significant role in addressing the growing burden of unchecked hearing loss.

### **4.3. Method**

#### **Study design and sample**

We conducted a cross-sectional study of the DIN SRT comparing diotic and dichotic presentation within and between listeners with varying hearing levels. A repeated measure balanced Latin square design was used to counteract test order bias. We recruited adult listeners with normal hearing ( $n=51$ ; pure tone average (PTA) audiometric threshold at 0.5, 1, 2 and 4 kHz,  $PTA \leq 25$  dB HL in both ears), symmetric sensorineural hearing loss ( $n=47$ ;  $PTA \geq 26$  dB HL) and asymmetric sensorineural hearing loss ( $n=24$ ;  $PTA \geq 26$  dB HL in the poorer ear) from a student population, University clinic, and hospital and private practices in the Gauteng province of South Africa. Asymmetric hearing loss was defined as an interaural difference  $> 10$  dB (PTA). Hearing sensitivity categories were based on poorer ear PTA and categorized as excellent (0-15 dB HL), good (16-25 dB HL), mild (26-40 dB HL), moderate (41-55 dB HL) and severe-to-profound (56-120 dB HL). Listeners had various levels of English

speaking competence. Non-native English speakers self-reported their level of competence on a non-standardized scale from 1-10, a higher score indicating better competence.

The Health Sciences Research Ethics Committee, University of Pretoria approved the study protocol (number 58/2017). All eligible persons were informed of the study aims and procedures and provided consent before participation.

### **Procedures**

All listeners underwent diagnostic pure tone audiometry at octave frequencies from 250 Hz to 8000 Hz to determine their type, degree and configuration of hearing loss. They then completed five 3-minute DIN tests on a Samsung Trend Neo smartphone with manufacturer supplied (wired) earbuds. The first training test used dichotic presentation. The remaining four DIN tests alternated between dichotic and diotic with a test and retest for each presentation. Diotic presentation applied identical speech and noise signals to both ears. For dichotic presentation, a 180° phase shift was applied to the speech signals in one ear, while keeping noise identical to both ears. Each DIN test compiled a list of 23 digit-triplets that were randomly selected for presentation at the beginning of each test.<sup>16</sup> Before the test, listeners self-selected a comfortable listening level. For both test presentations, the application used an adaptive procedure starting at 0 dB SNR; correct responses decreased the SNR by 2 dB, while incorrect responses improved the SNR by 2 dB.<sup>16</sup> The SRT was calculated by averaging the last 19 SNRs.<sup>16</sup>

### **Statistical Analysis**

We did all statistical analysis using SPSS (IBM SPSS v25.0). A sample size of 122 listeners (24 with normal hearing  $PTA \leq 25$  dB HL, 24 with asymmetric hearing losses and 74 with either symmetric normal hearing  $PTA \leq 25$  dB HL or hearing loss with  $PTA \geq 26$  dB HL) would provide a medium effect size (Cohen's  $f=0.25$ ), with 80% statistical power at a two-sided significance level of 0.05, to test both hypotheses. The effect of test method, symmetry of hearing loss and repetition number on the SRT was assessed using separate repeat-measures analysis of variance (ANOVA). Post hoc comparisons used Bonferroni adjustment for multiple comparisons. In cases where sphericity was violated, Greenhouse-Geisser corrections were applied. Analysis of covariance (ANCOVA) was run to determine the effect of age and English-speaking



competence on the dichotic SRT. General linear regression was used to test whether the slope of the relation between PTA and SRT differs between Dichotic and Diotic testing. Intraclass correlation coefficients (ICC) were calculated for the test and retest measurements for the dichotic and diotic presentations and were based on a mean rating ( $k=2$ ), absolute agreement and a 2-way mixed-effects model. All subsequent analysis was conducted by averaging the test-retest SRT values for the diotic and dichotic test method. Associations between poorer ear PTA and SRT were examined using Pearson's correlation. Results in the three hearing categories and five categories of PTA hearing sensitivity were assessed using ANOVA. Receiver Operating Characteristic (ROC) curves were calculated to determine sensitivity and specificity of the DIN tests to detect mild hearing loss and worse (PTA > 25 dB HL) and moderate hearing loss and worse (PTA > 40 dB HL).

#### 4.4. Results

Listeners with normal hearing had more sensitive SRTs than those with hearing loss using both dichotic and diotic testing (Fig. 1). However, dichotic testing was much more sensitive to either form of hearing loss than diotic testing (Table 1). Other results in Fig. 1 show a small training effect (improved SRT) following the first presentation of all tests, and an interaction between symmetry of hearing loss and type of test (dichotic, diotic; Table 1).

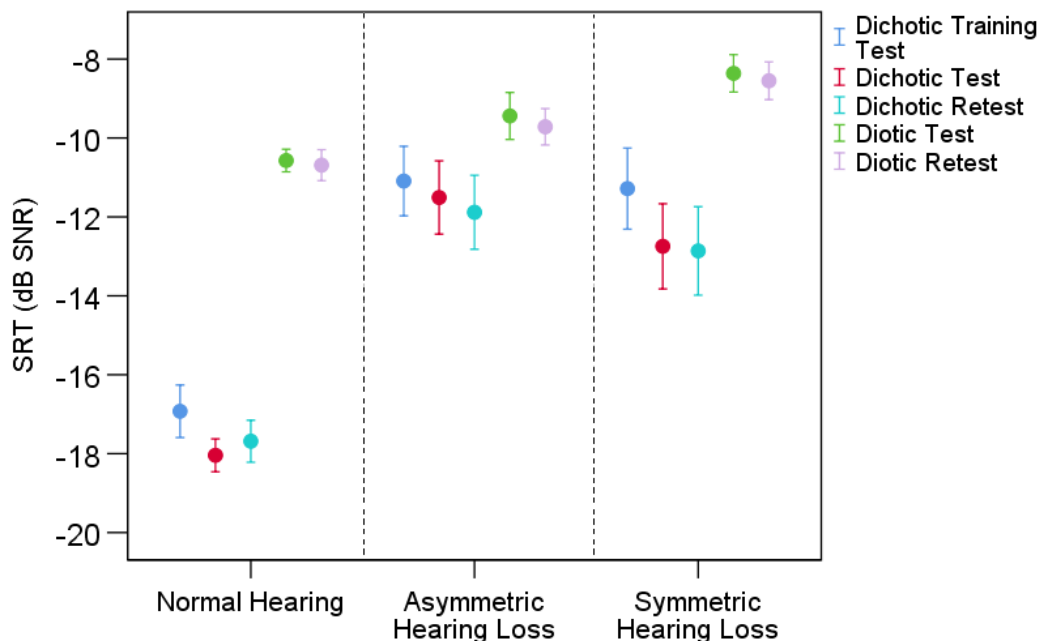
No effect of self-reported English competence on dichotic SRT was observed. Listeners were divided into high competence (>7;  $n=62$ ) and low competence ( $\leq 7$ ;  $n=60$ ) groups. After controlling for poorer ear PTA and age, no significant difference was found between the two groups on analysis of covariance ( $F[1,118]=0.40$ , partial  $\eta^2=0.003$ ).

Audiogram PTAs of listeners with normal hearing and symmetric hearing loss were strongly correlated with both dichotic ( $r[96]=0.84$ ) and diotic ( $r[96]=0.79$ ) SRTs (Figure 2). However, the slope of the fitted regression was much steeper for the dichotic SRTs ( $t(1)=-4.14$ ,  $p<.0001$ ), suggesting greater sensitivity of the dichotic test. Extent of asymmetric hearing loss (poorer ear PTA) was unrelated to SRT. Asymmetric loss generally resulted in higher dichotic (but not diotic) SRTs. However, three listeners with asymmetric loss had dichotic SRT in the normal range.

SRT test-retest reliability was high for both diotic and dichotic presentation, with all ICCs > 0.84 ( $p < 0.001$ ). ROC analysis including all listeners (Fig. 3) showed higher areas under the curve for dichotic (0.94; poorer ear PTA > 25 dB HL and > 40 dB HL) than for diotic SRT (0.85 and 0.78, respectively). Dichotic SRT was, therefore, more sensitive and specific to symmetric sensorineural hearing loss compared to diotic SRT.

Source		df	F	Sig
Training:	Dichotic repetition	2	17.09	< .001
	Error	242		
Training:	Diotic repetition	1	3.36	.069
	Error	121		
Test type:	Dichotic, Diotic	1	556.43	< .001
	Error	121		
Interaction:	Test type* Hearing category	2	57.29	< .001
	Error	119		

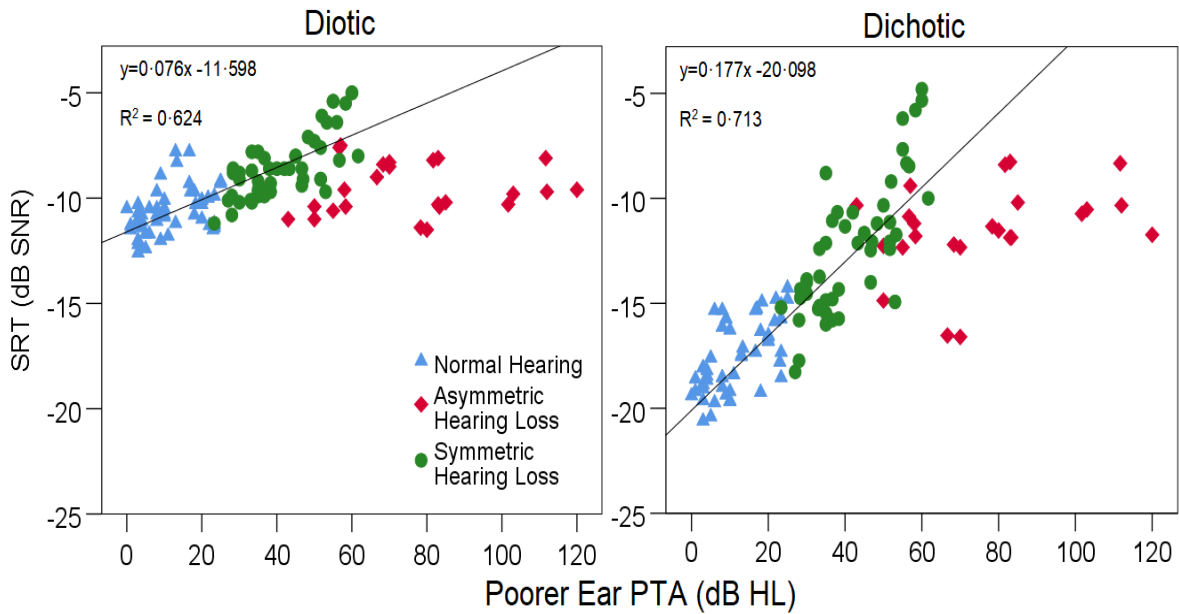
**Table 1. Analysis of variance statistics for the effect of test presentation, repetition and symmetry of hearing loss on the SRT.**



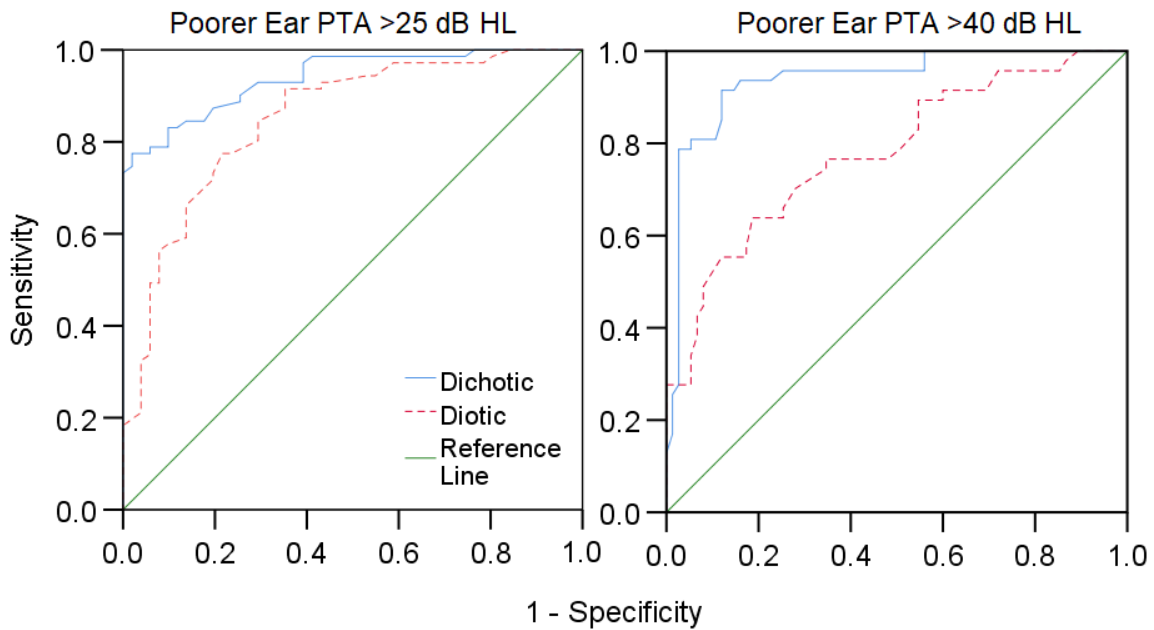
**Figure 1. Diotic and dichotic SRT according to hearing categories.** Dichotic SRTs produced larger threshold differences between hearing categories. SRT= speech reception threshold; dB=decibel; SNR= signal to noise ratio. Error bars indicate  $\pm 2$  standard errors from the mean.

			Excellent (0-15 dB)	Good (16-25 dB)	Mild (26-40 dB)	Moderate (41-55 dB)	Severe- profound (56-120 dB)
Normal hearing & symmetric hearing loss		<i>n</i>	31	20	24	17	6
		Age Range (Years)	19-84	23-84	47-84	51-84	71-79
	Diotic	Mean SRT(SD) SE	-10.9 (1.1) 0.19	-10.3 (1) 0.21	-9.3 (0.8) 0.17	-7.9 (1.4) 0.33	-6.4 (1.5) 0.59
	Dichotic	Mean SRT(SD) SE	-18.5 (1.3) 0.25	-16.7 (1.2) 0.30	-14.9 (2.4) 0.45	-11.7 (2.3) 0.51	-7.2 (2.1) 0.85
		<i>n</i>	0	0	0	4	20
Asymmetric hearing loss		Age Range (Years)	-	-	-	25-63	18-72
	Diotic	Mean SRT(SD) SE	-	-	-	-10.8 (0.3) 0.15	-9.6 (1.2) 0.27
	Dichotic	Mean SRT(SD) SE	-	-	-	-12.6 (2.1) 0.93	-11.5 (2.3) 0.49
		<i>n</i>	0	0	0	4	20
		Age Range (Years)	-	-	-	25-63	18-72

**Table 2. Diotic and Dichotic SRT for listeners with normal hearing, symmetric and asymmetric hearing loss according to PTA (0.5, 1, 2 & 4 kHz) hearing loss categories**



**Figure 2. Correlation of diotic and dichotic SRTs with poorer ear PTA.** Solid lines are regression lines fitted to Normal Hearing and Symmetric Hearing Loss groups. SRT= speech reception threshold; dB= decibel; SNR= signal to noise ratio; PTA= pure tone average; HL= hearing level.



**Figure 3. ROC curves presenting the test characteristics of the dichotic and diotic DIN for detecting worst ear PTA<sub>0-5,1,2,4</sub> >25 dB HL (left) and >40 dB HL (right) in all listeners with normal hearing, symmetric and asymmetric hearing loss.** The hyperbolic lines indicate the true positive rate (sensitivity) against false positive rate (1-specificity).

#### 4.5. Discussion

Dichotic digit presentation improved the accuracy of the DIN smartphone hearing test, with higher sensitivity and specificity to the degree and symmetry of hearing loss than the current Diotic method. For the first time during the same, initial screen, Dichotic DIN presentation was able to detect a unilateral hearing loss, accounting for about half of all hearing loss.<sup>18</sup> These advances will enable a step-change in the quality of population-based hearing screening. Utilizing the increasing global penetration of smartphones,<sup>15</sup> we can now provide widespread access to a rapid, reliable and versatile self-administered screen.

Listeners with normal hearing in both ears are at a significant advantage for understanding speech in noise compared to those with a hearing loss in either ear. This advantage is due to several mechanisms, but the primary one is binaural integration in the brain. Spatial hearing occurs mainly because the sound from a lateral source arrives at the nearer ear earlier in time than it does at the far ear, an 'interaural time difference' (ITD). Brainstem neurons can detect ITDs as small as 10  $\mu$ s<sup>19</sup>, equal to about 2° of space.<sup>20</sup> The 180° interaural phase difference used in the Dichotic DIN simulates an ITD, separating digits from the noise. This 'spatial release from masking' (SRM)<sup>21</sup> is an important mechanism used by the brain to increase audibility of target sounds in real, noisy environments. Listeners in our study with 'excellent' and 'good' hearing had 6-8 dB better SRT in diotic than dichotic DIN, in line with previous reports.<sup>22</sup> Peripheral hearing loss disrupts ITDs by desynchronizing neural activity from affected ear(s), reducing or eliminating the dichotic advantage.<sup>23-25</sup> Predicted poorer diotic SRTs due to loss of outer hair cell function and associated cochlear compression were also observed in listeners with symmetric hearing loss.

Identical (diotic) stimulation of both ears will not result in elevated SRTs for asymmetric hearing loss because overall performance will reflect that of the better (more sensitive) ear. Normally, we listen with both ears. Stimulating both ears simultaneously provides binaural summation, increasing sensitivity, as well as more significant binaural integration described above. Listeners with unilateral hearing loss typically hear sounds well when they come from the side of the better ear, but still not so well as normal hearing listeners if there is any noise, due to loss of SRM. Some listeners, however, may have enough residual hearing in the poorer ear to achieve some

binaural advantage in dichotic presentations. In this study, 3/24 achieved dichotic SRT within the normal range.

Although not assessed, dichotic listening would likely also be affected in cases of conductive hearing loss (CHL). Acute CHL both attenuates, and delays sounds passing through the ear,<sup>26</sup> thereby disrupting dichotic processing. Chronic CHL commencing in infancy impairs dichotic listening after the CHL has resolved<sup>27,28</sup> and produces a number of neurological changes affecting binaural integration.<sup>29</sup> When the digits are presented diotically, a person with conductive hearing loss could overcome loudness deficits of the signal by increasing the overall sound level. We thus predict that the Dichotic DIN will be sensitive to both CHL and at least some forms of central auditory dysfunction. CHL in children, in the form of otitis media (OM), is relatively more prevalent among underserved, remote and poor populations than other forms of hearing loss.<sup>30,31</sup> Since the DIN can be used with children as young as 4 years,<sup>32</sup> Dichotic DIN may be a means for identification and early intervention in those populations.

The possible impact of an accurate smartphone hearing test extends globally, but the opportunity to reach people in LMICs is especially important. Close to 90% of people with disabling hearing loss reside in LMICs,<sup>33</sup> where hearing healthcare is largely unavailable. Solutions facilitating preventative care are, therefore, crucial to mitigate the consequences of undetected and untreated hearing loss. Hearing loss accompanied by breakdowns in communication, can cause a sense of intense isolation and depression in many adults.<sup>34</sup> Furthermore, hearing loss has been associated with cognitive decline and dementia, the risk for developing dementia growing with increasing degree of hearing loss.<sup>10,11</sup> Aside from the pervasive impact on an individual's health, undetected hearing loss poses substantial cost to society because of reduced educational attainments<sup>2</sup> and work productivity.<sup>35</sup> Even in high-income countries, people with hearing loss have twice the rate of unemployment compared to their normal-hearing peers.<sup>35</sup> Preventive care for avoidable causes of hearing loss and early detection facilitated by routine hearing screening could produce a dramatic reduction in the cost of untreated hearing loss.<sup>36</sup>

The sensitivity of the dichotic DIN test extends across various hearing loss types, a major innovation for a rapid test undertaken in less than 3 minutes. Following up initial

screening with other DIN variants (e.g. monaural, filtered or modulated noise) for those who failed the dichotic test could allow for differential categorisation into bilateral, asymmetric, conductive and central hearing loss. This could allow for triaging and directed referrals from cloud-based data management platforms that can optimise resource allocation. As a global initiative, development of the smartphone DIN test platform in other languages could support earlier and more equitable access to hearing care for millions.

Our study demonstrated that a dichotic test method dramatically improves accuracy of the DIN test on a smartphone. The Dichotic DIN test on a smartphone can rapidly scale early detection of hearing loss at a fraction of the current cost. Furthermore, since many cases of hearing loss are due to preventable causes, routine hearing screening can facilitate preventive care. Widespread access to a dichotic DIN test on a smartphone platform can improve the capacity to prevent and address undetected hearing loss globally.

#### **4.6. References**

- 1 Vos T, Allen C, Arora M, Barber RM, Bhutta ZA, Brown A, Carter A, Casey DC, Charlson FJ, Chen AZ, Coggeshall M. Global, regional, and national incidence, prevalence, and years lived with disability for 310 diseases and injuries, 1990–2015: a systematic analysis for the Global Burden of Disease Study 2015. *Lancet*. 2016 Oct;388(10053):1545-602.
- 2 Deafness and Hearing Loss Factsheet. Geneva: World Health Organization; 2017. Available from: <http://www.who.int/mediacentre/factsheets/fs300/en/> [cited 2018 March 26].
- 3 Stevens G, Flaxman S, Brunskill E, Mascarenhas M, Mathers CD, Finucane M. Global and regional hearing impairment prevalence: an analysis of 42 studies in 29 countries. *Eu J Public Health*. 2011 Dec;23(1):146-52.
- 4 Ki-moon DM. Hearing loss: an important global health concern. *Lancet*. 2016 Jun;387(10036):2351-478.
- 5 Mackenzie I, Smith A. Deafness—the neglected and hidden disability. *Ann Trop Med & Parasitol*. 2009 Oct;103(7):565-71.

- 6 Mulwafu W, Ensink R, Kuper H, Fagan J. Survey of ENT services in sub-Saharan Africa: little progress between 2009 and 2015. *Global Health*. 2017 Jan;10(1):1289736.
- 7 Hallam R, Ashton P, Sherbourne K, Gailey L. Persons with acquired profound hearing loss (APHL): how do they and their families adapt to the challenge?. *Health*. 2008 Jul;12(3):369-88.
- 8 Mick P, Kawachi I, Lin FR. The association between hearing loss and social isolation in older adults. *Otolaryngol Head Neck Surg*. 2014 Mar;150(3):378-84.
- 9 Fellingner J, Holzinger D, Pollard R. Mental health of deaf people. *Lancet*. 2012 Mar;379(9820):1037-44.
- 10 Lin FR, Metter EJ, O'Brien RJ, Resnick SM, Zonderman AB, Ferrucci L. Hearing loss and incident dementia. *Arch Neurol*. 2011 Feb;68(2):214-20.
- 11 Livingston G, Sommerlad A, Orgeta V, Costafreda SG, Huntley J, Ames D, Ballard C, Banerjee S, Burns A, Cohen-Mansfield J, Cooper C. Dementia prevention, intervention, and care. *Lancet*. 2017 Dec;390(10113):2673-734.
- 12 WHA70.13. World Health Assembly resolution on prevention of deafness and hearing loss: In: Seventieth World Health Assembly, Geneva, 31 May 2017. Geneva: World Health Organization; 2017.
- 13 Chadha S, Cieza A, Krug E. Global hearing health: future directions. *Bull World Health Organ*. 2018 Mar;96(3):146.
- 14 Wilson BS, Tucci DL, Merson MH, O'Donoghue GM. Global hearing health care: new findings and perspectives. *Lancet*. 2017 Jul.
- 15 Planet of the phones. *The Economist*; 2015. Available from: <http://www.economist.com/news/leaders/21645180-smartphone-ubiquitous-addictive-and-transformative-planet-phones> [cited 2018 March 26].
- 16 Potgieter JM, Swanepoel DW, Myburgh HC, Hopper TC, Smits C. Development and validation of a smartphone-based digits-in-noise hearing test in South African English. *Int J Audiol*. 2016 Jul;55(7):405-11.
- 17 Potgieter JM, Swanepoel W, Myburgh HC, Smits C. The South African English Smartphone Digits-in-Noise Hearing Test: Effect of Age, Hearing Loss, and Speaking Competence. *Ear Hear*. 2017 Nov.
- 18 Agrawal Y, Platz EA, Niparko JK. Prevalence of hearing loss and differences by demographic characteristics among US adults: data from the National Health and



- Nutrition Examination Survey, 1999-2004. *Arch Int Med*. 2008 Jul;168(14):1522-30.
- 19 Brughera A, Dunai L, Hartmann WM. Human interaural time difference thresholds for sine tones: the high-frequency limit. *J Acoust Soc Am*. 2013 May;133(5):2839-55.
- 20 Middlebrooks JC, Green DM. Sound localization by human listeners. *Ann Rev Clin Psychol*. 1991 Feb;42(1):135-59.
- 21 Freyman RL, Balakrishnan U, Helfer KS. Spatial release from informational masking in speech recognition. *J Acoust Soc Am*. 2001 May;109(5):2112-22.
- 22 Smits C, Theo Goverts S, Festen JM. The digits-in-noise test: assessing auditory speech recognition abilities in noise. *J Acoust Soc Am*. 2013 Mar;133(3):1693-706.
- 23 Welsh LW, Rosen LF, Welsh JJ, Dragonette JE. Functional impairments due to unilateral deafness. *Ann Otol Rihmol*. 2004 Dec;113(12):987-93.
- 24 Jerger J, Smith MS. Effect of Peripheral Hearing Loss. *Arch Otolaryngol*. 1984;110:290-6.
- 25 Vannson N, James CJ, Fraysse B, Lescure B, Strelnikov K, Deguine O, Barone P, Marx M. Speech-in-noise perception in unilateral hearing loss: Relation to pure-tone thresholds and brainstem plasticity. *Neuropsychologia*. 2017 Jul;102:135-43.
- 26 Hartley DE, Moore DR. Effects of conductive hearing loss on temporal aspects of sound transmission through the ear. *Hear Research*. 2003 Mar;177(1-2):53-60.
- 27 Moore DR, Hutchings ME, Meyer SE. Binaural masking level differences in children with a history of otitis media. *Audiology*. 1991 Jan;30(2):91-101.
- 28 Pillsbury HC, Grose JH, Hall JW. Otitis media with effusion in children: binaural hearing before and after corrective surgery. *Arch Otolaryngol Head Neck Surg*. 1991 Jul;117(7):718-23.
- 29 Polley DB, Thompson JH, Guo W. Brief hearing loss disrupts binaural integration during two early critical periods of auditory cortex development. *Nat Commun*. 2013 Sep;4:2547.
- 30 Hunter LL, Davey CS, Kohtz A, Daly KA. Hearing screening and middle ear measures in American Indian infants and toddlers. *Int J Pediatr Otorhinolaryngol*. 2007 Sep;71(9):1429-38.

- 31 Cameron S, Dillon H, Glyde H, Kanthan S, Kania A. Prevalence and remediation of spatial processing disorder (SPD) in Indigenous children in regional Australia. *Int J Audiol*. 2014 May;53(5):326-35.
- 32 Koopmans WJ, Goverts ST, Smits C. Speech Recognition Abilities in Normal-Hearing Children 4 to 12 Years of Age in Stationary and Interrupted Noise. *Ear Hear*. 2018 May.
- 33 Community-based rehabilitation: promoting ear and hearing care through CBR. Geneva: World Health Organization; 2012. Available from: <http://www.who.int/pbd/deafness/news/CBREarHearingCare.pdf> [cited 2018 March 26].
- 34 Mick P, Kawachi I, Lin FR. The association between hearing loss and social isolation in older adults. *Otolaryngol Head Neck Surg*. 2014 Mar;150(3):378-84.
- 35 Ruben RJ. How did otolaryngology–head & neck surgery become an essential medical discipline for the 21st century?. *Int J Pediatr Otorhinolaryngol*. 2015 Jun;79(6):783-5.

## 5. DISCUSSION AND CONCLUSION

### 5.1. Discussion of Results

Analysis of large-scale hearing detection programmes, like that of *hearZA* provides valuable insight regarding consumers and test reach. This study determined the characteristics and test performance of users who completed the standard diotic DIN test. Furthermore, this study was the first to explore a binaural, dichotic test paradigm that could produce increased sensitivity of the test to unilateral and asymmetric hearing loss. Results indicated that dichotic speech presentation improved the accuracy of the binaural smartphone DIN test with higher sensitivity to symmetry and degree of hearing loss compared to standard diotic speech.

#### Study Aim #1

The *hearZA* national hearing test app had 30321 persons tested using the diotic DIN test version from March 3, 2016 to August 14, 2017. Overall the test had a referral rate of 22.4%. Compared with the 81% referral rate of the U.S. national hearing test (Watson et al., 2015), the referral rate of *hearZA* was low. The most likely explanation for this discrepancy is that *hearZA* targets a younger population group, where prevalence of hearing loss is low, accounting for the overall low SRTs across age groups. Also, since the binaural diotic test is not sensitive to unilateral and conductive hearing loss, it is possible that a portion of listeners with the latter types of hearing loss had a false-negative outcome. Where self-report of a hearing problem was available, 37% reported a known hearing difficulty. Most App users (40.5%) were between 31 and 50 years of age and 27.2% were 30 years of age and younger. The median age of listeners was 37 years. When compared to the Dutch National Hearing Test (Smits et al., 2006), the median age in this study was lower than both Internet (40 years) and telephone versions (54 years) of the test, suggesting that the *hearZA* app is reaching a younger population group. Over 50 years of age, test uptake dropped with less than a third (26.4%) of the sample in this category. The same was seen for the Dutch National Hearing Test. It has been suggested that among the elderly population, computer literacy is poorer (Moore, Rothpletz, & Preminger, 2015). Although computer literacy does not necessarily relate to smartphone use, it reflects general digital literacy and limited ability, and, perhaps, willingness to complete self-testing using Internet technology. Furthermore, physical restrictions such as visual impairment and limited

upper extremity dexterity, typical in ageing populations, were also suggested contributors to the limited use of digital health provision (Moore et al., 2015; Or et al., 2011). Of course, it is important to note that *hearZA* marketing efforts, mostly on digital media, also bias the sample to younger users.

Referral rates remained constant for N and NN English-speaking listeners between the ages of 16 and 50 years. Over the age of 50 years, however, hearing deteriorates quickly (Smits, Kramer, & Houtgast, 2006), and referral rates rapidly increase. In South Africa, a multilingual country with 11 official languages, N English speakers comprise only 9.6% of the population (Statistics South Africa, 2011). It was therefore interesting that most listeners in this analysis selected English as their first language. One apparent reason for the high rate of listeners designated as N English speakers in the data set is the fact that it was the default setting on the *hearZA* app (changed subsequently). Mantonakis, Rodero, Lessechaeve, and Hastie (2009) investigated how the order of choices affects selection and found that most individuals are likely to select the first option in a sequence. Another possibility could be attributed to the fact that the test is reaching mostly N English speakers because marketing campaigns were conducted and distributed in an English medium. In line with the study of Potgieter et al. (2017), self-rated English-speaking competence was a significant predictor of SRT. Although some listeners may have kept the default selection of English as the first language, English-speaking competence equal or better than 6 still performed significantly better than NN listeners with ratings equal or lower than 5. The self-reported English-speaking competence rating was also a significant predictor in NN listeners with English-speaking competence  $\leq 5$ , poorer scores showing poorer SRTs.

The high test uptake, especially among younger population groups indicates that the *hearZA* app is addressing a public health need. Although developed for adult users, there was a substantial sample ( $n=1275$ ) of listeners under 15 years of age. The ability to understand speech in noise is an intrinsic attribute of the auditory system that matures with age (Talarico et al., 2007). Koopmans, Goverts, and Smits (2018) demonstrated the effect of age on the Dutch DIN test SRT for a group of more than 100 children with normal hearing. It will, therefore, be essential to determine age-specific norms of the test for users between the ages of 5 and 15 years since it is clear

that parents want to use it for this purpose. Age, self-reported English-speaking competence, and hearing difficulty were all significant factors influencing test outcomes. Between the two groups with and without self-reported hearing difficulty, although statistically different, the difference was small (0.7 dB). Pronk, Deeg, and Kramer (2018) found that the self-report of hearing disability is influenced by other factors, such as demographics, personality, mood, and social situation, causing discrepancies between self-report and DIN test results. This could account for the small difference between groups.

## **Study Aim #2**

### *Dichotic presentation on symmetric normal hearing and hearing loss*

Correlations of the dichotic SRT to  $PTA_{0.5,1,2,4}$  were stronger for listeners with symmetric normal hearing and hearing loss ( $r=0.88$ ) compared to previous monaural Dutch ( $r=0.72$ ), French ( $r=0.77$ ) and American English ( $r=0.74$ ) telephone versions (Jansen et al., 2010; Smits et al., 2004; Watson et al., 2012). The correlation was also better than the binaural diotic smartphone test version used in this study ( $r=0.79$ ). Furthermore, dichotic SRTs demonstrated greater threshold differences between five  $PTA_{0.5,1,2,4}$  hearing sensitivity categories. Typically, listeners with normal binaural hearing are at a significant advantage for understanding speech in noise compared to those with a hearing loss in either ear. This advantage is achieved through multiple mechanisms, of which the primary one is binaural integration in the brain. Interaural time differences (ITD) are created when sound from a lateral source arrives at the nearer ear earlier than it does the far ear. With spatial processing, brainstem neurons can detect ITDs as small as 10  $\mu$ s (Brughera, Dunai, & Hartman, 2013) equal to about 2° of space (Middlebrooks & Green, 1991). In the dichotic DIN test, the 180° interaural phase difference simulates an ITD, separating the target speech from the noise. The phase reversal improves speech perception, commonly known as spatial release from masking (SRM), which is an essential mechanism of the brain to increase audibility of target signals in real, noisy environments (Freyman, Balakrishnan, & Helfer, 2001). Further enhancing speech perception in normal binaural hearing, is binaural summation. Having two neural representations of a target signal further enhances speech perception in noise with 1 to 3 dB (Smits et al., 2016). Benefitting from both auditory mechanisms, listeners with 'excellent' and 'good' hearing achieved 6-8 dB

better SRT in the dichotic than diotic DIN, in line with previous reports (Smits et al., 2016). Peripheral hearing loss, however, disrupts the ITD by desynchronizing neural activity in the affected ear(s), reducing the SNR improvement typically enjoyed in dichotic listening (Jerger, Brown, & Smith, 1984; Vannson et al., 2017; Welsh, Rosen, Welsh, & Dragonette, 2004). Poorer diotic SRTs due to loss of cochlear hair cell function and related cochlear compression were also observed in listeners with symmetric hearing loss.

#### *Dichotic presentation on unilateral and asymmetric hearing loss*

Diotic digit presentation to both ears will not result in elevated SRTs for asymmetric hearing loss because overall performance will reflect that of the better (more sensitive) ear. In this study, listeners with moderate hearing loss in their poorer ear had similar mean diotic SRTs compared to listeners with excellent bilateral hearing. Also, listeners with severe to profound unilateral hearing loss had mean diotic SRT scores corresponding to mild bilateral hearing loss. Diotic SRTs were thus not an accurate estimation of overall functional hearing ability. Several studies have demonstrated that listeners with unilateral and asymmetric hearing loss experience deficits in speech understanding, especially in the presence of competing background noise (Fitz, Reeder, & Holder, 2017; Picou, Charles, & Ricketts, 2017; Ruscetta, Arjmand, & Pratt, 2005). Also, listening effort and perceived real-life handicap in persons with unilateral and asymmetric hearing loss are often equivalent or worse than persons with bilateral hearing loss (Alhanbali, Dawes, Lloyd, & Munro, 2017; Gatehouse & Noble, 2004; Picou et al., 2017). Sensitivity of the DIN test to this type of hearing loss is, therefore, particularly important.

Dichotic digit presentation in this study improved the sensitivity of the DIN test to asymmetric hearing loss, and better reflected the degree of hearing loss in the poorer ear. With typical, normal symmetric hearing, stimulating both ears simultaneously provide binaural summation, increasing sensitivity, as well as more significant binaural integration described above. Listeners with unilateral hearing loss typically hear sounds well when they come from the side of the better ear, but still not so well as normal hearing listeners if there is any noise, due to loss of SRM. Some listeners, however, may have enough residual hearing in the poorer ear to achieve some binaural advantage in dichotic presentations. In this study, three out of twenty-four

participants with unilateral and asymmetric hearing loss produced dichotic SRT within the normal range.

## **5.2. Clinical Implications**

### **Study Aim #1**

Overall, this study demonstrated widespread uptake of the *hearZA* app across age groups with a substantial number of persons self-reporting hearing problems (37%) and failing the test (22.4%). This means it is reaching an important target audience, those who think they have hearing loss. Conversely, it also reaches a high proportion of persons not yet presenting with a clear hearing problem but having taken the test are aware of their hearing status and can then track it through the App's personal profile (Swanepoel, 2017). Users are also reminded annually (via in-app notifications) to conduct follow-up tests allowing for longitudinal tracking and the possibility of early detection of hearing problems. A failed DIN test result has demonstrated positive influence on uptake of interventions (Smits et al., 2005; Watson et al., 2015). This method of self-testing should, therefore, promote increased self-efficacy and accessible hearing health behaviours among users.

### **Study Aim #2**

Listeners with unilateral and asymmetric hearing loss were more affected in dichotic as opposed to diotic presentation, considerably deviating in their SRTs than listeners with normal hearing. This means that for the first time, during the same, binaural screen, dichotic DIN presentation was able to detect unilateral and asymmetric hearing loss, accounting for close to half of all hearing loss (Agrawal, Platz, & Niparko, 2008). These results are a significant innovation of a rapid test undertaken in less than 3 minutes. Including other DIN test variants (e.g. diotic, monaural, filtered or modulated noise), could allow for differential categorisation into bilateral, asymmetric or possibly even conductive or central hearing loss. Triaging and directed referrals, all from cloud-based data management platforms would be possible and can optimise resource allocation. The embedded location-based referral system on the DIN smartphone App can refer people who fail a dichotic DIN hearing screening for intervention at their closest hearing health professional (Swanepoel, 2017). In LMICs, this referral system would be crucial since services are often few and far between.

Conductive hearing loss, most commonly associated with otitis media, is highly prevalent with approximately 2.2 million cases per year (Shekelle et al., 2002). Although not assessed in this study, dichotic listening would likely be affected in cases of conductive hearing loss. Acute conductive hearing loss both attenuates and delays sound passing through the ear (Hartley & Moore, 2003), thereby disrupting dichotic processing. Chronic conductive hearing loss occurring in infancy impairs dichotic listening even after the hearing loss resolved (Moore, Hutchings, & Meyer, 1991; Pillsbury, Grose, & Hall, 1991) and produces several neurological changes affecting binaural brain integration (Polley, Thompson, & Guo, 2013). When the digits are presented diotically, a person with conductive hearing loss could overcome loudness deficits of the signal by increasing the overall sound level. Dichotic digit presentation could, therefore, increase sensitivity of the DIN test to both conductive hearing loss and some forms of central auditory dysfunction. Conductive hearing loss in children, caused by otitis media, is relatively more prevalent among underserved, remote and poor populations than other forms of hearing loss (Cameron, Dillon, Glyde, Kanthan, & Kania, 2014; Hunter, Davey, Kohtz, & Daly, 2007). Since the DIN can be used in children as young as four years (Koopmans et al., 2018), a dichotic DIN test may be a means for identification and early intervention in those populations. An investigation of the effect of conductive hearing loss on dichotic SRTs is thereby warranted.

Considering a global health perspective, an accurate smartphone hearing test has the potential to reach many people, especially in LMICs due to lack of other alternatives. Solutions facilitating preventative care, like a DIN test, are crucial to alleviating the consequences of undetected and untreated hearing loss. Hearing loss accompanied by breakdowns in communication can cause a sense of intense isolation in many adults (Mick, Kawachi, & Lin, 2014). Furthermore, hearing loss has been associated with cognitive decline and dementia, the risk increasing with increasing degree of hearing loss (Lin et al., 2011; Livingston et al., 2017). Aside from the pervasive impact on an individual's health, undetected hearing loss carries a significant price-tag for society because of reduced educational attainments (WHO, 2017) and work productivity (Ruben, 2015). Even in high-income countries, people with hearing loss have twice the rate of unemployment compared to their normal-hearing peers (Ruben, 2015). Preventative care for avoidable causes of hearing loss and early detection



facilitated by routine hearing screening could produce a dramatic reduction in the cost of untreated hearing loss (WHO, 2017).

### **5.3. Critical Evaluation**

A critical evaluation is necessary to evaluate the study regarding its strengths and limitations.

#### *Strengths of the study*

Phase one had a large study sample ( $n=24072$ ), allowing opportunity to accurately make deductions about the type of users and factors influencing their test performance. Phase two made use of a repeat-measures design, counterbalancing the test measures using a Latin square. In addition, power calculations were conducted to determine a sufficient sample size to prove the study hypothesis. Using this design, the results are reliable and provides a method for an improved test paradigm of the DIN test. This study was a first-time effort to explore dichotic speech presentation for enhanced sensitivity and time efficiency of the DIN test. Not only did the dichotic test paradigm improve sensitivity to unilateral and asymmetric hearing loss, but also distinctly enhanced sensitivity to bilateral symmetric hearing loss. Results of this study provide a model for an accurate, binaural hearing test. This time-efficient test highlights the opportunity for extensive uptake as well as earlier hearing loss detection and intervention using widely accessible smartphone technology.

#### *Limitations of the study*

For phase one of the study, all data was gathered by means of field testing. SRT results could, therefore, have been confounded by environmental factors such as noise. Also, results in phase one assume that all listeners correctly entered their information, such as age, known hearing problem and English competence, over which researchers had no control. The most significant limitation of phase two was that it only included persons with sensorineural hearing loss. The sensitivity of the dichotic DIN test to conductive and severely mixed hearing loss was, therefore, not assessed. Another limitation was the distribution of degrees of unilateral and asymmetric hearing loss, the majority (83%) of which had a severe-to-profound loss. Evidence on the effect of milder forms of unilateral and asymmetric hearing loss on

the dichotic SRT is, therefore, not demonstrated in this study. A possible design limitation was the variation in English language competence of participants, which could have confounded results.

#### **5.4. Future Research**

Based on the overall referral rate (22.4%) determined in the retrospective analysis (Aim 1), follow up on actions taken after a failed test result could provide insight into true influence of a DIN hearing screening. Furthermore, establishment of normative scores for children between the ages of 5 and 15 years old would expand the application of the test to younger listeners, an important target audience of the *hearZA* application. With the release of a dichotic test paradigm (proved a more sensitive test approach; Aim 2), establishment of normative SRTs across ages, including younger children, will be essential. Besides the possibility for improved detection of conductive hearing loss, dichotic presentation of the DIN test could further improve sensitivity to retrocochlear disorders. Reduced SRM due to brainstem disorders have already been established in MLD studies (Hirsch & Licklider, 1948; Jerger, Brown, & Smits, 1982). It would thus be reasonable to assume that a dichotic test paradigm should increase sensitivity to retrocochlear disorders as well. A study evaluating the effect of retrocochlear hearing loss, such as acoustic neuromas or vestibular schwannoma should be done. In addition, a possible effort can be made to improve efficiency of the test further. An investigation into reducing the number of steps in the test, without compromising test accuracy, could be a practical solution.

#### **5.5. Conclusion**

This study showed extensive uptake of a diotic SA English DIN test using the *hearZA* smartphone app across various ages. The test reached a substantial number of persons with and without self-report of a hearing problem, both an important target audience of the test. Furthermore, this study demonstrated that a dichotic test method dramatically improves accuracy of the DIN test to bilateral, unilateral and asymmetric sensorineural hearing loss. The dichotic DIN test on a smartphone could rapidly scale early detection of hearing loss at a fraction of the current cost. Furthermore, since many cases of hearing loss are due to preventable causes, routine hearing screening can facilitate preventive care and timely identification for earlier rehabilitation.

Widespread access to a dichotic DIN test on a smartphone platform can, therefore, improve the capacity to prevent and address undetected hearing loss globally.

## 6. REFERENCES

- Agrawal, Y., Platz, E. A., & Niparko, J. K. (2008). Prevalence of hearing loss and differences by demographic characteristics among US adults: data from the National Health and Nutrition Examination Survey, 1999-2004. *Archives of internal medicine*, 168(14), 1522-1530.
- Alhanbali, S., Dawes, P., Lloyd, S., & Munro, K. J. (2017). Self-reported listening-related effort and fatigue in hearing-impaired adults. *Ear and Hearing*, 38(1), e39-e48.
- Beins, B.C. (2009). *Research Methods: A tool for life* (2nd ed.). USA: Pearson Education.
- Brughera, A., Dunai, L., & Hartmann, W. M. (2013). Human interaural time difference thresholds for sine tones: The high-frequency limit. *The Journal of the Acoustical Society of America*, 133(5), 2839-2855.
- Cameron, S., Dillon, H., Glyde, H., Kanthan, S., & Kania, A. (2014). Prevalence and remediation of spatial processing disorder (SPD) in Indigenous children in regional Australia. *International Journal of Audiology*, 53(5), 326-335.
- Chadha, S., Cieza, A., & Krug, E. (2018). Global hearing health: Future directions. *Bulletin of the World Health Organization*, 96(3), 146.
- Fagan, J., & Jacobs, M. (2009). Survey of ENT services in Africa: need for a comprehensive intervention. *Global Health Action*, 2(1), 1932.
- Fellinger, J., Holzinger, D., & Pollard, R. (2012). Mental health of deaf people. *The Lancet*, 379(9820), 1037-1044.
- Ferguson, M. O., Cook, R. D., Hall, J. W., Grose, J. H., & Pillsbury, H. C. (1998). Chronic conductive hearing loss in adults: Effects on the auditory brainstem response and masking-level difference. *Archives of Otolaryngology–Head & Neck Surgery*, 124(6), 678-685.
- Folmer, R. L., Vachhani, J., McMillan, G. P., Watson, C., Kidd, G. R., & Feeney, M. P. (2017). Validation of a Computer-Administered Version of the Digits-in-

Noise Test for Hearing Screening in the United States. *Journal of the American Academy of Audiology*, 28(2), 161-169.

Freyman, R. L., Balakrishnan, U., & Helfer, K. S. (2001). Spatial release from informational masking in speech recognition. *The Journal of the Acoustical Society of America*, 109(5), 2112-2122.

Gatehouse, S., & Noble, W. (2004). The speech, spatial and qualities of hearing scale (SSQ). *International Journal of Audiology*, 43(2), 85-99.

Grant, K. W., & Walden, T. C. (2013). Understanding excessive SNR loss in hearing-impaired listeners. *Journal of the American Academy of Audiology*, 24(4), 258-273.

Hallam, R., Ashton, P., Sherbourne, K., & Gailey, L. (2008). Persons with acquired profound hearing loss (APHL): how do they and their families adapt to the challenge?. *Health*, 12(3), 369-388.

Hartley, D. E., & Moore, D. R. (2003). Effects of conductive hearing loss on temporal aspects of sound transmission through the ear. *Hearing Research*, 177(1-2), 53-60.

Hess, D. R. (2004). Retrospective studies and chart reviews. *Respiratory Care*, 49(10), 1171-1174.

Hirsh, I. J. (1948). The influence of interaural phase on interaural summation and inhibition. *The Journal of the Acoustical Society of America*, 20(4), 536-544.

Hunter, L. L., Davey, C. S., Kohtz, A., & Daly, K. A. (2007). Hearing screening and middle ear measures in American Indian infants and toddlers. *International Journal of Pediatric Otorhinolaryngology*, 71(9), 1429-1438.

Jansen, S., Luts, H., Wagener, K. C., Frachet, B., & Wouters, J. (2010). The French digit triplet test: A hearing screening tool for speech intelligibility in noise. *International Journal of Audiology*, 49(5), 378-387.

Jerger, J., Brown, D., & Smith, S. (1984). Effect of peripheral hearing loss on the masking level difference. *Archives of Otolaryngology*, 110(5), 290-296.

- Koole, A., Nagtegaal, A. P., Homans, N. C., Hofman, A., de Jong, R. J. B., & Goedegebure, A. (2016). Using the digits-in-noise test to estimate age-related hearing loss. *Ear and Hearing, 37*(5), 508-513.
- Koopmans, W. J., Goverts, S. T., & Smits, C. (2018). Speech recognition abilities in normal-hearing children 4 to 12 years of age in stationary and interrupted noise. *Ear and Hearing*, in press.
- Leedy, P., & Ormrod, J. (2015). *Practical Research: Planning and Design* (11th ed.). Harlow, England: Pearson.
- Licklider, J. C. R. (1948). The influence of interaural phase relations upon the masking of speech by white noise. *The Journal of the Acoustical Society of America, 20*(2), 150-159.
- Lin, F. R., Metter, E. J., O'Brien, R. J., Resnick, S. M., Zonderman, A. B., & Ferrucci, L. (2011). Hearing loss and incident dementia. *Archives of Neurology, 68*(2), 214-220.
- Livingston, G., Sommerlad, A., Orgeta, V., Costafreda, S. G., Huntley, J., Ames, D., ... & Cooper, C. (2017). Dementia prevention, intervention, and care. *The Lancet, 390*(10113), 2673-2734.
- Mackenzie, I., & Smith, A. (2009). Deafness—the neglected and hidden disability. *Annals of Tropical Medicine & Parasitology, 103*(7), 565-571.
- Mantonakis, A., Rodero, P., Lesschaeve, I., & Hastie, R. (2009). Order in choice: Effects of serial position on preferences. *Psychological Science, 20*(11), 1309-1312.
- Mick, P., Kawachi, I., & Lin, F. R. (2014). The association between hearing loss and social isolation in older adults. *Otolaryngology-Head and Neck Surgery, 150*(3), 378-384.
- Middlebrooks, J. C., & Green, D. M. (1991). Sound localization by human listeners. *Annual Review of Psychology, 42*(1), 135-159.
- Moore, D. R., Hutchings, M. E., & Meyer, S. E. (1991). Binaural masking level differences in children with a history of otitis media. *Audiology, 30*(2), 91-101.

- Moore, D. R., Edmondson-Jones, M., Dawes, P., Fortnum, H., McCormack, A., Pierzycki, R. H., & Munro, K. J. (2014). Relation between speech-in-noise threshold, hearing loss and cognition from 40–69 years of age. *PloS one*, 9(9), e107720.
- Moore, A. N., Rothpletz, A. M., & Preminger, J. E. (2015). The effect of chronological age on the acceptance of Internet-based hearing health care. *American Journal of Audiology*, 24(3), 280-283.
- Mouton, J. (2001). How to succeed in your master's and doctoral studies: A South African guide and research book. Pretoria: Van Schaik.
- Mulwafu, W., Ensink, R., Kuper, H., & Fagan, J. (2017). Survey of ENT services in sub-Saharan Africa: Little progress between 2009 and 2015. *Global Health Action*, 10(1), 1289736.
- Noble, W., & Gatehouse, S. (2004). Interaural asymmetry of hearing loss, Speech, Spatial and Qualities of Hearing Scale (SSQ) disabilities, and handicap. *International Journal of Audiology*, 43(2), 100-114.
- Olsen, W. O., & Noffsinger, D. (1976). Masking level differences for cochlear and brainstem lesions. *Annals of Otolaryngology, Rhinology & Laryngology*, 85(6), 820-825.
- Or, C. K., Karsh, B. T., Severtson, D. J., Burke, L. J., Brown, R. L., & Brennan, P. F. (2011). Factors affecting home care patients' acceptance of a web-based interactive self-management technology. *Journal of the American Medical Informatics Association*, 18(1), 51-59.
- Picou, E. M., Charles, L. M., & Ricketts, T. A. (2017). Child–Adult differences in using dual-task paradigms to measure listening effort. *American Journal of Audiology*, 26(2), 143-154.
- Pillsbury, H. C., Grose, J. H., & Hall, J. W. (1991). Otitis media with effusion in children: Binaural hearing before and after corrective surgery. *Archives of Otolaryngology–Head & Neck Surgery*, 117(7), 718-723.

- Polley, D. B., Thompson, J. H., & Guo, W. (2013). Brief hearing loss disrupts binaural integration during two early critical periods of auditory cortex development. *Nature Communications*, *4*, 2547.
- Potgieter, J. M., Swanepoel, D. W., Myburgh, H. C., Hopper, T. C., & Smits, C. (2016). Development and validation of a smartphone-based digits-in-noise hearing test in South African English. *International Journal of Audiology*, *55*(7), 405-411.
- Potgieter, J. M., Swanepoel, W., Myburgh, H. C., & Smits, C. (2018). The South African English Smartphone Digits-in-Noise Hearing Test: Effect of Age, Hearing Loss, and Speaking Competence. *Ear and Hearing*, *39*(4), 656-663.
- Pronk, M., Deeg, D., Versfeld, N.J., Heymans, M.W., Naylor, G. & Kramer, S.E. (2016). Predictors of help-seeking and hearing-aid uptake in older persons with hearing loss. *The Gerontologist*, *56*(13), 303.
- Ruben, R. J. (2015). How did otolaryngology–head & neck surgery become an essential medical discipline for the 21st century?. *International Journal of Pediatric Otorhinolaryngology*, *79*(6), 783-785.
- Ruscetta, M. N., Arjmand, E. M., & Pratt, S. R. (2005). Speech recognition abilities in noise for children with severe-to-profound unilateral hearing impairment. *International Journal of Pediatric Otorhinolaryngology*, *69*(6), 771-779.
- Shekelle, P., Takata, G., Chan, L. S., Mangione-Smith, R., Corley, P. M., Morphey, T., & Morton, S. (2002). Diagnosis, natural history, and late effects of otitis media with effusion. *Evidence Report/Technology Assessment (Summary)*, (55), 1.
- Smits, C., Kapteyn, T. S., & Houtgast, T. (2004). Development and validation of an automatic speech-in-noise screening test by telephone. *International Journal of Audiology*, *43*(1), 15-28.
- Smits, C., Kramer, S.E., & Houtgast, T. (2006). Speech reception thresholds in noise and self-reported hearing disability in a general adult population. *Ear and Hearing*, *27*(5), 538-549.



- Smits, C., Merkus, P., & Houtgast, T. (2006). How we do it: The Dutch functional hearing–screening tests by telephone and Internet. *Clinical Otolaryngology*, 31(5), 436-440.
- Smits, C., Goverts, S. T., & Festen, J. M. (2013). The digits-in-noise test: Assessing auditory speech recognition abilities in noise. *The Journal of the Acoustical Society of America*, 133(3), 1693-1706.
- Smits, C., Watson, C. S., Kidd, G. R., Moore, D. R., & Goverts, S. T. (2016). A comparison between the Dutch and American-English digits-in-noise (DIN) tests in normal-hearing listeners. *International Journal of Audiology*, 55(6), 358–365.
- Statistics South Africa. (2011). *Census in brief, South Africa*. Retrieved from <http://www.statssa.gov.za/publications/P03014/P030142011.pdf>
- Statistics South Africa. (2013). *General Household Survey*. Retrieved from <http://www.statssa.gov.za/publications/P03014/P030142011.pdf>
- Stevens, G., Flaxman, S., Brunskill, E., Mascarenhas, M., Mathers, C. D., & Finucane, M. (2011). Global and regional hearing impairment prevalence: an analysis of 42 studies in 29 countries. *The European Journal of Public Health*, 23(1), 146-152.
- Swanepoel, D. W. (2017). Smartphone-based National Hearing Test Launched in South Africa. *The Hearing Journal*, 70(1), 14-16.
- The Economist. (2015). *Smartphones: Planet of the Phones*. Retrieved from <https://www.economist.com/leaders/2015/02/26/planet-of-the-phones>
- The Economist. (2016). *Things are looking app*. Retrieved from <https://www.economist.com/business/2016/03/10/things-are-looking-app>
- Talarico, M., Abdilla, G., Aliferis, M., Balazic, I., Giaprakis, I., Stefanakis, T., ... & Paolini, A. G. (2007). Effect of age and cognition on childhood speech in noise perception abilities. *Audiology and Neurotology*, 12(1), 13-19.
- Terre Blanche, M., Durrheim, K., & Painter, D. (2006). *Research in practice: Applied methods for the social sciences*. (2nd ed.). Cape Town: UCT Press.

- Vannson, N., James, C. J., Fraysse, B., Lescure, B., Strelnikov, K., Deguine, O., ... & Marx, M. (2017). Speech-in-noise perception in unilateral hearing loss: Relation to pure-tone thresholds and brainstem plasticity. *Neuropsychologia*, *102*, 135-143.
- Vermiglio, A. J., Soli, S. D., Freed, D. J., & Fisher, L. M. (2012). The relationship between high-frequency pure-tone hearing loss, hearing in noise test (HINT) thresholds, and the articulation index. *Journal of the American Academy of Audiology*, *23*(10), 779-788.
- Watson, C. S., Kidd, G. R., Miller, J. D., Smits, C., & Humes, L. E. (2012). Telephone screening tests for functionally impaired hearing: Current use in seven countries and development of a US version. *Journal of the American Academy of Audiology*, *23*(10), 757-767.
- Watson, C. S., Kidd, G. R., Preminger, J. E., Miller, J. D., Maki, D. P., & Crowley, A. (2015). Benefits of a telephone-administered national screening test. *Audiology Online*, *27*(6), 1-8.
- Welsh, L. W., Rosen, L. F., Welsh, J. J., & Dragonette, J. E. (2004). Functional impairments due to unilateral deafness. *Annals of Otology, Rhinology & Laryngology*, *113*(12), 987-993.
- World Health Organization. (2017). World Health Assembly resolution on prevention of deafness and hearing loss. In *Seventieth World Health Assembly*. Geneva: World Health Organization.
- Wilson, R. H., Moncrieff, D. W., Townsend, E. A., & Pillion, A. L. (2003). Development of a 500-Hz masking-level difference protocol for clinic use. *Journal of the American Academy of Audiology*, *14*(1), 1-8.
- Wilson, B. S., Tucci, D. L., Merson, M. H., & O'Donoghue, G. M. (2017). Global hearing health care: new findings and perspectives. *The Lancet*, *390*(10111), 2503-2515.
- Zokoll, M. A., Wagener, K. C., Brand, T., Buschermöhle, M., & Kollmeier, B. (2012). Internationally comparable screening tests for listening in noise in several

European languages: The German digit triplet test as an optimization prototype. *International Journal of Audiology*, 51(9), 697-707.

## 7. APPENDICES

### Appendix A: Faculty of Humanities Ethical Clearance



UNIVERSITEIT VAN PRETORIA  
UNIVERSITY OF PRETORIA  
YUNIBESITHI YA PRETORIA

Faculty of Humanities  
Research Ethics Committee

2 October 2017

Dear Prof Swanepoel

**Project:** Smartphone-based national hearing test performance and characteristics  
**Researcher:** Prof DCDE Swanepoel  
**Department:** Speech-Language Pathology and Audiology  
**Reference number:** Staff research.(GW20170919HS)

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

I am pleased to inform you that the above application was **approved** by the **Research Ethics Committee** at a meeting held on 28 September 2017. 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 Studies and Ethics**  
**Faculty of Humanities**  
**UNIVERSITY OF PRETORIA**  
**e-mail:tracey.andrew@up.ac.za**

Research Ethics Committee Members: Prof MME Schoeman (Deputy Dean); Prof KL Harris; Dr L Blokland; Ms A dos Santos; Dr R Fasselt; Ms KT Govinder; Dr E Johnson; Dr C Panebianco; Dr C Puttergill; Dr D Reyburn; Dr M Taub; Prof GM Spies; Prof E Taljard; Ms B Tsebe; Dr E van der Klashorst; Dr G Wolmarans; Mr V Sithole

## Appendix B: Faculty of Health Sciences Ethical Clearance

The Research Ethics Committee, Faculty Health Sciences, University of Pretoria complies with ICH-GCP guidelines and has US Federal wide Assurance.

- FWA 00002567, Approved dd 22 May 2002 and Expires 28 August 2018.
- IRB 0000 2235 IORG0001762 Approved dd 22/04/2014 and Expires 22/04/2017.



UNIVERSITEIT VAN PRETORIA  
UNIVERSITY OF PRETORIA  
YUNIBESITHI YA PRETORIA

Faculty of Health Sciences Research Ethics Committee

23/02/2017

### Approval Certificate New Application

**Ethics Reference No.: 58/2017**

**Title:** Hearing screening with the DigIts in Noise test: Improving test sensitivity for asymmetrical hearing loss

Dear Karina Cecilia Swanepoel

The **New Application** as supported by documents specified in your cover letter dated 30/01/2017 for your research received on the 30/01/2017, was approved by the Faculty of Health Sciences Research Ethics Committee on its quorate meeting of 22/02/2017.

Please note the following about your ethics approval:

- Ethics Approval is valid for 1 year
- Please remember to use your protocol number (**58/2017**) on any documents or correspondence with the Research Ethics Committee regarding your research.
- Please note that the Research Ethics Committee may ask further questions, seek additional information, require further modification, or monitor the conduct of your research.

**Ethics approval is subject to the following:**

- The ethics approval is conditional on the receipt of **6 monthly written Progress Reports**, and
- The ethics approval is conditional on the research being conducted as stipulated by the details of all documents submitted to the Committee. In the event that a further need arises to change who the investigators are, the methods or any other aspect, such changes must be submitted as an Amendment for approval by the Committee.

We wish you the best with your research.

Yours sincerely

Dr R Sommers; MBChB; MMed (Int); MPharm, PhD

Deputy Chairperson of the Faculty of Health Sciences Research Ethics Committee, University of Pretoria

*The Faculty of Health Sciences Research Ethics Committee complies with the SA National Act 61 of 2003 as it pertains to health research and the United States Code of Federal Regulations Title 45 and 46. This committee abides by the ethical norms and principles for research, established by the Declaration of Helsinki, the South African Medical Research Council Guidelines as well as the Guidelines for Ethical Research: Principles Structures and Processes, Second Edition 2015 (Department of Health).*

☎ 012 356 3084      ✉ [depeka.behari@up.ac.za](mailto:depeka.behari@up.ac.za)      🌐 <http://www.up.ac.za/healthethics>  
✉ Private Bag X323, Arcadia, 0007 - Tswelopele Building, Level 4, Room 60, Gezina, Pretoria

The Research Ethics Committee, Faculty Health Sciences, University of Pretoria complies with ICH-GCP guidelines and has US Federal wide Assurance.

- FWA 00002567, Approved dd 22 May 2002 and Expires 03/20/2022.
- IRB 0000 2235 IORG0001762 Approved dd 22/04/2014 and Expires 03/14/2020.



UNIVERSITEIT VAN PRETORIA  
UNIVERSITY OF PRETORIA  
YUNIBESITHI YA PRETORIA

Faculty of Health Sciences Research Ethics Committee

1/02/2018

**Approval Certificate  
Amendment**

**(to be read in conjunction with the main approval certificate)**

**Ethics Reference No: 58/2017**

Title: "Hearing screening with the Digits in Noise: Improving test sensitivity"

Dear Karina Cecilia Swanepoel

The **Amendment** as described in your documents specified in your cover letter dated 16/11/2017 received on 20/11/2017 was approved by the Faculty of Health Sciences Research Ethics Committee on its quorate meeting of 31/01/2018.

Please note the following about your ethics amendment:

- Please remember to use your protocol number (58/2017) on any documents or correspondence with the Research Ethics Committee regarding your research.
- Please note that the Research Ethics Committee may ask further questions, seek additional information, require further modification, or monitor the conduct of your research.

**Ethics amendment is subject to the following:**

- The ethics approval is conditional on the receipt of **6 monthly written Progress Reports**, and
- The ethics approval is conditional on the research being conducted as stipulated by the details of all documents submitted to the Committee. In the event that a further need arises to change who the investigators are, the methods or any other aspect, such changes must be submitted as an Amendment for approval by the Committee.

We wish you the best with your research.

**Yours sincerely**

*\*\* Kindly collect your original signed approval certificate from our offices, Faculty of Health Sciences, Research Ethics Committee, Tswelopele Building, Level 4-60*

**Dr R Sommers; MBChB; MMed (Int); MPharm; PhD**  
Deputy Chairperson of the Faculty of Health Sciences Research Ethics Committee, University of Pretoria

*The Faculty of Health Sciences Research Ethics Committee complies with the SA National Act 61 of 2003 as it pertains to health research and the United States Code of Federal Regulations Title 45 and 46. This committee abides by the ethical norms and principles for research, established by the Declaration of Helsinki, the South African Medical Research Council Guidelines as well as the Guidelines for Ethical Research: Principles Structures and Processes, Second Edition 2015 (Department of Health).*

☎ 012 356 3084    ✉ [deepeka.behari@up.ac.za](mailto:deepeka.behari@up.ac.za) / [fhsethics@up.ac.za](mailto:fhsethics@up.ac.za)    🌐 <http://www.up.ac.za/healthethics>  
✉ Private Bag X323, Arcadia, 0007 - Tswelopele Building, Level 4, Room 60 / 61, 31 Bophelo Road, Gezina, Pretoria

## Appendix C: Consent for anonymized data from the hearX Group



Faculty of Humanities  
Department of Speech-Language Pathology and Audiology

1 September 2017

TO: **Mr Nic Klopper, CEO (HearX Group)**

RE: **Permission to use anonymous hearZA data for a research project**

Dear Mr Nic Klopper,

I, Prof De Wet Swanepoel am conducting a project around the use of mHealth technology in hearing healthcare. As primary focus is on the smartphone-based national hearing test (hearZA™), I am writing to request permission to use the anonymous test data for users of the hearZA App for our research project entitled, *Smartphone-based national hearing test-performance and characteristics*.

The purpose of the project is to describe the participants taking the test regarding their overall age, referral rates across age groups and to correlate results with their self-reported level of English language competence. Furthermore, the study will aim to determine indications of user characteristics, patterns of normative scores across age groups and to compare these results with previous findings.

Should you require any additional information, do not hesitate to contact me at 012 420 4280.

Sincerely,



**Professor De Wet Swanepoel**  
**Researcher**

---

Room 4-1.7, Level 4, Building  
University of Pretoria, Private Bag X20  
Hatfield 0028, South Africa  
Tel +27 (0)12 420 1234  
Fax +27 (0)12 420 5578  
Email name.surname@up.ac.za  
www.up.ac.za

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

**PERMISSION TO ACCESS DATA OF THE HEARZA™ NATIONAL HEARING TEST  
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 anonymous hearZA™ test data for his project entitled: "A *smartphone-based national hearing test- performance and characteristics*". We will provide you with an anonymous datasheet with test results recorded dating back from 3 March 2016.

Date: 4 September 2017



---

**Nic Klopper**  
Chief Executive Officer: hearX Group



Appendix D: Consent from the CEO at Steve Biko Academic Hospital

**Permission to access Records / Files / Data base at the Steve Biko Academic Hospital**

**To:** Chief Executive Officer/Information Officer  
Steve Biko Academic Hospital  
Dr M Kenoshi

**From:** Karina Swanepoel  
The Department of Speech-Language Pathology and Audiology

**Re: Permission to do research at the Audiology and Speech Language Therapy Department, Steve Biko Academic Hospital**

Prof De Wet Swanepoel, Dr Cas Smits and I are researchers working at the Department of Audiology and Speech Language Pathology at the University of Pretoria. I am requesting permission on behalf of all of us to conduct a study on the patients of the Audiology Clinic of Steve Biko Academic Hospital grounds that involves access to patient records.

The request is lodged with you in terms of the requirements of the Promotion of Access to Information Act. No. 2 of 2000.

**The title of the study is: Hearing screening with the Digits in Noise test: Improving test sensitivity for asymmetrical hearing loss.**

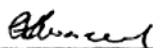
The researchers request access to the following information:  
Access to the clinical files for patients with asymmetrical and bilateral sensorineural hearing loss.

We intend to publish the findings of the study in a professional journal and/ or at professional meeting like symposia, congresses, or other meetings of such a nature.

We intend to protect the personal identity of the patients by assigning each patient a random code number.

We undertake not to proceed with the study until we have received approval from the Faculty of Health Sciences Research Ethics Committee, University of Pretoria.

Yours sincerely

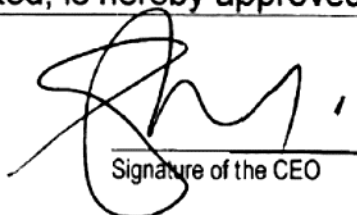


**Karina Swanepoel (Researcher)**  
**M Audiology Student (University of Pretoria)**

**Permission to do the research study at this hospital and to access the information as requested, is hereby approved.**

Chief Executive Officer  
Steve Biko Academic Hospital

Dr \_\_\_\_\_



Signature of the CEO

**DR ME KENOSHI**  
CHIEF EXECUTIVE OFFICER  
STEVE BIKO  
ACADEMIC HOSPITAL

**Hospital Official Stamp**

24/1/2017

## Appendix E: Consent from the Dean of Student Affairs



UNIVERSITEIT VAN PRETORIA  
UNIVERSITY OF PRETORIA  
YUNIBESITHI YA PRETORIA  
Denkleiers • Leading Minds • Dikgopolo tsa Dihalefi

Faculty of Humanities  
Department of Speech-Language Pathology and Audiology

February 2017

**Attention: Dr Matete Madiba**

**DIRECTOR: Department of Student Affairs**

Dear Dr Matete Madiba

### **REQUEST FOR PARTICIPANTS IN AN INSTITUTION**

I, Karina Swanepoel, am a master student in Communication Pathology, at the University of Pretoria. I am required to conduct a research project in order to obtain my degree. My project focusses on sensitizing the Digits in Noise test for unilateral and asymmetrical hearing loss for the application called hearZA™.

**Title:** Hearing screening with the Digits in Noise test: Improving test sensitivity for asymmetrical hearing loss

**Background and Rationale:** Approximately 360 million people worldwide suffer from disabling hearing loss, with the majority residing in low- and middle-income countries. Despite this widespread prevalence and adverse impact, only a minority of cases are identified and receive treatment. This could be attributed to the inaccessibility of hearing healthcare services and a severe shortage of audiologists. In order to improve and decentralize hearing loss detection, methods of phone-based hearing screening using speech-in-noise tests have been developed and validated such as the hearZA™ smartphone application. The current version of the hearZA™ application tests both ears at the same time and is therefore not sensitive enough to detect hearing loss occurring in only one ear, therefore this study aims to sensitize this application to better detect these types of hearing losses.

**Design and Procedure:** A quantitative comparative, quasi-experimental research design will be followed. The aim is to purposively approach students from the University of Pretoria willing to participate in the study.

**Participants:** Twenty four participants will be requested to visit the Department of Speech Language Pathology and Audiology; where, upon arrival it will be asked of them to participate in diagnostic hearing testing in order to establish normal hearing. Thereafter they will be expected to complete the Digits in Noise test. For the Digits in Noise test they will be expected to listen to a list of digit triplet e.g. 4-6-7 in the presence of background noise and to type in the sequence heard on a keypad. All tests will be completely non-invasive and without charge.

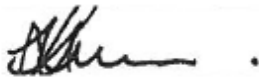
**Ethical considerations:** A student's participation will only take place after they have consented to, and fully understood the terms of the study. The participants will have full authority to withdraw from participating in the study at any given time. They will be informed that anonymity and confidentiality will be granted. The data collected will be stored for 15 years for research purposes.

**Risks and Benefits:** There are no risks or benefits associated with this study.

I believe that this study will assist in the advancement of knowledge within the field of Audiology.

Should you require any additional information, please do not hesitate to contact myself at 082 556 5431 or my research supervisor, Prof. De Wet Swanepoel at 012 420 4280.

Kind Regards



---

**Karina Swanepoel**  
M. Communication Pathology  
Researcher




---

**Prof De Wet Swanepoel**  
Research Supervisor

**PERMISSION FOR THE USE OF STUDENTS FROM THE UNIVERSITY OF PRETORIA IN RESEARCH**

Herewith, I Dr **Matete Madiba** give permission for the students from the University of Pretoria to be used as voluntary subjects in the research titled: *Hearing screening with the Digits in Noise: Improving test sensitivity for asymmetrical hearing loss.*



**Dr Matete Madiba**

**DIRECTOR: Department of Student Affairs**



## **INFORMATION LEAFLET AND INFORMED CONSENT**

### **HEARING SCREENING WITH THE DIGITS IN NOISE TEST: IMPROVING TEST SENSITIVITY**

---

Dear Participant,

#### **1) INTRODUCTION**

You are invited to participate in a research study that I am conducting at the Department of Speech-Language Pathology and Audiology, Faculty of Humanities, University of Pretoria. This information leaflet will help you decide if you want to participate in my research study. Before you agree to take part, you should fully understand what is involved. If you have any questions that this leaflet does not fully explain, please do not hesitate to ask me, Ms. Karina Swanepoel in person or by phone at 082 556 5431 for clarification.

#### **2) THE NATURE AND PURPOSE OF THIS STUDY**

Approximately 360 million people worldwide suffer from disabling hearing loss, with the majority residing in low- and middle-income countries. Despite this widespread occurrence and adverse impact, only a minority of cases are identified and receive treatment. To improve hearing loss detection, methods of smartphone-based hearing screening have been developed such as the hearZA™ smartphone application. The current version of the hearZA™ application tests both ears at the same time and is therefore not sensitive enough to detect hearing loss occurring in only one ear. Also, the test is not sensitive enough to pick up hearing loss due to outer or middle ear problems. Therefore this study aims to sensitize this application to better detect these types of hearing losses.

#### **3) EXPLANATION OF PROCEDURES TO BE FOLLOWED**

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:

### 1. 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).

### 2. 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.

### 3. Hearing test

For this test, you will wear earphones on your ears. You will be expected to respond to a soft sound 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.

### 4. 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.

## **4) RISK AND DISCOMFORT INVOLVED**

All tests will be non-invasive, and no risk is involved in participating in the study.

## **5) POSSIBLE BENEFITS OF THIS STUDY**

Although you may not benefit directly from this study, the results of this study may help researchers to sensitize the digits in noise test of the hearZA™ smartphone application. Should I diagnose you with a hearing loss, you will be referred to the Department of Speech-Language Therapy and Audiology at the University of Pretoria where you will further be examined and be treated for the identified problem.

## **6) 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 Department of Steve Biko Academic Hospital or the Department of Speech-Language Pathology and Audiology at the University of Pretoria.

## **7) HAS THE STUDY RECEIVED ETHICAL APPROVAL**

The study has received written approval from the Research Ethics Committee of the Faculty of Humanities and the Research Ethics Committee of the Faculty of Health

Sciences at the University of Pretoria. The contact person of the Ethics Committee for the study is Mrs. Manda – 012 356 3085.

## **8) INFORMATION AND CONTACT PERSON**

The contact person for the study is me, Ms. Karina Swanepoel. If you have any questions about the study, please contact me at 082 556 5431 or karinaswanepoel@live.com. Alternatively, you can contact my supervisor, Prof De Wet Swanepoel at dewet.swanepoel@up.ac.za.

## **9) COMPENSATION**

Participation is entirely voluntary. No extra costs will be expected to be concurred from you.

## **10) 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 a 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 Health Sciences, University of Pretoria.

## **11) CONSENT TO PARTICIPATE IN THIS STUDY**

I have read this information document, and I understand the above information. I have been given the opportunity to ask questions, and I am satisfied that they have been answered satisfactorily. I understand that if I do not participate, it will not alter my medical treatment in any way. I am aware that the results of this study, including my personal details, will anonymously be processed in research reports. I am participating willingly.

I have received a signed copy of this informed consent agreement.

Participant name: \_\_\_\_\_  
(Please Print)

Participant signature: \_\_\_\_\_ Date \_\_\_\_\_

Investigators name: \_\_\_\_\_

(Please Print)

Investigators signature: \_\_\_\_\_ Date \_\_\_\_\_

Witness Name \_\_\_\_\_

(Please Print)

Witness's Signature \_\_\_\_\_ Date \_\_\_\_\_

### **VERBAL INFORMED CONSENT**

I, the undersigned, have read and have fully explained the participant information leaflet, which explains the nature, process, risks, discomforts and benefits of the study, to the participant whom I have asked to participate in the study.

The participant indicates that s/he understands that the results of the study and that his/her personal details will be anonymously processed into a research report. The participant indicates that s/he has had an opportunity to ask questions and had no objection to participating in the research study. S/he understands that there is no penalty should s/he wish to discontinue the study. The withdrawal will have no effect on his/her medical treatment in any way. I hereby certify that the participant has agreed to participate in this study.

Participant's Name: \_\_\_\_\_

(Please Print)

Person seeking consent: \_\_\_\_\_

(Please Print)

Signature: \_\_\_\_\_ Date \_\_\_\_\_

Witness's name \_\_\_\_\_

(Please Print)

Signature \_\_\_\_\_ Date \_\_\_\_\_