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Remote monitoring of adult cochlear implant recipients using speech-in-noise testing

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(17149984)

In fulfilment of the requirements for the degree **MA Audiology** in the
Department of Speech Language Pathology and Audiology,
Faculty of Humanities, University of Pretoria

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PLAGIARISM DECLARATION

Student name: Lize van der Mescht

Student number: 17149984

Degree: Masters in Audiology

The title of the work: Remote monitoring of adult cochlear implant recipients using speech-in-noise testing

I declare that this is my own original work. Where secondary material is used, it has been carefully acknowledged and referenced in accordance with university requirements. I understand what plagiarism is and am aware of university policy and implications in this regard.



Lize van der Mescht

2 December 2022

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LIST OF ABBREVIATIONS

CI – Cochlear Implant

DIN – Digits-in-Noise

HAs – Hearing Aids

PCIU – Pretoria Cochlear Implant Unit

EAS – Electro-acoustic stimulation

SSD – Single-sided deafness

SIN – Speech-in-Noise

SNR – Signal-to-Noise Ratio

SRT – Speech Reception Threshold

ICC – Intraclass correlation coefficient

SEM – Standard error of measurement

ECAP – Electrically evoked compound action potential

dB HL – Decibel hearing level

dB SNR – Decibel Signal-to-Noise Ratio

ABSTRACT

Tele-audiology has progressed from information sharing and diagnostic testing to remote fitting, programming, and maintenance of hearing aids (HAs) and cochlear implant (CI) devices. The demand for remote service options has increased dramatically as a result of the communicable nature of COVID-19 and the need for social distancing. Remote services have provided a means to continue monitoring outcomes and detect changes in the hearing and speech recognition of CI recipients. The smartphone Digits-in-Noise (DIN) test offers a way to provide clinicians with speech recognition information remotely. The DIN test is a widely used and preferred test due to its reliability, validity, user-friendly self-test applications, time efficiency, and low linguistic demands. The DIN test has also been shown to produce robust results across various sound field transducers, which makes home-based monitoring possible. This study evaluated the reliability and accuracy of the DIN test conducted by adult CI recipients in a simulated home environment compared to a clinic set-up. Perceptions of remote monitoring using speech-in-noise (SIN) testing were also explored.

A retrospective, explorative, within-subjects repeated measures study design was utilised. Thirty-three adult CI recipients (mean age 46.7 years, 20.4 SD) conducted the DIN test in a clinic and simulated home environment setup. Comparisons between test settings and test-retest reliability across the two environments were assessed. The perceptions of adult CI recipients regarding remote monitoring and use of the DIN self-test were explored by means of a self-administered survey.

Results of the study indicated that mean aided speech reception thresholds (SRTs) in the clinic and simulated home environment test conditions (mean 7.9, 10.7 SD) and clinic and simulated home environment retest conditions (mean 5.4, 9.6 SD) did not differ significantly. Mean test-retest SRTs in the clinic ($p = .037$) and simulated home environment ($p = .014$) were significantly different. Low standard error of measurement (SEM) and high intraclass correlation coefficient (ICC) scores revealed good and excellent reliability between test–retest measures and between clinic and simulated home environment measures. The majority of the participants were positive about using the DIN test at home to self-assess speech perception although some test

adjustments such as including training items and a less adverse starting signal-to-noise ratio (SNR) may be required.

This explorative study indicated that adult CI recipients could use the smartphone DIN test to self-assess aided SIN performance in a home environment with accuracy and reliability relatively similar to clinic testing. DIN self-testing can potentially assist with troubleshooting of CI devices and reduce the need for regular visits to the CI clinic. As a result of the COVID-19 pandemic, CI recipients are more inclined to use remote CI services and tests such as the DIN test to self-assess speech perception at home. With minor changes to testing procedures, the DIN test could possibly be used by clinicians as part of the standard test battery as a reliable and accurate SIN test for adult CI recipients.

CHAPTER 1: INTRODUCTION AND STUDY RATIONALE

Globally, individuals with a moderate-to-complete hearing loss have increased from 225.3 million in 1990 to 403.3 million in 2019 (Haile et al., 2021). In spite of the global prevalence of hearing loss, only a small portion of individuals with hearing loss who could benefit from intervention services are receiving the necessary care (WHO, 2021). The consequences of unidentified and unaddressed hearing loss in adults are reduced social participation and social isolation, restricted vocational opportunities, stigmatisation, and less financial independence (Moeller et al., 2007; Brodie et al., 2018). Hearing loss has been identified as the primary modifiable risk factor that can prevent or reduce dementia (Livingston et al., 2020). The provision of prompt hearing healthcare to those affected by hearing loss is critical to minimise the effects of untreated hearing loss (Wilson et al., 2017). The barriers faced by numerous individuals with hearing loss to access hearing healthcare services, highlight the need to address hearing loss identification and treatment from a different viewpoint, using innovative solutions (Swanepoel, 2020).

Telehealth refers to using communication and information technology to provide healthcare at a distance (Wootton et al., 2009). Services offered through telehealth may address some of the challenges related to the shortage of healthcare professionals (Powell et al., 2019) and the need for services. As a service delivery model, telehealth is beneficial since hearing healthcare is expanded to be more accessible to underserved communities. Telehealth is a valuable tool to improve hearing healthcare access, reduce costs and support more effective and efficient quality services (Swanepoel & Hall, 2010; Swanepoel & Clark, 2018).

Tele-audiology services can include hearing screenings, diagnostic intervention, remote intervention and/or rehabilitation services (Swanepoel & Hall, 2010). Recent research indicates that tele-audiology can improve patient engagement and accessibility, reduce travel time, and cost, and achieve improved loss to follow-up (D'Onofrio & Zeng, 2022). Tele-audiology has progressed from information sharing and diagnostic testing to the maintenance, fitting and programming of hearing aids (HAs) and cochlear implant (CI) devices with support (Swanepoel & Hall, 2010; Bush et al., 2016; Tao et al., 2021). Several studies have described the feasibility of tele-

fitting of CI devices and HAs (Ramos et al., 2009; Wersag et al., 2010; Eikelboom et al., 2014; Schepers et al., 2019; Luryi et al., 2020; Kim et al., 2021). The remote programming of CI devices has been demonstrated to be effective, safe, and accepted by most CI recipients and health professionals (Ramos et al., 2009; McElveen et al., 2010; Wesarg et al., 2010; Eikelboom et al., 2014; Kuzovkov et al., 2014; Samuel et al., 2014; Schepers et al., 2019).

A remote care model will enable patients to self-assess at home whether the clinic visit is necessary or not. This may offer advantages such as more stable hearing, reduced travel cost, inconvenience and time and increased confidence in CI recipients to self-manage hearing (Cullington & Agyemang-Prempeh, 2017). The demand for remote care options has increased significantly as a result of the communicable nature of COVID-19 and the need for social distancing (Blandford et al., 2020). All healthcare systems, including the audiology industry (Swanepoel & Hall, 2020), have been obligated to discover alternative ways to deliver services to patients during the COVID-19 pandemic (Cassar et al., 2021). CI recipients and their families have experienced great challenges accessing services during the COVID-19 pandemic (Ayas et al. 2020).

Adult CI recipients have reported that the pandemic affected their social and personal lives and led to increased difficulty communicating with family and friends (Wilson et al., 2021). The travel restrictions implemented amid the pandemic prevented access to hearing healthcare facilities that provide services such as troubleshooting and replacing faulty CI speech processors (Sahoo et al., 2020). This led to the provision of suboptimal care to CI recipients. A study by Knickerbocker et al. (2021) indicated decreased performance over time on speech tests for elderly CI recipients implanted shortly before the pandemic, possibly due to rescheduled/ missed appointments, less exposure to complex listening environments and reduced CI speech processor use.

Audiologists rapidly increased the use of remote care appointments since the COVID-19 restrictions were implemented and are optimistic about remote service delivery (Glista et al., 2020). Previous studies indicated that CI recipients' and audiologists' experiences of telemedicine services were very positive (Rodríguez et al., 2010; Swanepoel & Hall, 2010; Wasowski et al., 2010; Wesarg et al., 2010; Eikelboom et al.,

2014; Kuzovkov et al., 2014; Goehring & Hughes, 2017; Slager et al., 2019; Eikelboom et al., 2021; Saunders & Roughley, 2021). Audiologists in the public healthcare sector in South Africa confirmed an increase in the use of telehealth during the COVID-19 pandemic (Bhamjee et al., 2022). A survey by Saunders and Roughley (2021) revealed that most audiologists indicated that they would continue using telehealth even after COVID-19 restrictions have been lifted. According to Cullington et al. (2016), adult CI recipients who wear their CI devices during every waking hour were open to the idea of making telehealth part of their device management routine. Similarly, a study by Cullington and Aidi (2017) indicated that most adult CI recipients could administer a remote speech perception test in a simulated home environment and indicated a preference for remote testing above clinic tests.

Ideally, by performing remote assessment of speech testing, clinicians could determine the need for clinical management without an in-person clinic appointment. The results of the remote assessment would be sent to the clinician to decide whether an in-person follow-up appointment is necessary or not (Maruthurkkara et al., 2022). A goal of remote assessment is to eliminate the need for specialized equipment and rather make use of existing or mainstream technology to evaluate hearing performance (Chen et al., 2021). Additional benefits include that the CI recipients have more stable and better hearing, convenience of not travelling regularly for routine appointments which also reduces travel time, costs, and time off work. Remote self-assessment provides an increased empowerment and confidence to manage one's own hearing and provides greater equality in service delivery (Cullington et al., 2022).

Routine speech testing occurs at the CI clinic, as the primary goal of cochlear implantation is improved speech understanding (Cullington & Aidi, 2017). Assessment of speech perception in quiet and noise is an essential part of obtaining a complete view of hearing in everyday listening situations (Willberg et al., 2021). Accurate evaluation of speech perception skills prior to and after cochlear implantation provides valuable clinical information (Philips, 2013; Li et al., 2016). Speech perception testing provides information about the effectiveness of CI intervention, establishes goals for aural rehabilitation, and determines the need for modifications to the CI speech processor settings (Philips, 2013; Li et al., 2016). The wide-ranging performance of HA users and CI recipients are evident in their speech perception scores, especially

when the test is performed in the presence of noise (Gifford et al., 2008, 2015; Zeitler et al., 2008; Meister et al., 2015; Ricketts et al., 2019). This is the result of linguistic, technical, and cognitive factors and diverse patient demographics (Rähmann et al., 2018; James et al., 2019; de Graaff et al., 2020; Zhao et al., 2020; van Wieringen et al., 2021). In an ideal world, speech perception skills should be measured with one speech-in-noise (SIN) test that is internationally comparable (Willberg et al., 2021). However, there is currently no SIN test that can integrate the differences in test environments (clinic versus home), patient-related factors (i.e., age, memory span, language knowledge), and testing requirements (accurate clinical diagnostic versus screening) (Willberg et al., 2021).

SIN tests hold clinical value for CI recipients as the information permits the monitoring, comparison, and adjustment of CI settings (Smits et al., 2013; Kaandorp et al. 2015). Measuring speech perception skills using DIN in adult CI recipients has been successful during recent years (Cullington & Agyemang-Prempeh, 2017). Smits et al. (2004) introduced the first DIN test as a SIN self-test in which digit triplets (e.g., 5-9-2) are presented in the presence of speech-shaped noise. The DIN test also has an important role in the counselling and follow-up of CI recipients during rehabilitation as the low cognitive demands of the test permits regular retesting of auditory abilities of CI recipients (Smits et al., 2013; Kaandorp et al. 2015; Van den Borre et al., 2021).

The DIN test is known for its reliability, validity, user-friendly application, time-efficiency, and low linguistic demands that allows the test to be used as a baseline for speech recognition (Kaandorp et al., 2015; Cullington & Agyemang-Prempeh, 2017; Cullington & Aidi, 2017; Potgieter et al., 2018; De Sousa et al., 2020). Additionally, the DIN test is highly correlated with sentence-in-noise tests, and has a low measurement error (Smits et al., 2013). Therefore, it has successfully been applied to HA users and CI recipients in evaluating hearing ability (Kaandorp et al., 2015; Cullington & Agyemang-Prempeh, 2017; Cullington & Aidi, 2017; Van den Borre et al., 2021). Additionally, DIN technology is consumer friendly, allowing even children with CIs and HAs as young as five years old to perform the test (Smits et al., 2013; Vroegop et al., 2021). The South African English DIN was developed and validated as a smartphone-based test in 2016 (Potgieter, Swanepoel, & Smits, 2018).

The DIN test can be self-administered at home and the test scores can indicate whether an in-person audiology appointment is necessary (Kaandorp et al., 2015; Cullington & Aidi, 2017; Cullington & Agyemang-Prempeh, 2017; de Graaff et al., 2018). Performing the DIN test in the home environment can reduce patient travel and expenses and improve the follow-up of CI recipients as it allows regular re-testing of auditory abilities (van den Borre et al., 2021). The COVID-19 pandemic demonstrated the value of a self-test that can be used to serve patients with financial constraints and those outside of conventional clinic environments (Swanepoel et al., 2019). The need exists to establish an accurate and reliable self-test that can be used by a diverse range of CI recipients in a home environment to monitor aided SIN performance.

CHAPTER 2: METHODOLOGY

2.1 Research aims

Main aim

To determine the accuracy and reliability of an aided DIN test for adult CI recipients to evaluate SIN performance.

Objectives:

This aim was achieved through the following objectives:

- i) To compare SIN performance in a simulated home environment to a clinic set-up.
- ii) To explore the perceptions of adult CI recipients regarding remote monitoring using SIN testing.

2.2 Research design

This research study employed an explorative, within-subjects repeated measures study design. In a within-subjects research design all participants receive all experimental treatments (Leedy & Ormrod, 2021). The current study was exploratory as relatively little information was available about the reliability and accuracy of the DIN test when conducted by adult CI recipients in a simulated home environment compared to a clinic set-up (Salkind, 2010).

As a result of the impact of the COVID-19 pandemic on hearing health care service delivery, the Pretoria Cochlear Implant Unit (PCIU) investigated alternative ways to serve their CI patients. Therefore, the DIN test (conducted in the clinical set-up/ audio booth and in a simulated home environment) was added to the standard audiological protocol for adult CI recipients (phase one of the study). Concurrently, adult CI recipients completed a self-administered survey (Appendix A) to investigate their perceptions of remote monitoring using the DIN test (phase two of the study). The

already obtained DIN test and survey data were analysed and reported retrospectively for the purposes of this study.

2.3 Research participants

DIN test and survey data obtained at the PCIU from March 2021 to August 2021 was reviewed. Adult CI recipients who attended routine post-operative CI device programming/ follow-up appointments at the PCIU were considered as research participants. Non-probability convenience sampling was used to select participants for the purpose of this study. This method enables the researcher to include a sample in a way that there is no guarantee or prediction that the entire population will have an equal chance of being included as participants (Leedy & Ormrod, 2021). As a result of the format of the DIN test and the requirement to complete a survey in writing, adult CI recipients were 18 years or older at the time of DIN testing CI recipients were pre- or post- lingually deafened and unilateral, bilateral, or bimodal CI users. None of the participants made use of electroacoustic stimulation systems, and all were oral communicators. Adult CI recipients with single-sided deafness were excluded. The final study sample included 33 adult CI recipients. A sample size calculation was not performed. The participants were English first-language speakers (21.2%) and English second-language users (78.8%). This study included a diverse sample of participants as excluding fewer participants can better reflect participants' wide-ranging speech recognition results (Kropp et al., 2020). Hence, no pre-screening for speech perception abilities was performed (no pre-selection of participants occurred).

2.4 Ethical considerations

A fundamental principle of conducting ethical research is to safeguard and protect the rights and human dignity of the participants involved in the study (Chabon et al., 2011). Researchers have a responsibility to adhere to this code in an accountable, honest, and ethically justifiable way (Babbie, 2010). The study complied with guidelines stipulated to student researchers in the University of Pretoria research code of ethics (University of Pretoria, 2018) and guidelines applicable to the South African context (Mouton, 2001; Health Professions Council of South Africa, 2008; Department of Health Republic of South Africa, 2015; University of South Africa, 2016). An information letter was provided to the PCIU team coordinator (Appendix E), outlining

the purpose and procedures of the study. Permission was obtained from the PCIU team coordinator to use already obtained survey and DIN testing data for the purpose of this study (Appendix F). Following permission from the PCIU, the study received ethical clearance from the Faculty of Humanities Research Ethics Committee, University of Pretoria (Appendix G). The ethical principles implemented during the study are stated and explained below.

2.4.1 Ethical clearance and scientific integrity

The research objectives were scientific, and a sound research design was incorporated to address the aim of the study. Institutional ethical clearance (HUM016/0721) was obtained from the Research Ethics Committee of the Faculty of Humanities, University of Pretoria (Appendix G).

2.4.2 Informed consent

Participants should be aware of the nature of the study and provide written permission to participate (Leedy & Ormrod, 2021). During routine post-operative CI device programming/ follow-up appointments, audiologists at the PCIU provided adult CI recipients (who adhered to the inclusion criteria for this study) with an information letter with a consent slip (Appendix C). The information letter and consent slip (Appendix C) explained the purpose and procedures of the remote monitoring protocol (DIN testing) and the survey, stated the participants' rights and confidentiality measures, COVID-19 precautions and lastly results sharing and data storage information. Adult CI recipients were required to sign the consent slip prior to proceeding with DIN testing and completing the survey. In addition, as part of routine PCIU patient procedures, all adult CI recipients are required to complete and sign a PCIU permission slip to release information (Appendix D). By signing the PCIU permission slip, the participants agreed that the PCIU have access and copying rights to any of their audiological, medical, and psychological records and that it may be used for the purpose of research and publication in scientific literature. Only the data obtained for adult CI recipients who completed and signed both the consent slip of the information letter and the PCIU permission to release information slip (Appendix D) was utilised for the purpose of this study. The CI team coordinator of the PCIU was approached to enquire whether the PCIU routine audiological protocol information can be utilised to report retrospectively as part of a research study. The CI team coordinator of PCIU provided consent that

the mentioned data may be accessed and utilised for the purpose of this study (Appendix F).

2.4.3 Possible risks and benefits from research

The risk of being involved in a study should not exceed the normal risk of an individual's everyday living (Leedy and Ormrod, 2021). The participants were made aware in the information letter (Appendix C) that within the context of the COVID-19 pandemic, the risks related to the study procedures were minimal. Strict infection control protocols were implemented to ensure that possible risks are minimised. Remote services became an essential part of overcoming the barriers created by worldwide lockdowns during the COVID-19 pandemic. Through this survey and remote monitoring protocol, the PCIU and possibly other CI units can discover alternative ways to reach and best serve their CI patients. The DIN test can possibly be used in the future as a remote speech perception test. Alternatively, the DIN can be implemented as part of routine testing in the clinic as a validated test, applicable to a multilingual population.

2.4.4 Right to privacy and confidentiality

Participants were informed that obtained data would be handled with strict confidentiality and identifying information of all participants would not be disclosed. Only the PCIU staff members and involved researchers had access to the data. The researcher received an anonymised data sheet to ensure participant confidentiality during data analysis and reporting. Participants' right to privacy was confirmed in the information letter and informed consent slip (Appendix C) and the PCIU permission to release information slip (Appendix D).

2.4.5 Storage of data

Data obtained will be stored electronically at the Department of Speech-Language Pathology and Audiology at the University of Pretoria for 15 years for research and archiving purposes, and at the PCIU. The data will also be shared to the Research Data Repository (Figshare) of the University of Pretoria. The data generated for this study may be used for further research/ future studies. This information was specified in the participant information letter (Appendix C).

2.4.6 Respect for persons (autonomy and dignity)

Researchers are obliged to treat all participants with respect, while simultaneously permitting them to freely make informed decisions and exercise self-determination. The researcher is also responsible for ensuring that participants can live according to their own preferences, beliefs, and values. Lastly, the researcher must prioritise the participants' dignity, safety interests, intrinsic worth, sense of value, and well-being. Each participant was able to make their own informed decisions and had a choice to either take part in the DIN testing and complete the survey or not during their routine post-operative CI device programming/ follow-up appointment at the PCIU.

2.4.7 Protection from harm

Participants should be protected from psychological and physical harm (Leedy & Ormrod, 2021). Permission was obtained from the CI team coordinator of the PCIU to access and utilise the already obtained PCIU DIN testing and survey data for the purpose of this study (Appendix F) and to study the retrospective data. The procedures in which data was collected did not pose any harm to participants.

2.4.8 Fair selection of participants

The exclusion, inclusion, and selection of participants were fair, just and based on scientific and ethical principles. A diverse sample of participants using CI devices were included. No participant was discriminated against based on gender, age, marital status, disability, religion, social origin, economic status, education, ethnicity, or language.

2.4.9 Plagiarism

The research dissertation reflects the researcher's own work. Secondary resources cited in the final research report were referenced in accordance with the regulations of the University of Pretoria and the Faculty of Humanities. A plagiarism declaration has been signed and included on the fourth page of this dissertation.

2.4.10 Release of findings

The researcher collated the results of the study in a dissertation to be made available online in the library of the University of Pretoria. A research article was published, and

the study findings may be shared at conference presentations and academic seminars.

2.5 Research materials and equipment

Table 1 provides an overview of the equipment that was included in the remote monitoring protocol conducted at the PCIU.

Table 1. Materials and equipment used during PCIU remote monitoring protocol

Materials/ equipment	Rationale
<i>Survey</i>	A hard copy survey (Appendix A) containing nine questions to investigate the perceptions of CI recipients on remote monitoring was developed. The survey was compiled by considering, adapting, and using items from multiple existing surveys (Cullington & Agyemang-Prempeh, 2017; Cullington & Aidi, 2017; de Graaff et al., 2019; Ayas et al., 2020). This survey also determined how participants experience the DIN test in the simulated home environment. The questions inquired whether participants were able to perform the DIN test in both the clinical environment and simulated home environment and related to the COVID-19 pandemic. Additional questions included asking participants whether they would consider using the DIN test as a self-test at home. A five-point Likert scale (from strongly agree to strongly disagree) was used as a rating scale for all nine questions.
<i>Data recording sheet</i>	A data recording sheet (Appendix B) was used to capture participants' demographic information, information related to their CI(s) and the DIN test data in both the clinic set-up and simulated home environment.
<i>Samsung Galaxy Trend NEO smartphone (Android OS, 5.1)</i>	The hearDigits™ application (DIN test) was operated on the smartphone. The hearDigits™ smartphone application was used to compare the DIN speech reception threshold (SRT) results of CI recipients in the two different conditions (clinic set-up vs simulated home environment).
<i>JBL Flip 4 portable speaker and ADAM A7X speaker</i>	The JBL portable speaker was used to present the three digits and speech-shaped noise in the simulated home environment. The ADAM A7X speaker was situated in the audiometric booth of the PCIU and used to present the digits and speech-shaped noise in the clinic environment.
<i>The hearDigits™ smartphone application (DIN test)</i>	The South African English digits-in-noise (DIN) test was developed and validated as a smartphone-based test in 2016 (Potgieter et al., 2016). The DIN is a speech-in-noise (SIN) self-test in which digit triplets (e.g., 5-9-2) are presented in the presence of speech-shaped noise. The test measured a signal-to-noise ratio (SNR) where the participant correctly identified 50% of the digit triplets. A research version of the application was used.
<i>Soundbooth and Interacoustics AC40 audiometer</i>	The smartphone was connected to an Interacoustics AC40 audiometer to present the digits and speech-shaped noise in the sound field through the loudspeaker. The smartphone was connected to the Interacoustics AC40 audiometer by a 3.5 mm x 5-metre audio cable.

2.6 Research context and procedures

The DIN test was included in the PCIU routine audiological protocol (in two environments, namely a simulated home environment and the clinic set-up). DIN testing served as the first phase of the study. For the second phase of the study, adult CI recipients who completed the DIN testing, were also requested to complete a survey to investigate their perceptions of remote monitoring using the DIN test (Appendix A).

The PCIU is situated in the Department of Speech-Language Pathology and Audiology (Communication Pathology building) at the University of Pretoria. The DIN test was administered twice in each condition to evaluate test-retest reliability. Test-retest reliability was performed for every participant to calculate the agreement amongst the two sets of scores acquired using either the same Bluetooth speaker or the same loudspeaker. The test and retest were performed on the same day as some CI recipients need to travel far distances to attend CI appointments at the PCIU and would not be able to perform the test and retest on consecutive days. The test environments were counterbalanced to avoid first-order carryover effects and control the two listening environments (Brown et al., 2019). Clinical audiologists at the PCIU identified adult CI recipients who attended routine post-operative CI follow-up appointments at PCIU that fit the inclusion criteria. While CI recipients were seated in the waiting room at the PCIU, they were given an information letter with a consent slip (Appendix C) as well as a permission to release information slip (Appendix D). After the audiologist completed routine CI device programming and post-operative audiological testing in the audio booth (aided pure tone and speech perception testing), the Samsung smartphone was connected to the audiometer to start with the South African DIN test in the sound field in the clinic set-up. Adult CI recipients were seated one metre from the loudspeaker at 0° azimuth.

If a participant had bilateral CIs, they were required to choose their dominant ear for testing purposes and remove the CI speech processor from the non-dominant ear. In the case of a bimodal CI user, the participant was required to remove the hearing aid and only use their CI speech processor during testing (Philips et al., 2018; Kropp et al., 2020; Cullington & Aidi, 2017). The participant was instructed to use the program

and volume setting of their CI speech processor that they use in everyday situations. Once the hearDigits™ application was opened, the audiologist was required to type in the CI recipient's name, surname, year of birth, code, and home language. Thereafter, a three-step tutorial screen provided instructions on how the application works. The audiologist also provided verbal instructions such as informing the participant that the digits will be presented in the presence of background noise. The participant was instructed to try to ignore the background noise. Furthermore, the participant was made aware that the test is not an easy task and that the test will start straight away. Lastly, the participant was informed that the test is adaptive (i.e., the noise will become louder and softer).

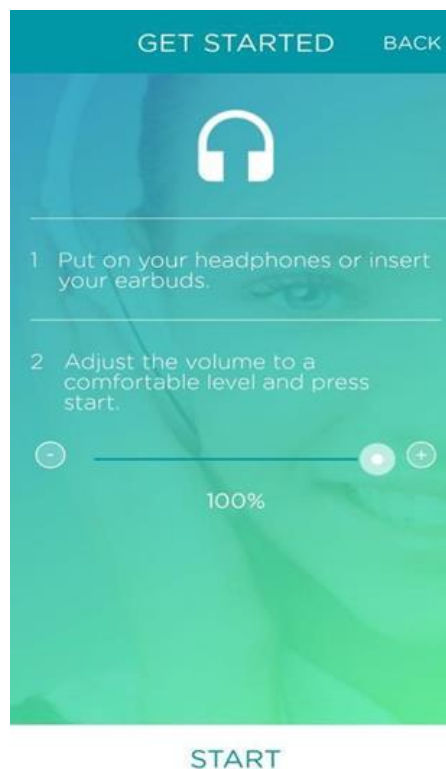


Figure 1. Volume adjustment Digits-in-Noise test screen

Three practice digits (e.g., 5,3,1) were presented by a female voice without the presence of background noise. The participant was informed that they will be required to say when they feel the digits are at a comfortable listening level. The audiologist then adjusted the intensity of the audiometer until a comfortable listening level was reached (see Figure 1). Once a comfortable listening level was reached, the audiologist pressed the “NEXT” button for testing to commence. The DIN test used a

binaural diotic (in-phase) stimulus paradigm. The CI recipient was required to listen and identify three digits in the presence of broadband speech-shaped noise (Potgieter et al., 2016; Potgieter et al., 2018). Once identified, the CI recipient was required to type the three digits into the hearDigits™ application. An adaptive signal-to-noise (SNR) one-up one-down procedure was used (4 dB for the first 3 steps, thereafter, continuing in 2 dB steps), measuring the SNR at which the CI recipient correctly identified 50% of the digit triplets. During the first three steps, 16 incorrect responses resulted in a 2 dB SNR increase per step and correct responses decreased the SNR by 4 dB per step. Only if all the digits were entered correctly were the digit-triplet regarded as correct. Each DIN test contains 23-digit triplets and the last 19 SNRs are averaged to work out the SRT (De Sousa et al., 2020).

DIN testing in the simulated home condition (office) was administered in an office in the Communication Pathology building (room 3-27) at the University of Pretoria in close proximity to the PCIU. A simulated home environment may be more controlled when compared to a real-world home environment that may possibly be more susceptible to noise, distraction, internet connectivity issues, environmental sounds, and different sound presentation systems. If the DIN test was administered in the simulated home environment first, the participant was provided with an information letter and consent slip (Appendix C) and a permission slip to release information (Appendix D). An audiologist supported the participant with the DIN test setup. Once the participant's details were entered on the hearDigits™ application, the participant was instructed that three practice digits will be presented without the presence of background noise. Similar to in the clinic environment, this was read by a female voice vocalizing three English digits at a time (e.g., 5,3,1) through the Bluetooth speaker. Participants were seated one metre from the Bluetooth speaker positioned between eye-level and 45° from eye-level. The participant was informed that they will be required to say when they feel the digits are at a comfortable listening level. The volume on the hearDigits™ application was then adjusted until the CI recipient reached a comfortable listening level. The participant was instructed by the audiologist to use the program and volume setting on their CI speech processor that they use in everyday situations. Once complete, final instructions followed. The test started once the "NEXT" button was pressed. The test consisted of 23 sets of three digits (digit-triplets) presented in the presence of speech-weighted noise. The listener (participant)

had to type the digits into the hearDigits™ application. If participants were unsure of the digits they were allowed to guess. Once the participant completed the DIN test twice in both conditions, they were required to complete the hard copy survey in writing (Appendix A).

2.7 Data analysis

Descriptive statistics were used to define the sample population and analyse means, average SNR, and standard deviations of both environments (clinic set-up and simulated home environment) in the test and retest conditions of the study. DIN test data was retrospectively retrieved from the research Android OS application and survey data from the hard copy surveys was captured on an Excel sheet and retrieved retrospectively. MS Excel 2013 was used to code DIN test and survey data. The data was then analysed using the Statistical Package for the Social Sciences Version 26.0 (IBM SPSS, Chicago, Illinois) (SPSS). SPSS was used to generate the graphs depicting the survey data. DIN testing data (SNRs), data from clinical files (demographic information) and survey data were captured on the Excel sheets. A thematic analysis was used to identify themes in the free text section of the survey. The Shapiro–Wilk’s normality test ($p < 0.05$) indicated that the data were not normally distributed. Therefore, non-parametric analysis was used to compare the mean SNRs between the simulated home and clinic environment in the test and retest stages of the study. A Wilcoxon signed-rank test was conducted to establish whether there was a statistically significant mean difference between the SNRs when comparing the initial test to the retest ($p < 0.05$) in each environment and when comparing the SNRs between the two environments. It was expected that there will not be a significant difference in mean SNRs between the clinic and the simulated home environment. A two-way mixed effects model was used to assess reliability by using the intraclass correlation coefficient (ICC). Intraclass correlations measure the relationship between variables that measure the same thing (Liljequist et al., 2019). The standard error of measurement (SEM) and ICC also reflected the degree of agreement and degree of correlation amongst measurements. The 2-way mixed- effects model, agreement and averaged measures were used to calculate the ICCs and their 95% confidence intervals.

2.8 Validity and reliability

Validity refers to the extent to which the measurement strategy produces an accurate evaluation of the phenomenon or characteristic in question (Leedy & Ormrod, 2021). There is a possibility for validity errors to occur when reviewing retrospective data (Panacek, 2007). According to Leedy and Ormrod (2021) reliability refers to the extent to which a measurement produces consistent results while there was no change in the measured entity. ICC was performed between the test and retest measures in the different test environments to examine the agreement between the measures. In addition, the SEM was used to indicate the degree to which the different measurements correlate and agree.

CHAPTER 3: RESEARCH ARTICLE

Title: *Remote monitoring of adult cochlear implant recipients using digits-in-noise self-testing*

Journal: American Journal of Audiology

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3.1 Abstract

Purpose: The COVID-19 pandemic has accelerated the uptake and scope of telehealth. This study determined the accuracy and reliability of a smartphone digits-in-noise (DIN) test when conducted by adult CI recipients in a simulated home environment compared to a clinic setup. Perceptions of remote monitoring using speech-in-noise (SIN) testing were also explored.

Method: Thirty-three adult CI recipients between 18 and 78 years of age ($M = 46.7$, $SD = \pm 20.4$) conducted the DIN test in a simulated home environment and a clinic setup. Test-retest reliability across the two environments and comparisons between test settings were evaluated. A survey explored the perceptions of adult CI recipients regarding remote monitoring and use of the DIN self-test.

Results: Mean aided SRTs in the clinic and simulated home environment test conditions and clinic and simulated home environment retest conditions did not differ significantly. Mean test-retest SRTs in the clinic and simulated home environment were significantly different ($p < .05$). High intraclass correlation coefficient (ICC) and low standard error of measurement (SEM) scores reflected good and excellent

reliability between test-retest measures and between clinic and simulated home environment measures. Most participants were positive about the possibility of using the DIN test at home to self-assess speech perception although some test adjustments such as including training items and a less adverse starting SNR may be required.

Conclusions: Adult CI recipients can use the smartphone DIN test to self-assess aided speech-in-noise performance in a home environment with accuracy and reliability relatively similar to clinic testing.

3.2 Introduction

The COVID-19 pandemic has exceeded 251 million confirmed cases in less than two years, with more than 5 million deaths globally (Dong et al., 2020). As a result, governments and authorities were forced to implement preventive measures such as social distancing, lockdowns, self-isolation, and quarantine to contain the spread of the virus (Shah et al., 2020). The need for physical distancing and the communicable nature of COVID-19 has led to a significant increase in demand for telehealth options (Blandford et al., 2020). COVID-19 has compelled healthcare systems, including the audiology industry (Swanepoel & Hall, 2020), to be innovative in the way in which services are delivered to patients (Cassar et al., 2021).

Telehealth has been recommended to overcome some of the current audiological service delivery challenges amid the pandemic (Swanepoel & Hall, 2020; Manchaiah et al., 2021). Traditionally the goal of telemedicine was to enable individuals who reside in underserved or remote regions to access medical services and care. However, the target audience of telemedicine has seen a dramatic change during COVID-19, with safety becoming the primary driver (Zeng, 2020). The technology-driven nature of audiology regarding hearing assessment and intervention further offered unique opportunities to deliver remote care (Swanepoel & Hall, 2020). Telefitting of cochlear implant (CI) devices and hearing aids (HAs) have received limited attention until the COVID-19 pandemic (Swanepoel & Hall, 2010; et al., 2020; Kim et al., 2021). Most recently, a study by Meeuws et al. (2020) demonstrated that with audiologist supervision, it is possible to remotely fit CIs when supported by artificial intelligence.

Telehealth has been used with great success with CI recipients in terms of CI device programming (Ramos et al., 2009; McElveen et al., 2010; Rodríguez et al., 2010; Wasowski et al., 2010; Eikelboom et al., 2014; Samuel et al., 2014; Slager et al., 2019), intraoperative testing (Shapiro et al., 2008) and objective tests such as electrode impedance testing and the measurement of electrically evoked compound action potential (ECAP) thresholds (Goehring et al., 2012; Hughes et al., 2012). Studies have demonstrated that remote fitting of CI devices is safe, effective, and accepted by most CI recipients and health professionals (Ramos et al., 2009; McElveen et al., 2010; Wesarg et al., 2010; Eikelboom et al., 2014; Kuzovkov et al., 2014; Samuel et al., 2014; Schepers et al., 2019). Slager et al. (2019) confirmed that the amount of time required to complete remote versus in-office CI device programming is similar.

Previous studies have found that CI recipients' and audiologists' experience using telemedicine services is highly positive (Rodríguez et al., 2010; Swanepoel & Hall, 2010; Wasowski et al., 2010; Wesarg et al., 2010; Eikelboom et al., 2014; Kuzovkov et al., 2014; Goehring & Hughes, 2017; Slager et al., 2019; Eikelboom et al., 2021). According to Cullington et al. (2016), adult CI recipients who wear their devices during every waking hour are open to the idea of making telehealth part of their device management routine. Similarly, a study by Cullington and Aidi (2017) indicated that most adult CI recipients could administer a remote speech perception test in a simulated home environment and indicated a preference for the above clinic tests.

Remote CI device programming and testing have demonstrated feasibility and preference in some cases, but certain CI recipients may still need or prefer the clinic. During initial CI device activation, clinicians usually determine magnet strength, measure the length of the speech processor cable, explain CI device use and demonstrate how batteries should be changed (Buckman & Fitzharris, 2020). These interactions require the clinician and CI recipient to be at the same location (Buckman & Fitzharris, 2020). In addition, as part of the audiological protocol, CI recipients' speech perception abilities are routinely assessed at the clinic, as improved speech understanding is usually the primary goal of cochlear implantation (Cullington & Aidi, 2017).

Speech-in-noise (SIN) tests are clinically valuable for CI recipients as it allows the monitoring, comparison, and adjustment of CI settings (Smits et al., 2013; Kaandorp

et al., 2015). Recently, Davidson et al. (2021) demonstrated a direct relationship between SIN tests and increased hearing aid (HA) satisfaction. Stimuli routinely used during speech perception testing for adult CI recipients include sentences, monosyllabic words or digits presented through the sound field in quiet (de Graaff et al., 2018) or in the presence of background noise (Brown et al., 2019). As a SIN test, the Digit-in-Noise (DIN) test has an essential role in the counselling and follow-up of CI recipients during rehabilitation (Smits et al., 2013; Kaandorp et al., 2015). In a recent study from Maruthurkkara et al. (2021), adult CI recipients successfully used the DIN as part of the *Remote Check* application to self-assess hearing in a home environment.

The DIN test is a widely used and preferred test due to its reliability, validity, user-friendly self-test applications, time-efficiency, and low linguistic demands (Kaandorp et al., 2015; Cullington & Agyemang-Prempeh, 2017; Cullington & Aidi, 2017; Potgieter et al., 2018; Swanepoel et al., 2019; De Sousa et al., 2020). The World Health Organization has also adopted this test approach for their widely used smartphone-based self-test application (hearWHO app) for hearing screening (Swanepoel et al., 2019). The DIN test is highly correlated with sentence-in-noise tests and has a low measurement error (Smits et al., 2013) and has therefore been successfully applied to HA and CI recipients in evaluating hearing ability (Kaandorp et al., 2015; Cullington & Agyemang-Prempeh, 2017; Cullington & Aidi, 2017; Van den Borre et al., 2021). The DIN test has also been shown to produce robust results across various sound field transducers (Brown et al., 2019) using a smartphone DIN test, which makes home-based monitoring possible.

We investigated if the DIN test can be used by CI recipients as an alternative speech test. The DIN test is a self-test that can be administered at home and test results can give an indication if face-to-face device programming is required. The need for a self-test arose during the COVID-19 pandemic when alternative ways to reach patients were explored. The objective of this study was to describe the accuracy and reliability of an aided DIN test for CI recipients to evaluate SIN performance in a simulated home environment. A secondary objective was to explore adult CI recipients' perceptions of remote monitoring using SIN testing.

3.3 Method and materials

Institutional review board approval from the Research Ethics Committee of the University of Pretoria (HUM016/0721) was obtained prior to data analysis.

3.3.1 Research design

As a result of the impact of the COVID-19 pandemic on hearing health care service delivery, the Pretoria Cochlear Implant Unit (PCIU) explored alternative means to serve their CI patients. Hence, SIN testing using the DIN test was added to the standard routine audiological protocol for adult CI recipients. This study investigated DIN test outcomes by employing an explorative, within-subjects repeated measures design. The adapted PCIU audiological protocol involved the DIN test in two listening environments, namely a simulated home environment and a clinic setup, which was the study's first phase. The DIN test was administered twice in each condition to evaluate test-retest reliability. The test environments were counterbalanced to avoid first-order carryover effects and control the two listening environments (Brown et al., 2019).

The second phase of the study included a survey completed by the adult CI recipients to investigate their perceptions of remote monitoring using the DIN test. The DIN test and survey results provided information about remote CI monitoring. This already obtained DIN test and survey data were analysed and reported retrospectively.

3.3.2 Participants

Thirty-three adult CI recipients with a mean age of 46.7 years (SD = ± 20.4 ; range: 18–78 years) who attended routine postoperative CI device programming/ follow-up appointments at the PCIU between April 2021 and August 2021 were included. CI recipients were pre- or postlingually deafened and unilateral, bilateral, or bimodal CI users. None of the participants made use of electro-acoustic stimulation (EAS) systems and all were oral communicators. Adult CI recipients with single-sided deafness were excluded. The participants were English first-language speakers (21.2%) and English second language users (78.8%). Table 2 describes the sample population.

Table 2. Characteristics of adult cochlear implant recipients (n=33)

	All participants % (n)
Onset of hearing loss Prelingual deafness Postlingual deafness	39.4% (13) 60.6% (20)
Age at study (years) Mean (SD) Range	46.7 (20.4) 18 - 78
Gender Male Female	42.4% (14) 57.6% (19)
Hearing device(s) Bilateral cochlear implants Unilateral cochlear implant ¹ Bimodal ²	27.3% (9) 42.4% (14) 30.3% (10)
Age at onset of severe - profound hearing loss (years) Mean (SD) Range	21.8 (23.0) 0 - 61
Duration of severe - profound hearing loss prior to cochlear implantation³ (years) Mean (SD) Range	11.3 (11.8) 0.25 - 44
CI experience⁴ (years) Mean (SD) Range	10.9 (8.0) 0.3 - 28
Implant type Cochlear MedEI Advanced Bionics	78.8% (26) 18.2% (6) 3% (1)
Speech processor model Cochlear Nucleus 7 (CP 1000) Cochlear Nucleus 6 (CP910 and CP920) Cochlear Nucleus 5 (CP810) Kanso 2 Medel Sonnet 2 Medel Rondo 2 Naida CI Q70 (Advanced Bionics)	48.5% (16) 18.2% (6) 3% (1) 9.1% (3) 12.1% (4) 6.1% (2) 3% (1)
DIN testing starting environment Clinic Simulated home environment	48.5% (16) 51.5% (17)

¹ Not using hearing aid in non-implanted ear

² Unilateral cochlear implant, using hearing aid in non-implanted ear

³ Time-lapse (years) between onset of (severe) hearing loss and (first) cochlear implantation

⁴ Time-lapse between activation of (first) CI device and DIN testing (data collection)

3.3.3 Data collection material and equipment

Phase I – Cochlear implant aided DIN test accuracy and reliability in a simulated home environment

3.3.3.1 Smartphone DIN test

A binaural diotic (in-phase) stimulus paradigm with South African English digits was used on the smartphone (Android OS) DIN test research application (hearDigits™, hearX Group, South Africa) (Potgieter et al., 2016). During this test, three bi- and monosyllabic digits (0-9) were presented in the presence of speech-weighted masking noise from a list of 120 available digit triplets (Potgieter et al., 2016, 2018). The triplet is assembled by the program by concatenating the appropriate digits with 500 ms silent intervals at the beginning and end of every triplet. The following digits are presented in 200 ms silences with 100 ms jitter in between (Potgieter et al., 2016). An adaptive signal-to-noise ratio (SNR) one-up one-down procedure was used (4 dB for the first 3 steps, thereafter, continuing in 2 dB steps), which measured the SNR at which the listener correctly identified 50% of the digit triplets. During the first three steps, incorrect responses resulted in a 2 dB SNR increase per step, and correct responses decreased the SNR by 4 dB per step. Only if all the digits were entered correctly was the digit triplet regarded as correct. Each DIN test contained 23 combinations of three digits (digit triplets), and the last 19 SNRs were averaged to work out the Speech Reception Threshold (SRT) (De Sousa et al., 2020). A lower SRT (dB SNR) score indicated a better speech recognition in noise result and a higher SRT (dB SNR) score referred to poorer speech recognition in noise (Cullington & Agyemang-Prempeh, 2017).

3.3.3.2 Test environments and setup

DIN testing in the simulated home environment was administered in an office at the Department of Speech-Language Pathology and Audiology, University of Pretoria, South Africa. The office was in the same building where the PCIU is situated. This office was selected to imitate a home environment with background noise, reverberation, and some distraction. Participants were seated at a table, with the Bluetooth speaker positioned one meter between eye-level and 45° from eye-level on the table (Figure 2B). A portable JBL Flip 4 speaker was connected to the Samsung Trend Neo smartphone through a Bluetooth connection to present the DIN in the sound field. An audiologist assisted with the test setup, but the participant completed the test using the smartphone application independently and without any assistance.

In the clinic setup, DIN testing was conducted in the PCIU audiometric booth through a single loudspeaker (ADAM A7X). The Samsung smartphone was connected to the Interacoustics AC40 clinical audiometer by a 3.5 mm x 5-metre audio cable. The length of the cable allowed the smartphone to reach the participant seated in the audio booth. In the audio booth, participants were positioned at 0° azimuth and one metre from the loudspeaker (see Figure 2A). The audiologist assisted with the test setup, but each participant held the smartphone to type in their response independently and without any assistance.

Phase II – Survey on perceptions of remote monitoring

3.3.3.3 Perceptions of remote monitoring survey

A self-administered survey was developed for this study to explore adult CI recipients' perceptions of remote monitoring (Supplemental material 1). Items from several existing surveys were considered, adapted, and used to compile the survey used in this study (Cullington & Agyemang-Prempeh, 2017; Cullington & Aidi, 2017; de Graaff et al., 2019; Ayas et al., 2020). Adaptations were made to ensure the questions encompass the COVID-19 pandemic theme and refer to the specific smartphone DIN test utilised in this study.

The survey determined how participants experience the DIN test in the simulated home environment. The survey included a total of ten questions. In addition to the four questions that related to the DIN testing, five questions related to the COVID-19 pandemic and the possibility to receive CI related services at home. A five-point Likert scale was used as a rating scale (from strongly agree to strongly disagree) in which participants rated their level of agreement to the nine statements. Participants were also provided with one open-ended question to comment on their experiences of the DIN test.

3.3.4 Data collection procedures

Clinical audiologists at the PCIU identified adult CI recipients who attended routine postoperative CI follow-up appointments at the PCIU that adhered to the inclusion criteria. After the audiologist completed routine CI device programming and

postoperative audiological testing in the audiometric booth (aided pure tone and speech perception testing), DIN testing proceeded.

In the case of bilateral CI users, CI recipients were required to use their better hearing (dominant) ear for testing purposes. In the case of bimodal CI users, CI recipients were required to remove the hearing aid in the non-implanted ear and only use their CI's speech processor during testing (Cullington & Aidi, 2017; Philips et al., 2018; Kropp et al., 2020). CI recipients were instructed to use the program and volume setting of their CI speech processor that they use in everyday situations.

In the clinic setup, the Samsung smartphone was connected to the audiometer to start with the South African DIN test in the sound field. Adult CI recipients were seated one metre from the loudspeaker at 0° azimuth (Figure 2A).



Figure 2. Participant and speaker positioning during (A) clinic setup and (B) simulated home environment Digits-in-Noise testing

For both test environments, once the application (hearDigits™, hearX Group, South Africa) was opened, the audiologist was required to type in the CI recipient's name, surname, year of birth, code, and home language. The following DIN test application screen required participants to rate their English proficiency on a scale of 1-10, in line

with the study by Potgieter et al. (2018). Thereafter, a three-step tutorial screen provided instructions on how the application works. The audiologist also provided uniform and consistent verbal instructions informing each CI recipient that the digits will be presented in the presence of background noise, which the CI recipient should try to ignore. The CI recipient was made aware that the test will start immediately, is adaptive (i.e., the noise will become louder and softer), requires careful listening and might be perceived as difficult. In both test environments, three practice digits (e.g., 5,3,1) read by a female voice in English were presented without the presence of background noise. The CI recipients were asked to indicate when the practice digits were perceived at a comfortable listening level in the clinic set-up. The audiologist adjusted the intensity on the audiometer (in dBHL) until a comfortable listening level was reached. Once a comfortable listening level was reached, the audiologist tapped on the "NEXT" icon on the application screen for testing to commence. The three digits without background noise were presented through the Bluetooth speaker in the simulated home environment to allow CI recipients to select a comfortable listening level. This was achieved by CI recipients dragging the volume control on the application screen to a preferable level. CI recipients tapped on the "NEXT" icon on the application screen for testing to commence as soon as a comfortable listening level was reached.

The CI recipient was required to listen and identify three digits in the presence of broadband speech-shaped noise (Potgieter et al., 2016; Potgieter et al., 2018). Once identified, the CI recipient was required to type the three digits into the digits-in-noise application (hearDigits™, hearX Group, South Africa). In both environments the CI recipients were required to enter the digits in the keypad themselves. If CI recipients were unsure of the digits, they were instructed to guess.

After performing the DIN test in both environments, CI recipients were asked to complete a hard copy survey about their perceptions of remote monitoring.

3.3.5 Data analysis

Retrospective DIN test results were retrieved from the research Android OS application and retrospective survey data from the hard copy surveys. DIN test and survey data were coded into MS Excel 2013 and then analysed using the Statistical

Package for the Social Sciences Version 26.0 (IBM SPSS, Chicago, Illinois) (SPSS). SPSS was used to generate the graphs demonstrating survey data. DIN testing data (SNRs), data from clinical files (demographic information) and survey data were captured on the Excel sheets. Descriptive statistics were used to define the sample population (Table 1). Means, average SNR, and standard deviations of both environments in the test and retest stages of the study were analysed using descriptive statistics. The Shapiro–Wilk's normality test ($p < 0.05$) indicated that the data were not normally distributed. Therefore, non-parametric analysis was used to compare the mean SNRs between the clinic and simulated home environment in the test and retest stages of the study. A Wilcoxon signed-rank test was conducted to verify whether there was a statistically significant mean difference between the SNRs when comparing the initial test to the retest ($p < 0.05$) in each environment and when comparing the SNRs between the two environments. A two-way mixed-effects model was used to assess reliability using the intraclass correlation coefficient (ICC). The ICC and standard error of measurement (SEM) also reflected the degree of agreement and degree of correlation amongst measurements.

3.4 Results

Cochlear implant aided DIN test accuracy and reliability in a simulated home environment

All participants completed the DIN test twice in both test environments, with the test environments counterbalanced (Table 3). There were no significant mean SRT differences for either the initial clinic and simulated home test ($p = .254$; $z = 1.14$), or between the clinic and simulated home retest conditions ($p = .224$; $z = 1.22$). However, there was a statistically significant improvement between the clinic test and retest of 3.2 dB SNR ($p = .037$) as well as an improvement of 1.8 dB SNR ($p = .014$) between the simulated home environment test-retest (Figure 3). There were five outliers (four in the clinic and one in the simulated home environment) who performed poorly on the initial test instead of the retest in each condition (Figure 4).

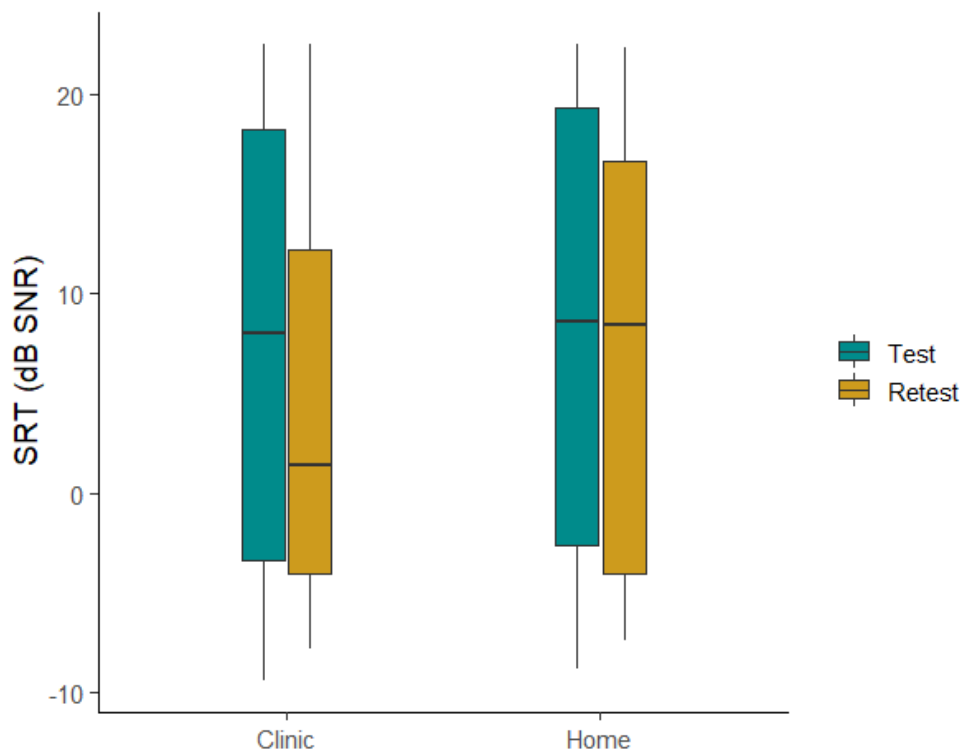


Figure 3. Box plots representing test versus retest scores measured in dB SNR of the Digits-in-Noise (DIN) test conducted in the clinic environment (left) and in the simulated home environment (right). The box displays the portion of the distribution falling between the lower and upper quartiles (25th and 75th percentiles). The median is represented by the horizontal line. The vertical lines outside the box (whiskers) include the smallest and largest values that are not classified as extreme values or outliers. A lower SRT (dB SNR) score represents a better result and a higher SRT (dB SNR) score represents a poorer result.

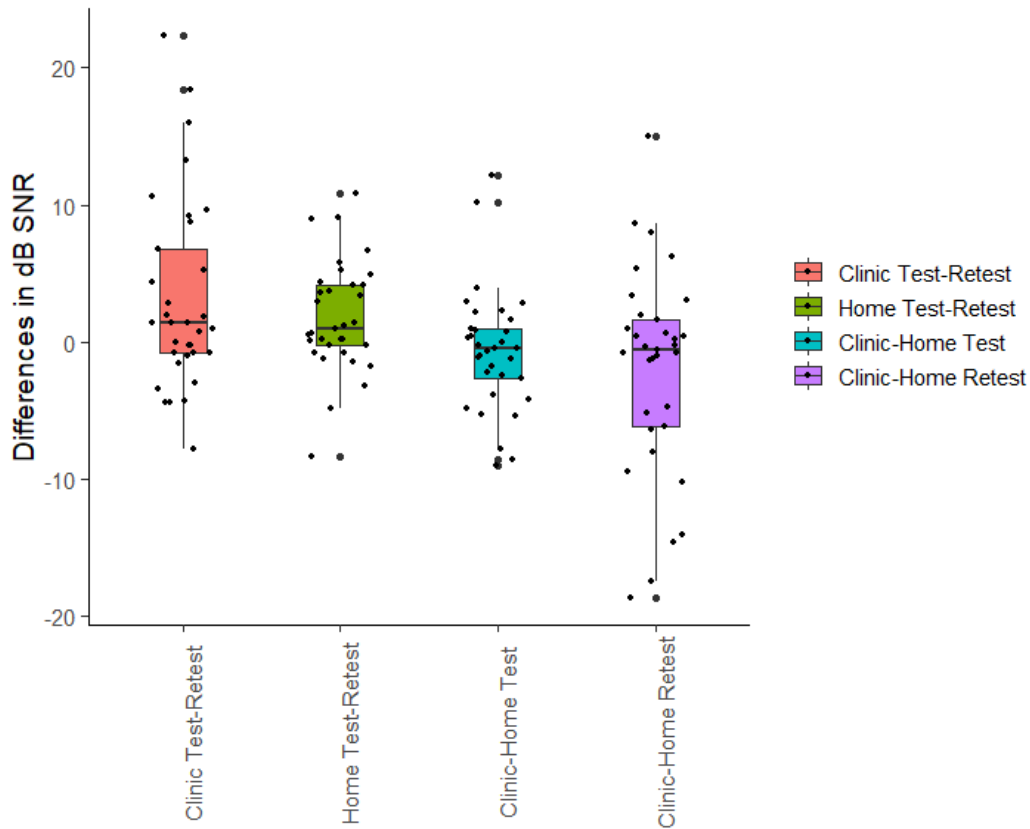


Figure 4. Box plots indicating the intrasubject variability in dB SNR within (left and second from left) and between (right and second from right) the test environments. The dots above and below the box plots are deemed as outliers by SPSS due to its positions more than 1.5 box lengths below the lower quartile and above the upper quartile. A lower SRT (dB SNR) score represents a better result and a higher SRT (dB SNR) score represents a poorer result.

The SEM (Table 3) indicated the agreement between measures with the lowest SEM for simulated home test-retest. The ICCs in both the clinic and simulated home environment test-retest measures were high (Table 3), reflecting good and excellent reliability, respectively (Portney & Watkins, 2000). In addition, there was good to excellent agreement (Portney & Watkins, 2000) between the initial test of the clinic and simulated home environment, as well as between the clinic and simulated home retests (Table 3).

Table 3. Characteristics of digit-in-noise speech recognition thresholds and comparisons between clinic and home test and test-retest (n=33).

	Mean (SD)	Range	IQR	ICC (95% CI)	SEM
<i>DIN scores</i>					
Clinic #1	7.6 (11.1)	-9.4 – 22.5	22.8	-	-
Clinic #2	4.4 (10.2)	-7.8 – 22.5	17.7	-	-
Home #1	8.2 (10.9)	-8.8 – 22.5	22.5	-	-
Home #2	6.4 (10.5)	-7.4 – 22.3	20.7	-	-
<i>DIN comparisons (difference scores)</i>					
Clinic test-retest	3.2 (7.0)	-7.8 – 22.3	8.7	0.861 (0.694 - 0.934)	1.2
Home test-retest	1.8 (4.0)	-8.4 – 10.8	4.8	0.957 (0.900 - 0.980)	0.7
Clinic #1 vs Home #1	7.9 (10.7)	-7.7 – 22.2	23.7	0.957 (0.912 - 0.979)	1.9
Clinic #2 vs Home #2	5.4 (9.6)	-7.2 – 22.2	16.7	0.850 (0.691 - 0.926)	1.7

IQR – interquartile range; ICC – intraclass correlation coefficient; SEM – standard error of measurement

No significant difference between the prelingually deafened and postlingually deafened groups were identified in the simulated home environment ($p = .196$) and in the clinic ($p = .182$). The mean test duration in the clinic was 3.49 minutes (1.42 SD) and in the simulated home environment 3.48 minutes (1.47 SD).

3.4.1 Perceptions of remote monitoring

All participants (n=33) agreed or strongly agreed that they could perform the DIN test in both DIN test environments. Most participants agreed or strongly agreed (90.9%) that they would feel comfortable using the DIN test to self-test speech perception abilities with their CI at home and responded positively (78.7%) to the possibility of receiving regular CI services from their home. Most participants however agreed or strongly agreed (93.9%) that they were comfortable attending a face-to-face appointment with their audiologist during COVID-19 pandemic. Most participants agreed or strongly agreed (81.9%) that they struggle to hear speech in the presence of background noise with their CI(s), but they agreed or strongly agreed (78.8%) that

the quality of the speech testing conducted in the simulated home environment was similar to the quality of the speech testing conducted in the clinical environment (Figure 5 and 6).

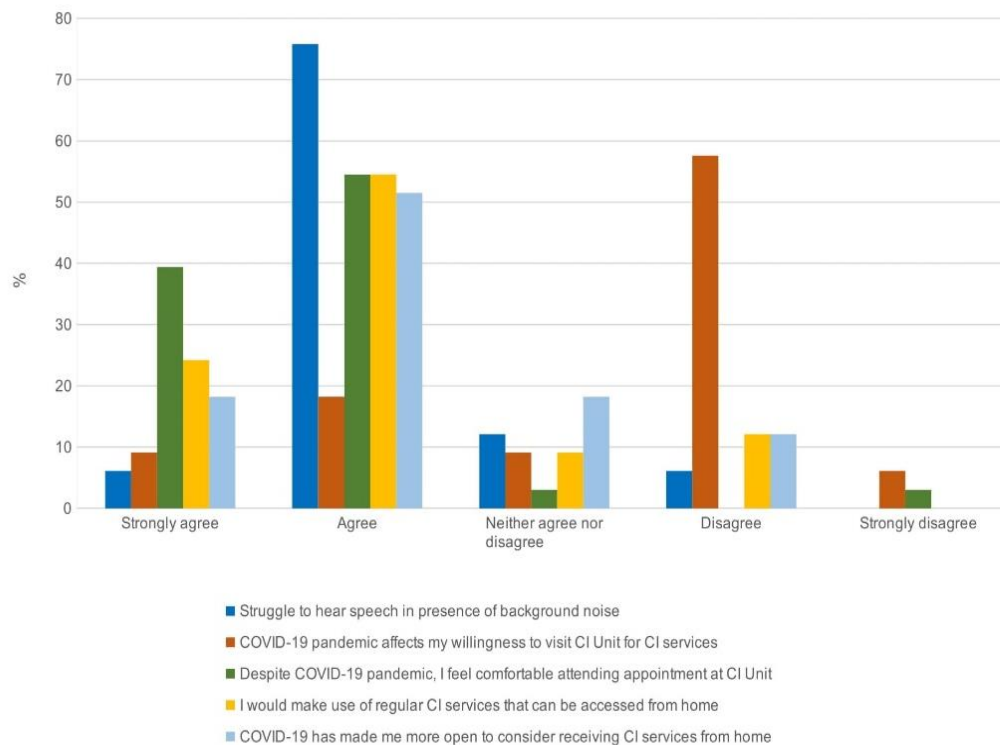


Figure 5. Results of survey items related to remote services for CI patients (n=33)

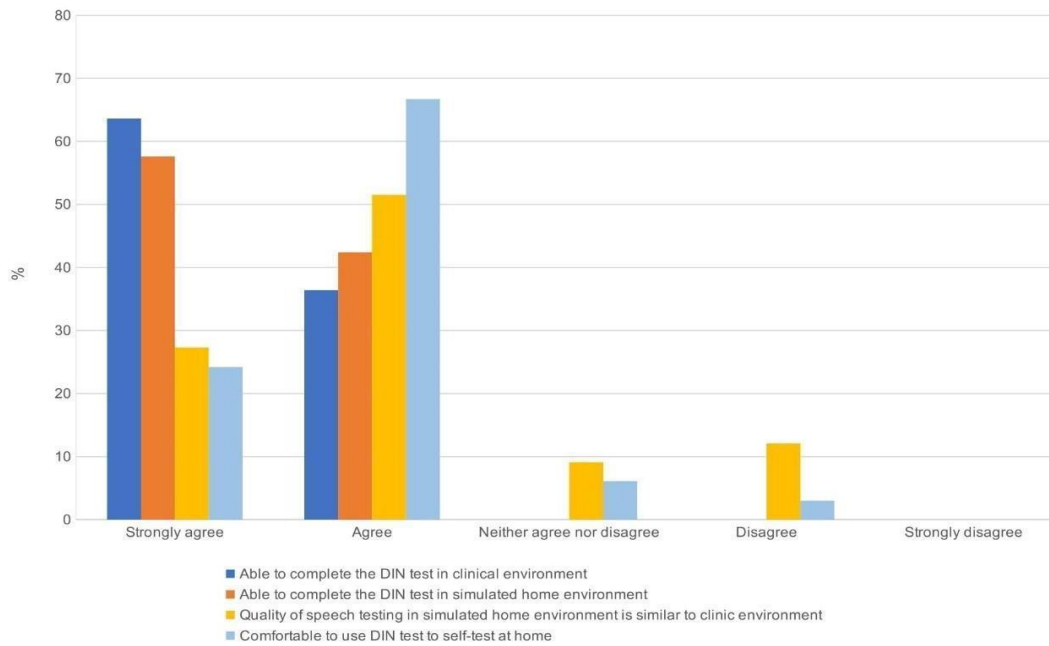


Figure 6. Results of survey items related to the Digits-in-Noise test (n=33)

The free text section of the survey for participants’ experiences of the DIN test was analysed thematically with two themes identified as indicated in Table 4.

Table 4. Thematic analysis of participant reported experiences of using the Digits-in-Noise (DIN) test

Themes	Examples
Positive test experiences	<p><i>“The DIN test was enjoyable”</i></p> <p><i>“An interesting test”</i></p> <p><i>“An amazing test”</i></p> <p><i>“An excellent test”</i></p> <p><i>“A good test to use”</i></p>
Test concerns	<p><i>“The test was somewhat difficult”</i></p> <p><i>“The test was hard”</i></p> <p><i>“Sometimes hearing the digits well but sometimes struggling to hear the digits”</i></p> <p><i>“The test is more difficult in the simulated home environment”</i></p> <p><i>“The lack of delay at the start of the test caused confusion”</i></p>

3.5 Discussion

This explorative study determined the accuracy and reliability of an aided DIN self-test for adult CI recipients to evaluate SIN performance in a simulated home environment. All CI recipients were able to complete the DIN self-test in both environments. The mean SRTs between the clinic and simulated home environment were not significantly different, indicating that adult CI recipients can conduct the smartphone DIN test in a home environment with reliability and accuracy relatively similar to the clinic (via loudspeaker in the audiometric booth). De Graaf et al. (2018) found similar results where a strong correlation was identified between clinician-led audio booth testing and home testing, although a connection with an audio cable was used to perform the DIN test instead of a loudspeaker in the home environment.

In contrast to previous DIN studies that used a direct connection (audio cable) between the CI sound processor and computer/ tablet (Cullington & Agyemang-Prempeh, 2017; de Graaff et al., 2018; Philips et al., 2018), the present study was conducted in the sound field. Although an audio cable connection eliminates or reduces the background noise, sound field testing with a loudspeaker enables the clinician to assess the entire hearing pathway (Cullington & Aidi, 2017) and allows testing without specialised equipment. In addition, direct connection prevents the functional assessment of the speech processor microphone(s) since dirty microphone covers may negatively affect speech perception (de Graaff et al., 2018). More favourable speech perception results may be obtained with an audio cable, resulting in an inaccurate reflection of actual speech perception in daily life (de Graaff et al., 2018; Sevier et al., 2019). Although Brown et al. (2019) did not identify any significant difference in DIN test results when comparing different speakers in a quiet environment, the influence of loudspeaker quality in a noisy home environment is yet to be investigated. Wireless streaming for a device to the CI sound processor recently became a possibility for remote testing and should be explored in future studies as an alternative to direct audio input and loudspeaker testing in the home environment (van Wieringen et al., 2021).

Significantly better ($p < .05$) DIN results were recorded for retest instances within each environment. Several studies (Kaandorp et al., 2015; de Graaff et al., 2018; Kropp et al., 2020) have also reported a procedural learning effect between test and retest in the DIN test. In the study by Kropp et al. (2020), some participants overcame the

learning effect using a third test. However, despite administering a practice list, Kaandorp et al. (2015) still identified a small learning effect between test and retest (of 0.3 dB) between the second and third test lists in adult CI recipients. In this study, large test-retest differences were identified in some participants, similar to a study by Kaandorp et al. (2015). Despite this effect, the SEM values correlated to the values of 1.7 (DIN administered with loudspeakers) and 1.2 (audio cable connection to conduct DIN) in a study by de Graaff et al. (2018) and 1.1 in a study by Kaandorp et al. (2015). The current study calculated the SEM and ICC for both environments and demonstrated a good agreement level and high reliability for the test overall (Table 2). More importantly, the SEM and ICC values indicated that the simulated home environment test-retest values are comparable to the test-retest reliability obtained in the clinic. Furthermore, the lower SEM allows the DIN test to be compared in various conditions such as CI only versus bimodal situations, CI or HA settings, or bilateral versus unilateral conditions (Kaandorp et al., 2015). According to Philips et al. (2018), when CI recipients conduct the DIN test in a home environment, familiarity with the test reduces the learning effect, and fatigue would have a minor effect on outcomes.

In the current study, an average improvement of 1.8 dB between test and retest was found in the simulated home environment, and a greater test-retest improvement of 3.2 dB was seen in the clinic environment. These results support the need for at least one training list, especially for CI recipients who often experience difficulty with listening in noisy environments (Gifford et al., 2008; Dorman & Gifford, 2017; Willberg et al., 2021).

The test and retest SRT scores for both test instances range from -9.4 to 22.5 dB in the clinic and -8.8 to 22.5 dB in the simulated home environment, indicating a wider range of results than the SRT range of -6.6 to 12.4 dB SNR in the study by Kropp et al. (2020) and the -2.55 and 12 dB range in the study by Cullington and Aidi, (2017). The current study's DIN test setup used a starting SNR of 0 dB which was intended to differentiate normal hearing from hearing loss and not for CI recipients who already have a significant SNR loss (Smits et al., 2004; Potgieter et al., 2016; De Sousa et al., 2020). More than half of the CI participants in this study had SRTs that were higher than the starting SNR of 0 dB. This starting SNR is likely to be too adverse for CI

recipients as a starting intensity and could be adjusted in addition to a training list to be administered prior to testing.

All adult CI recipients, except those with SSD, were included in this study, which reflected the wide-ranging speech perception abilities and performance of adult CI recipients (Kropp et al., 2020). The CI experience of participants at the time of data collection ranged from three months to 28 years, also reflecting the heterogeneity of the study sample. Patient-related variables were controlled for by using a within-subjects design (Maruthurkkara et al., 2021). In addition, test environments were counterbalanced. Although numerous factors have been investigated to explain the wide-ranging speech perception outcomes in CI recipients, a large part of the variance is yet to be explained (Roditi et al., 2009; Lazard et al., 2012; Blamey et al., 2013). The variety of factors influencing speech perception performance in adult CI recipients is well recognised, for example, the position of the electrodes (Finley et al., 2008; Lazard et al., 2012), duration of severe to profound hearing loss prior to implantation (Blamey et al., 1996, 2013; Budenz et al., 2011; Holden et al., 2013; Mosnier et al., 2014; Roditi et al., 2009), residual hearing, and preoperative speech recognition (Leung et al., 2005; Lazard et al., 2012). Studies by Taylor et al. (2020) and Potgieter et al. (2018) demonstrated the potential influence of language abilities on DIN test performance. In addition, Van Wijngaarden et al. (2002) and Zokoll et al. (2013) stated that cognition, auditory memory, and linguistic complexity of the test material could potentially affect the performance of English second language speakers. However, the DIN relies minimally on top-down processing (e.g., linguistic skills) (Smits et al, 2013), English digits are used in a variety of languages and the self-reported English competence of non-native listeners can be used to adjust reference scores to accommodate this population.

Participant feedback indicated that most (69.7%) were more open to the possibility of receiving regular CI related services that can be accessed from home as a result of COVID-19. The majority of participants responded positively to the possibility of using the DIN test at home to self-assess speech perception (90.9%) and possibly receiving regular CI services from home (78.7%). All participants stated being able to perform the DIN test in both test environments without any difficulties. The time taken to complete the DIN test was fast (3.5 minutes per test in each environment) and is

consistent with the DIN test times of 2 to 3 minutes reported by Kropp et al. (2020). SIN testing through a Bluetooth speaker enables CI recipients to perform the DIN test easily and quickly at home without any additional specialised equipment. Testing of speech perception abilities in noise with the DIN test allows clinicians to evaluate and optimise the fitting parameters of CIs and use the DIN test for rehabilitation follow-up purposes (Smits et al., 2013; Kaandorp et al., 2015; Van den Borre et al., 2021). Although DIN test speech material is restricted and sentence tests might be more representative of real-life listening conditions, the DIN test may be more useful than the sentence test for the evaluation of cochlear implant fitting (Smits et al., 2013). Numerous studies have demonstrated a high correlation between the DIN test and other sentences-in-noise tests in CI recipients (Kaandorp et al., 2015, 2016; Cullington & Aidi, 2017; Willberg et al., 2021). A study by van Wieringen et al. (2021) indicated the DIN in the home environment proved to be more useful than the sentences-in-noise to identify ear-specific changes in auditory performance and monitor progress at regular intervals. In contrast to the sentences-in-noise test, the DIN can be administered repeatedly without a clinician.

A limitation of the current study was the relatively small sample size. It is important to keep in mind that the DIN test was not originally developed to evaluate the hearing ability of individuals with severe to profound hearing loss (Smits et al., 2004) and the results of this population cannot be compared to those with normal hearing as almost all of them would obtain perfect scores (Cullington & Aidi, 2017). Another potential limitation may be the difficulties related to home testing as opposed to testing in a simulated home environment. Test accuracy can be compromised by problems with internet connectivity, technical competence, and noisy testing environments. However, recent studies indicate that reliable results can be obtained for home-based testing despite less control over sound level and quality (Swanepoel & Hall, 2010; Molander et al., 2013; Masalski et al., 2014). In the present study the audiologist assisted with the setup in both environments. Although a self-setup may empower participants to be able to independently perform the setup in their home, an initial explanation or demonstration of the setup by the audiologist may still be necessary. Due to the ease of the setup, the explanation can be done remotely. Numerous studies have however noted the value of patient-site facilitators in providing optimal and

efficient services (Hughes et al., 2012; Wesarg et al., 2010; Crowell et al., 2011; Eikelboom et al., 2014).

Future recommendations for the DIN test in CI recipients would be to include training items and a less adverse SNR to create a more beneficial starting level for this population, which could decrease the test-retest differences obtained in this study.

3.6 Conclusions

The results of this explorative study have demonstrated that although various factors may influence remote testing, the DIN test can be conducted by adult CI recipients in a home environment with accuracy and reliability relatively similar to clinic testing. As a result of the COVID-19 pandemic, CI recipients are more inclined to use remote CI services and tests such as the DIN test to self-assess speech perception at home. With minor changes to testing procedures, the DIN test could possibly be used by clinicians as part of the standard test battery as a reliable and accurate SIN test for adult CI recipients.

CHAPTER 4: DISCUSSION AND CONCLUSION

4.1 Summary and discussion of results

This explorative study aimed to determine the accuracy and reliability of an aided DIN test conducted by adult CI recipients to evaluate SIN performance in a simulated home environment compared to a clinic set-up. In addition, the perceptions of adult CI recipients regarding remote monitoring using SIN testing were explored. To obtain a comprehensive understanding of the CI recipient's hearing in everyday listening situations, it is necessary to test speech perception in both quiet and noise. International guidelines advise CI clinics to include at least one type of SIN test in the test battery utilised for the evaluation of CI candidacy and rehabilitation outcomes (Adunka et al., 2018).

The DIN self-test was completed by all participating CI recipients in both test environments. Mean aided SRTs in the clinic and simulated home environment test ($p = 0.957$) conditions and clinic and simulated home environment retest ($p = 0.850$) conditions did not differ significantly, suggesting that the smartphone DIN test can be conducted by adult CI recipients in a home environment with similar accuracy and reliability to the clinic (via the audiometric booth loudspeaker). Comparable results were identified by de Graaff et al. (2018) where an audio-cable connection was used for DIN testing as opposed to sound field testing in adult CI recipients. The study by de Graaff et al. (2018) identified no significant difference between audiometric booth clinician-led testing and home self-testing.

To evaluate possible test-retest differences in SRT results, the test-retest reliability was performed. In the clinic ($p = .037$) and simulated home environment ($p = .014$), significantly better results were recorded for the retest instances. On average, there was a 1.8 dB SNR improvement between test and retest in the simulated home environment, and the clinic environment reflected a test-retest improvement of 3.2 dB SNR. Other studies (de Graaff et al., 2018; Kropp et al., 2020) also reported a procedural learning effect between the test and retest instances of the DIN test. In the current study, intraclass correlation coefficient (ICC) and standard error of measurement (SEM) values revealed high reliability and a good agreement level for the overall DIN test results (Table 3). SEM values were comparable to a study by de

Graaff et al. (2018) that obtained values of 1.2 (audio cable connection to conduct DIN testing) and 1.7 (DIN testing administered with loudspeakers) and a 1.1 SEM value reported by Kaandorp et al. (2015).

The test and retest SRT scores for both test instances of the current study reflected a wider range of test results. SRT scores ranged from -9.4 to 22.5 dB in the clinic and -8.8 to 22.5 dB in the simulated home environment. A narrower range of SRT scores were obtained by Kropp et al. (2020) (-6.6 to +12.4 dB) and Cullington and Aidi (2017) (-2.55 and 12 dB). The wide range of SRT scores may be due to the DIN test setup in the current study that used a starting SNR of 0 dB, which was intended to differentiate individuals with a hearing loss from normal hearing individuals, and not CI recipients who already have a substantial SNR loss (Smits et al., 2004, 2013). In the current study both pre- and postlingually deafened CI recipients formed part of the study sample, which differed from most other similar studies that only used postlingually deafened CI recipients in their study samples (Kaandorp et al., 2015; de Graaff et al., 2016; de Graaff et al., 2018; van Wieringen et al., 2021).

Most participants responded positively to the possibility of receiving CI services from home (78.7%) and to using the DIN test at home to self-assess speech perception (90.9%). The simulated home environment is significantly different from the well-controlled clinic environment in terms of background noise, equipment setup and possibly increased patient anxiety in performing the test. However, after providing proper test instructions, all participants could complete the DIN test in both environments without experiencing any problems. This corresponds to a study by Kropp et al. (2020) which agreed that CI recipients could perform the DIN test without any assistance after a short introduction has been given due to the comprehensibility and low cognitive demands of the test. The study by Kropp et al. (2020) however only included postlingually deafened CI recipients and users of Cochlear Nucleus CI systems, whereas the present study included pre- and postlingually deafened individuals using various CI systems (Table 2). According to participant responses, the COVID-19 pandemic resulted in most of them (69.7%) being more open to receiving regular CI related services in their home environment.

The findings of the current study demonstrate that adult CI recipients can perform the DIN test in a simulated home environment with similar accuracy and reliability to clinic

testing. Home DIN testing is beneficial, especially during times such as the COVID-19 pandemic and for CI recipients with mobility issues. Remote testing with the DIN self-test allows CI recipients to be re-tested frequently and makes adequate remote rehabilitation possible (Van den Borre et al., 2021).

4.2 Clinical implications and recommendations

Study results indicate that it is possible for adult CI recipients to perform the smartphone DIN test in a simulated home environment with similar accuracy and reliability to the CI clinic. This is an important finding as it may reduce the number of clinic visits that will benefit CI recipients with mobility difficulties and those with financial constraints (Nassiri et al., 2022). Participants also indicated that they are open to the possibility of receiving regular CI related services at home and the majority were positive about the possibility of using the DIN test at home to self-assess speech perception.

The DIN test uses easy familiar words (digits) with a closed-set paradigm as speech material and mainly examines auditory speech perception skills. Therefore, the influence of top-down processes like linguistic skills is minimised (Smits et al., 2013). The DIN test is an excellent alternative to use for patients who are not able to perform more demanding tests such as sentences-in-noise tests, where floor or even ceiling effects often occur (Kaandorp et al., 2015). The DIN test can be incorporated into the standard audiological test battery for CI recipients (Willberg et al., 2021) as a validated SIN test that is applicable to a multilingual population due to digits being highly familiar stimuli commonly known even by individuals with restricted language skills (Cullington et al., 2022). SIN tests provide a more accurate estimation of auditory performance in real-world situations (Vroegop et al., 2021). The current recommended protocol for pre-operative and post-operative speech perception testing for adult CI recipients includes AzBio sentences in quiet and noise, CNC words, and the BKB-SIN test (*Minimum Speech Test Battery*, 2011).

Consequently, the DIN test can be utilised to determine a baseline for speech perception skills of adult CI recipients. A study by de Graaff et al. (2019) revealed that home self-testing of speech perception skills may be appropriate for approximately

80% of newly implanted patients. This opens the possibility of the DIN being used not only by experienced CI recipients, but also in newly implanted patients. Using the DIN in newly implanted patients is important as it provides detailed speech perception progress over the first three months of rehabilitation (de Graaff et al., 2019). In newly implanted individuals it would be important to use a more beneficial starting SNR and a training list to avoid learning effects. Access to detailed progress information enables clinicians to identify opportunities for intensifying auditory training and recognizing the need for clinic visits (de Graaff et al., 2019). The fact that the DIN test can be used without audiologist supervision on a regular basis at home (van Wieringen et al., 2021), makes it possible to compare CI settings and conduct remote rehabilitation, and amplification monitoring (Van den Borre et al., 2021).

Evidence suggests that CI recipients and their families are increasingly demanding greater control of their hearing care, including self-assessment at home (Tsay, 2013; Cullington, 2013). As cochlear implantation requires continuous technology management, it is crucial that CI recipients have sufficient self-care routines and involvement in their treatment (Saunders, 2019). Thus, by administering the DIN test at home, CI recipients are empowered to manage their hearing needs at home and can act swiftly if any decrease in speech recognition performance is identified (Cullington & Aidi, 2017).

Speech perception test results may be a valuable addition to already existing data logs (Busch, Vanpoucke, & van Wieringen 2017; Oberhoffner et al., 2018) as they provide insight into the development of speech perception postoperatively (Kropp et al., 2020). Remote services may not suit all patients as some CI recipients may be unwilling or unable to complete a self-test at home (Cullington & Agyemang-Prempeh, 2017). However, remote speech testing enables audiologists to stay connected with their patients and allows continual access to a holistic care model during and after the COVID-19 pandemic (Bhamjee et al., 2022).

A personalised long-term remote care follow-up protocol including a home self-test, self-adjustment of hearing device, and online support tool for adult CI recipients has been proven to be acceptable and feasible to both clinicians and patients, which resulted in more empowered patients (Cullington et al., 2018). SIN testing can be

implemented as part of a routine monitoring protocol to assess hearing and device functioning. The *Remote Check* application was recently developed to remotely monitor CI recipients (Maruthurkkara et al. (2021). It is recommended that CI recipients perform all the various features of this application, including SIN testing, at a first clinic visit. Thereafter, clinicians can send CI recipients alerts to complete the SIN test and the additional tasks (aided threshold test, a questionnaire that includes items from the Speech, Spatial and Qualities of Hearing Scale (SSQ), automated impedance telemetry, data logs, and implant site photos, sound processor diagnostics) on the application. The CI recipient's audiologist would also have access to the obtained results for continuous monitoring of CI recipients, which are expected to have stabilised within the first year after cochlear implantation. Routine monitoring will permit the audiologist/ clinician to determine if the CI recipient needs an annual clinic visit when changes in speech perception and device issues are identified (Maruthurkkara et al., 2022). Numerous studies display substantial improvement outcomes when CI recipients use self-management tools (Panagioti et al., 2014), and those who are involved and take an active role in their care are more likely to have better health outcomes (Mosen et al., 2007; Hibbard et al., 2015). Although telemedicine might not be suitable for all adult CI recipients, the choice of the pathway to follow should involve a shared decision-making between the clinician, patient, and their families (Cullington et al., 2022).

4.3 Critical evaluation

It is important to evaluate the research study critically in order to interpret and understand the strengths and limitations of the findings. These are stated below:

Strengths of the study:

- The smartphone DIN test was used in an actual clinical environment and workflow, presenting results that were ecologically valid. The validity and reliability of the DIN test conducted in a home environment, as well as the ability of the DIN test to adequately differentiate across adult CI recipients allows the test to possibly be added as part of the current speech perception test protocol (Kropp et al., 2020). The use of a smartphone to perform testing allowed

clinicians to perform a quick and easy setup in the testing environment. Testing duration was quick (on average 3.5 minutes per test in each environment) which allowed DIN testing to take place on the same day as the CI recipient's clinic appointment.

- The study sample included a wide range of participants and the age of the participants ranged from 18 to 78 years. In addition, pre- and postlingually deafened CI recipients were included in the study. Excluding fewer participants aids in reflecting the wide-ranging speech performance of adult CI recipients (Kropp et al., 2020). For CI recipients whose speech perception falls within the floor or ceiling category on the WRS test, due to the lexical complexity of the test (Van den Borre et al., 2021), the DIN can be used (Kropp et al., 2020). The DIN test is a good alternative to use as the test primarily focuses on auditory speech perception abilities, makes use of a closed-set paradigm, and limits the effect of linguistic skills (Van den Borre et al., 2021).
- The DIN is clinically applicable and has an increased sensitivity to changes in speech perception compared to other tests (Kropp et al., 2020). Including pre- and postlingually deafened CI recipients contributes valuable information to literature and provides clinicians with a useful guideline on what to expect from pre- and postlingually deafened CI recipients in speech perception in noise tests (Vroegop et al., 2021). Including both pre- and postlingually deafened CI recipients is significant since the current study indicates that the DIN test can be performed not only on postlingually deafened CI recipients but also on pre-lingually deafened CI recipients.
- The use of a within-subjects design allowed for patient-related variables to be controlled (Maruthurkkara et al., 2021) and the cross comparison of DIN test results in both the clinic and simulated home environments.
- The test environments were counterbalanced to avoid first-order carryover effects and control the two listening environments (Brown et al., 2019).

Limitations of the study:

- A relatively small sample size containing only English first-language speakers and English second-language users were included in the study. Thus, the study

sample should be increased and broadened to be a more accurate representation of the entire adult CI database.

- A simulated home environment was used in this study, which can be seen as slightly more controlled in comparison to a real-world home environment that is susceptible to noise, distraction, internet connectivity issues, environmental sounds, and different sound presentation systems. In a real-world home environment, the CI recipient has to perform a self-set-up of the equipment and needs to perform the test independently, which may cause anxiety in some CI recipients. All the above-mentioned factors vary widely across home environments and could potentially affect test outcomes.
- In the present study, the audiologist assisted with the DIN testing setup in both the clinic and simulated home environments, which may have influenced the confidence of the participants to conduct the setup independently at home. CI recipients were seated one metre from the loudspeaker at 0° azimuth in the clinic environment. In the simulated home environment, participants were seated one metre from the Bluetooth speaker positioned between eye-level and 45° from eye-level. Although a self-setup may empower participants to perform the setup more independently in their home environment, an initial explanation or demonstration of the setup by the audiologist may still be necessary. Audiologists could use the initial stimulation/ CI device activation or routine follow-up appointments to provide CI recipients with information and instructions regarding remote speech perception testing and ensure that CI recipients are able to perform the test independently at home. However, the setup used in the current study was fairly simple and clinicians would be able to explain these steps over a remote meeting or video call.
- In the current study, some participants experienced the DIN test to be somewhat difficult due to the start of the test being sudden and introduced with high noise compared to signal level. A few participants reached a ceiling effect on the DIN test, which correlated to their reports of struggling with the test. Participants only started to get used to the SNR after the first few digit-triplets, highlighting the need for a practice round. The smartphone DIN test could be adapted to include training items and a less adverse SNR in order to ensure a more beneficial starting level for CI recipients who often experience great difficulty listening to speech in noise (Gifford et al., 2018).

- The test and retest were performed on the same day as some CI recipients need to travel far distances to attend CI appointments at the PCIU and would not be able to perform the test and retest on consecutive days. Not only is a procedural learning effect between test and retest possible, but it is likely that some participants became fatigued as four DIN tests were performed consecutively with a relatively short break in-between.
- Participants were required to only use the CI on the better hearing (dominant) ear in the case of bilateral implantation and remove the HA if they were bimodal users. This may have influenced test results as the study by Willberg et al. (2021) allowed bilateral use of hearing devices during DIN testing. However, using one CI only for DIN testing provides an indication of changes needed to the settings of that particular CI device and for rehabilitation purposes (Kaandorp et al., 2015).

4.4 Future research

By critically evaluating the research project, the following recommendations for future research were identified:

Participants were required to be 18 years or older in order to participate in the study. However, a study by Vroegop et al. (2021) has demonstrated that children as young as five years old with different degrees of hearing loss using CIs or HAs can successfully administer the aided DIN test. Therefore, future studies can investigate using the smartphone DIN test in the home environment with older (> 5 years old) paediatric CI recipients. Consequently, it can be explored whether the reduced CI clinic visits as a result of the home DIN test led to more stable hearing and better hearing, and increased empowerment for patients and parents in this population as well (Cullington et al., 2022).

Future research studies should investigate CI recipients performing the DIN test in a true home environment and secondly in a home environment using different loudspeaker systems to more accurately represent the testing conditions in which the participants would conduct the test. In addition, the various sound presentation systems that may influence test results should also be evaluated (Brown et al., 2019).

Evaluating the difference of the DIN test versions with the adaptations as opposed to the version without the updates could be conducted to explore whether there is a difference in test outcomes. The adaptations of the DIN test would include training items and a less adverse SNR to create a more beneficial starting level, which would then be added to the updated DIN test version.

The South African DIN test is used in the current study as it has been validated for the South African context. The digits are however easy, familiar words that are used in a closed-set paradigm which could possibly be used by other countries and language groups as well, since the test is not language-dependent. This could be explored in a future study.

In order to enhance the clinical applicability of the DIN test, future research should use the DIN test to monitor hearing status over time for CI recipients. The comparison of a CI recipient's most recent score with previous scores provides better clinical insight into an individual's progress over time and helps to notice problems that require intervention. It is important for the test-retest difference to be as small as possible to ensure that any change is as a result of deterioration rather than a test-measurement error.

Future studies can investigate how CI recipients' perceptions of remote testing relate to their DIN test scores and individual aided performance. This would provide a valuable person-centred perspective to outcome data obtained.

Future research studies should evaluate whether wireless streaming to a CI sound processor compared to sound field DIN testing and direct audio input testing has an effect on DIN test results in the home environment. This could be valuable as there are various factors known to influence speech perception testing in the home environment (Goehring et al., 2012). It would be interesting to explore if wireless streaming would limit the extraneous factors in the home environment and produce better speech perception results. Direct connection eliminates dependence on speaker quality and removes or reduces the effects of background noise in the home environment. In addition, microphone input is excluded during direct connection testing

(Cullington & Aidi, 2017). CI speech processor microphones are often vulnerable to damage, dust or humidity (Cullington et al., 2018). However, sound field testing allows the evaluation of the entire hearing pathway. Consequently, the influence of the sound processor microphone could also be evaluated in a home test (Cullington & Aidi, 2017).

4.5 Conclusion

The current study demonstrated that the DIN test can be conducted by adult CI recipients in a simulated home environment with reliability and accuracy relatively similar to clinic testing. Since the COVID-19 pandemic, CI recipients are more inclined to use remote CI services and tests such as the DIN test to self-assess speech perception at home. With minor changes to testing procedures such as including training items and a less adverse SNR, the DIN test could possibly be incorporated in the postoperative test battery as an accurate and reliable SIN test for adult CI recipients.

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APPENDICES

Appendix A: Survey



Survey

Name and surname (for office use only): _____

Home language: _____

(Please note, identifying information will only be used for data tracking purposes)

At each of the following questions, select and mark only ONE answer/ option

1. I struggle to hear speech in the presence of background noise with my cochlear implant(s)

- Strongly agree
- Agree
- Neither agree nor disagree
- Disagree
- Strongly disagree

2. The COVID-19 (coronavirus) pandemic still affects my willingness to visit the Pretoria Cochlear Implant Unit for regular cochlear implant related services

- Strongly agree
- Agree
- Neither agree nor disagree
- Disagree
- Strongly disagree

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3. Despite the current COVID-19 pandemic, I feel comfortable attending a face-to-face appointment with my audiologist at the Pretoria Cochlear Implant Unit

- Strongly agree
- Agree
- Neither agree nor disagree
- Disagree
- Strongly disagree

4. I was able to complete the Digits-in-Noise (DIN) test in the clinical environment (audio booth)

- Strongly agree
- Agree
- Neither agree nor disagree
- Disagree
- Strongly disagree

5. I was able to complete the Digits-in-Noise (DIN) test in the simulated home environment (office)

- Strongly agree
- Agree
- Neither agree nor disagree
- Disagree
- Strongly disagree

6. I feel the quality of the speech testing conducted in the simulated home environment is similar to the quality of the speech testing conducted in the clinical environment (audio booth) at the Pretoria Cochlear Implant Unit

- Strongly agree
- Agree
- Neither agree nor disagree
- Disagree
- Strongly disagree

7. I would feel comfortable to use the Digits-in-Noise (DIN) test to self-test my speech perception abilities/ skills with my cochlear implant(s) at home

- Strongly agree
- Agree
- Neither agree nor disagree
- Disagree
- Strongly disagree

8. I would make use of regular cochlear implant related services that can be accessed from home (receive these services in my home environment)

- Strongly agree
- Agree
- Neither agree nor disagree
- Disagree
- Strongly disagree

9. The COVID-19 pandemic has made me more open to consider the possibility of receiving regular cochlear implant related services that can be accessed from home (receive these services in my home environment)

- Strongly agree
- Agree
- Neither agree nor disagree
- Disagree
- Strongly disagree

Please comment on your experiences of the Digits-in-Noise (DIN) test:

Thank you for completing the survey!

Appendix B: Data recording sheet



Name and surname of CI recipient: _____ Subject number: _____

Home language: _____ PCIU audiologist: _____

DOB: _____ Date of testing: _____

Gender: _____

English speaking competency (Rating: 1-10)

Unilateral CI user	Bilateral CI user	Bimodal CI user
Tested ear (dominant/ preferred ear as specified by CI user)		
Survey completed	Yes	No
Tested ear - Hybrid device	Yes	No
Onset of postlingual HL	Progressive	Sudden
Age at onset of severe HL		
Duration of severe HL prior to CI (years)		
Cochlear implant experience		
Implant type (ear to be tested)		
Speech processor type/ model (ear to be tested)		

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In which condition the test was conducted FIRST

Clinic environment DIN test (audio booth)	Simulated home environment DIN test
--	--

1. Clinic environment DIN test (audio booth)

	SNR RESULT	TIME (as recorded on DIN test)	Comfortable listening level
Test:			
Retest:			

2. Simulated home environment DIN test

	SNR RESULT	TIME (as recorded on DIN test)	Comfortable listening level
Test:			
Retest:			

Additional comments:

Effects of the Coronavirus Pandemic on service delivery at the Pretoria Cochlear Implant Unit (PCIU)

April 2021

Dear cochlear implant recipient,

Thank you for your willingness to participate in this PCIU survey.

Purpose of the survey:

COVID-19 has forced hearing healthcare professionals to rethink the way in which services are delivered to cochlear implant (CI) recipients. The PCIU is investigating new innovative ways to reach CI recipients during this time. The aim of this survey and accompanying task is to evaluate the impact that this pandemic has on service delivery to CI recipients at the PCIU. The task includes the *South African Digits-In-Noise* (DIN) test and is also part of this survey. The *South African DIN test* is a hearing screening test that was initially developed as a smartphone application. Currently, it can also be administered on other devices such as laptops or tablets. We want to explore if the DIN test can possibly be used by CI recipients as an alternative speech test (your ability to hear speech within the presence of background noise). The DIN test is a self-test that can be administered at home and test results can give an indication if face-to-face device programming/ mapping (at the PCIU) is required. The DIN test is included in this survey to get an idea of how CI recipients experience such a self-test, and NOT to evaluate performance of CI recipients. We (PCIU) would like to explore if such a self-test can be useful for CI recipients.

Participation in this survey will enable us to explore alternative ways for CI recipients to access CI services.

Information gathered through this survey and task will also be used for research purposes (in collaboration with the Department of Speech-Language Pathology and Audiology, University of Pretoria).

Procedures:

The Digits-in-Noise (DIN) test will be performed as part of our routine audiological protocol. The DIN test will be conducted in a simulated home environment (office) and in a clinical environment (the audio booth). It will take approximately 12 minutes to complete this test in both environments.



For the DIN test, you will use the program and volume setting for your speech processor(s) that you use in everyday situations (default program).

Similar to the speech perception testing that is done in the sound booth at the PCIU, this test (speech stimuli and noise) will also be presented through a speaker.

Once you are ready, the DIN test will proceed as follows:

1. The audiologist will ask you to select a comfortable listening level.
2. Three English digits (any number from 0-9) will be said by a female speaker in the presence of background noise.
3. You are required to type in the three digits that you have heard.

On completion of the DIN test in both conditions, you will be required to complete a short survey (9 questions) to provide feedback on your experiences of the DIN test. This will take approximately 4 minutes to complete.

In addition to survey data, selected demographic and CI related information will be collected from patient files/ clinical records at PCIU.

Participants' rights:

Your participation in these procedures (completing a short survey and administering the DIN test in two different environments) is entirely voluntary. You have the right to withdraw from these procedures at any time.

Confidentiality

Data obtained from the survey, the DIN test, and patient files/ clinical records at PCIU will be handled with strict confidentiality and identifying information of all participants will not be disclosed.

Risks and discomforts

Within the context of the current COVID-19 pandemic, the risks related to these procedures are minimal. Strict infection control protocols have been implemented to ensure that possible risks are minimised.

COVID-19 precautions

The PCIU staff and assistants will adhere to COVID-19 protocols at all times.

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Sharing of results

Results obtained from the survey and DIN test procedures will be shared in the form of a scientific research article and a research dissertation in the future, which will be made available to hearing health care professionals.

Data storage

Data obtained will be stored at the Department of Speech-Language Pathology and Audiology at the University of Pretoria for 15 years for research and archiving purposes, and also at the PCIU. All data acquired may be reused for further research/ future studies.

Should you require any additional information, or clarification of the information indicated above, please feel free to contact Nicolize Cass (PCIU team coordinator) at 0791063495 or nicolize.cass@pretoriacochlear.com



Nicolize Cass
Coordinator: Pretoria Cochlear Implant Unit



PERMISSION

I freely agree to complete the survey and associated DIN testing tasks to explore the *Effects of the Coronavirus Pandemic on service delivery at the Pretoria Cochlear Implant Unit (PCIU)*.

I hereby give permission that the data collected may be used for research purposes (for this current study and also for future studies) and for publication in scientific literature. I also give permission that the data in my patient file (clinical records) at the Pretoria Cochlear Implant Unit may be accessed and utilized. The data generated for this study will be accessible for further research/ future studies. I am aware that patient confidentiality will be maintained at all times.

- Yes, I clearly understand and accept the above-mentioned information and freely agree to complete the survey and associated DIN testing tasks

- No, I do not accept the above-mentioned information and do not want to complete the survey and associated DIN testing tasks

Name: _____

Date: _____

Signature: _____

Directors: Nicolize Cass, Dr. Elnèmarie Burden, Prof. Johan Hanekom | Company Reg. No. 2015/241478/08

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Appendix D: PCIU Permission to release information



PERMISSION TO RELEASE INFORMATION

I, _____ give permission to the Pretoria Cochlear Implant Unit (PCIU), to have access and copying rights to any of my medical, audiological, and psychological records. This information may be used for the purpose of research, publication in scientific literature, and to share with the appropriate bodies concerned with the performance of the cochlear implant. I understand that patient confidentiality will be maintained at all times unless specific permission to release identifying data is granted by me.

Signed: _____ **Date:** _____

Name: _____

Witness: _____

Name: _____

Role: _____

Appendix E: Information letter to the Pretoria Cochlear Implant Unit



Faculty of Humanities
Fakulteit Geesteswetenskappe
Lefapha la Bomotheo



Attention: Mrs Nicolize Cass

Cochlear implant team coordinator: Pretoria Cochlear Implant Unit

June 2021

RE: Permissions to use survey and Digits-in-Noise (DIN) test data obtained from adult cochlear implant recipients at the Pretoria Cochlear Implant Unit (PCIU) for a research project

I am a Master's degree (MA Audiology) student from the Department of Speech-Language Pathology and Audiology at the University of Pretoria. My research is in the field of cochlear implants (CIs). The aim of my study is to compare the accuracy and reliability of the DIN test conducted in a simulated home environment to a clinic set-up, and to describe the perceptions of adult CI recipients on remote monitoring using DIN testing. I am aware of a survey that was conducted by the PCIU titled *Effects of the Coronavirus pandemic on service delivery at the PCIU*. I am also aware that this survey and DIN testing were conducted during the routine appointments of adult CI recipients at PCIU to determine the feasibility of an alternative method of service delivery. Therefore, I would like to write up the results of this survey and the DIN testing results for my postgraduate research study.

This research study will employ a retrospective descriptive research design. Prior to completing the PCIU survey and DIN testing, adult CI recipients at PCIU received an information letter and completed a consent slip in which permission was granted that survey data, DIN test data, and the information in their patient files/ clinical records may be used for research purposes. Data obtained will be handled with confidentiality and identifying data of participants will not be disclosed.



Faculty of Humanities

Fakulteit Geesteswetenskappe
Lefapha la Bomotheo



A unique alpha-numeric code will be assigned to each participant, which will be used for data analysis and interpretation. The study results will be shared in the form of a scientific research article and a research dissertation in the future, which will be made available to hearing health care professionals. Once published, the article will be made available to the PCIU. Data obtained will be stored electronically at the Department of Speech-Language Pathology and Audiology at the University of Pretoria for 15 years for research and archiving purposes, and also at the PCIU. All data acquired may be reused for further research/ future studies.

Adult CI recipients who completed the survey and the DIN testing and who provided permission that the survey, DIN testing and PCIU clinical file data may be utilized for research purposes, will be included in the study.

This study requires access to and utilization of data from an Excel sheet which captured the survey data. Additionally, access to and utilization of DIN test data (which was also conducted as part of the routine appointments/ audiological protocol at the PCIU) is also required. Further information will be obtained from clinical files (patient records) of the involved CI recipients as well.

Should you as CI team coordinator of the PCIU grant permission that the mentioned data may be accessed and utilized for the purposes of this research study, you will be requested to complete the attached consent slip. Please copy and paste the consent slip information onto an official PCIU letterhead before you sign, and also add an official stamp (if possible).

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Email talita.leroux@up.ac.za | www.up.ac.za/faculty-of-humanities



Faculty of Humanities

Fakulteit Geesteswetenskappe
Lefapha la Bomotheo



Should you require any additional information, please do not hesitate to contact me at lizevdmescht@gmail.com or 0715868786.

A handwritten signature in black ink, appearing to be 'Lize van der Mescht'.

Lize van der Mescht

Post-graduate student/ researcher (MA Audiology)

A handwritten signature in black ink, appearing to be 'De Wet Swanepoel'.

Prof De Wet Swanepoel

Research supervisor

A handwritten signature in black ink, appearing to be 'Talita le Roux'.

Dr Talita le Roux

Research supervisor

A handwritten signature in black ink, appearing to be 'Faheema Mahomed-Asmail'.

Dr Faheema Mahomed-Asmail

Research supervisor

Room 3-27, Communication Pathology Building
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Appendix F: Letter of Permission to access data from the Pretoria Cochlear Implant Unit



**PERMISSION FROM THE TEAM COORDINATOR OF THE
PRETORIA COCHLEAR IMPLANT UNIT:
ACCESS TO AND UTILIZATION OF SURVEY AND DIGITS-IN-NOISE (DIN) TEST DATA
FOR A RESEARCH PROJECT**

Herewith, I Nicolize Cass, state that I understand the aim and involved procedures of the research study described in the information letter provided to me. I acknowledge that I have received the necessary information about this study and have had the opportunity to ask questions regarding this project.

I give permission on behalf of the Pretoria Cochlear Implant Unit to Lize van der Mescht from the University of Pretoria to access the MS Excel sheet of the *Effects of the Coronavirus pandemic on service delivery at the PCIU* survey data and Digit-in-Noise (DIN) test data for her research project entitled: *Remote monitoring of adult cochlear implant recipients using speech-in-noise testing*.

I also give permission to the researcher to access the clinical files (patient records) of the adult CI recipients who provided consent that survey, DIN testing and PCIU clinical file data may be used for research purposes. Additionally, I give permission for the researcher to use the required data for the purpose of this study (and also possible future studies).

Date: 08/06/2021

PRETORIA COCHLEAR
IMPLANT UNIT
NPC 2015/24147/08

Mrs Nicolize Cass

Cochlear Implant Team Coordinator: Pretoria Cochlear Implant Unit

Appendix G: Humanities Faculty: Ethical Clearance form



Faculty of Humanities

Fakulteit Geesteswetenskappe
Lefapha la Bomotho



4 August 2021

Dear Miss L van der Mescht

Project Title: Remote monitoring of adult cochlear implant recipients using speech-in-noise testing
Researcher: Miss L van der Mescht
Supervisor(s): Dr TE le Roux
Prof DCDW Swanepoel
Dr F Mahomed Asmail
Department: Speech Language Path and Aud
Reference number: 17149984 (HUM016/0721)
Degree: Masters

I have pleasure in informing you that the above application was **approved** by the Research Ethics Committee on 29 July 2021. 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 Innocent Pikirayi
Deputy Dean: Postgraduate Studies and Research Ethics
Faculty of Humanities
UNIVERSITY OF PRETORIA
e-mail: PGHumanities@up.ac.za

Fakulteit Geesteswetenskappe
Lefapha la Bomotho

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

Appendix H: American Journal of Audiology article acceptance confirmation

From: AJA <em@editorialmanager.com>

Sent: 30 March 2022 6:44 PM

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Subject: AJA Manuscript Decision

Ref.: Ms. No. AJA-21-00248R1

Remote monitoring of adult cochlear implant recipients using digits-in-noise self-testing

American Journal of Audiology

Dear Dr. Swanepoel,

Thank you for submitting a revision and addressing reviewers' recommendations. I am pleased to accept your manuscript for publication in the special issue of the American Journal of Audiology.

If you haven't already selected the open access option, please consider doing so now. Choosing the open access publishing option can increase readership, online attention, and citation levels. ASHA assesses an article processing charge (APC) of \$2,000 for the open access option. You can find out more about Open Access by visiting <https://academy.pubs.asha.org/asha-journals-author-resource-center/manuscript-submission/open-access/>

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Comments from the Reviewers can be found below.

Thank you for the opportunity to review and publish your work.

Sincerely,

Dr. Valeriy Shafiro

Guest Editor

American Journal of Audiology

Complimentary Author PDF: Not for Broad Dissemination



Research Article

Remote Monitoring of Adult Cochlear Implant Recipients Using Digits-in-Noise Self-Testing

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ABSTRACT

Purpose: The COVID-19 pandemic has accelerated the uptake and scope of telehealth. This study determined the accuracy and reliability of a smartphone digits-in-noise (DIN) test when conducted by adult cochlear implant (CI) recipients in a simulated home environment compared with a clinic setup. Perceptions of remote monitoring using speech-in-noise (SIN) testing were also explored.

Method: Thirty-three adult CI recipients between 18 and 78 years of age ($M = 48.7$, $SD = 20.4$) conducted the DIN test in a simulated home environment and a clinic setup. Test-retest reliability across the two environments and comparisons between test settings were evaluated. A survey explored the perceptions of adult CI recipients regarding remote monitoring and use of the DIN self-test.

Results: Mean-aided speech reception thresholds (SRTs) in the clinic and simulated home environment test conditions and clinic and simulated home environment retest conditions did not differ significantly. Mean test-retest SRTs in the clinic and simulated home environment were significantly different ($p < .05$). High intraclass correlation coefficient and low standard error of measurement scores reflected good and excellent reliability between test-retest measures and between clinic and simulated home environment measures. Most participants were positive about the feasibility of using the DIN test at home to self-assess speech perception, although some test adjustments such as including training items and a less adverse starting signal-to-noise ratio may be required.

Conclusion: Adult CI recipients can use the smartphone DIN test to self-assess aided SIN performance in a home environment with accuracy and reliability relatively similar to clinic testing.

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The COVID-19 pandemic has exceeded 251 million confirmed cases in less than 2 years, with more than 5 million deaths globally (Dong et al., 2020). As a result, governments and authorities were forced to implement preventive measures such as social distancing, lockdowns,

self-isolation, and quarantine to contain the spread of the virus (Shah et al., 2020). The need for physical distancing and the communicable nature of COVID-19 has led to a significant increase in demand for telehealth options (Blandford et al., 2020). COVID-19 has compelled health care systems, including the audiology industry (Swanepoel & Hall, 2020), to be innovative in the way in which services are delivered to patients (Casar et al., 2021).

Telehealth has been recommended to overcome some of the current audiological service delivery challenges amid the pandemic (Manchaiah et al., 2021; Swanepoel & Hall, 2020). Traditionally, the goal of

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Disclaimer: This article is part of the Special Issue: 5th International Meeting on Internet and Audiology. **Disclosure:** The relationship between De Wet Swanepoel and the host:J Group includes equity, consulting, and potential royalties. All other authors have declared that no other competing interests existed at the time of publication.