

Remote Ear-Nose-and-Throat Specialist Screening in Adult Potential First-Time Hearing Aid Users

A Randomized Clinical Trial

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DOI (link to publication from Publisher):
[10.54337/aau620105598](https://doi.org/10.54337/aau620105598)

Publication date:
2023

Document Version
Publisher's PDF, also known as Version of record

[Link to publication from Aalborg University](#)

Citation for published version (APA):
Siggaard, L. D. (2023). *Remote Ear-Nose-and-Throat Specialist Screening in Adult Potential First-Time Hearing Aid Users: A Randomized Clinical Trial*. Aalborg Universitetsforlag. <https://doi.org/10.54337/aau620105598>

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**REMOTE EAR-NOSE-AND-THROAT SPECIALIST
SCREENING IN ADULT POTENTIAL FIRST-TIME
HEARING AID USERS**

A RANDOMIZED CLINICAL TRIAL

**BY
LENE DAHL SIGGAARD**

DISSERTATION SUBMITTED 2023



AALBORG UNIVERSITY
DENMARK

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by

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DISSERTATION SUBMITTED 2023

Dissertation submitted: September 1, 2023

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ISSN (online): 2246-1302
ISBN (online): 978-87-7573-639-3

Published by:
Aalborg University Press
Kroghstræde 3
DK – 9220 Aalborg Ø
Phone: +45 99407140
aauf@forlag.aau.dk
forlag.aau.dk

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Printed in Denmark by Stibo Complete, 2023



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ENGLISH SUMMARY

Age-related hearing loss in elder individuals can significantly diminish quality of life by heightening social isolation, prompting premature retirement, and contributing to psychological disorders. Yet, due to systemic inefficiencies in Denmark's hearing healthcare structure—including prolonged wait times and intricate legislation—required treatments for this population often face unnecessary delays. This issue is anticipated to intensify as the global demographic aged over 60 years is predicted to almost double from 12% to 22% between 2015 and 2050, placing considerable strain on existing healthcare provisions.

In Denmark, initial hearing aid users traditionally undergo a physical ear-nose-and-throat (ENT) specialist assessment to screen for severe or complicated hearing loss or serious ear disorders necessitating specialized hospital care. While aligned with current national guidelines and legislation, this practice extends the diagnostic process, delaying treatment initiation, and often necessitates repeated audiological tests. To meet future challenges effectively, it is imperative to devise innovative strategies that can augment efficiency protocols and optimize allocation of socioeconomic resources within the hearing healthcare system.

In response to these challenges, the Danish Ministry of Health's 2018 publication, 'The Future of Hearing, an Enhanced Effort for Citizens with Hearing Loss', proposed six initiatives to equip the Danish hearing healthcare system for future demands. The inaugural initiative focuses on developing and testing a remote ENT specialist assessment screening method to streamline assessments, reduce diagnostic delays, and address present bottlenecks. The subsequent initiatives encompass the provision of transparent treatment information, implementation of new national quality standards, enhanced resource utilization, systematic data collection methodologies, and strategies to ensure unbiased treatment processes.

This thesis explores the first initiative, developing and testing a remote ENT specialist assessment method, through a randomized clinical trial involving 751 potential adult first-time hearing aid users. It focuses on the key issues of patient safety, treatment benefit, and satisfaction, which arise when direct patient-physician contact is omitted.

Manuscript 1 compares remote and physical ENT specialist assessment screening accuracy in diagnosing severe/complicated hearing loss or serious ear disorders, finding the former had significantly higher sensitivity, thereby not compromising patient safety.

Manuscript 2 observes no significant difference in self-reported treatment benefit and satisfaction between the test and control groups undergoing remote and physical ENT specialist screening, respectively, implying that remote assessment does not negatively affect patients' perceptions of hearing aid treatment.

Manuscript 3 details the cross-cultural translation and adaptation process for the Consumer Ear Disease Risk Assessment (CEDRA) in Danish, titled 'Risikovurdering

af Høreapparatbrugere' (RiHab). This tool, which has been integrated into the remote ENT specialist assessment screening routine, aims to evaluate the risk of targeted ear diseases associated with hearing loss in adult potential first-time hearing aid users.

Manuscript 4 analyzes the remote screening accuracy of four ENT specialist assessors – two private ENT specialists and two ENT specialists with medical audiological expertise, demonstrating their equal qualifications to perform remote assessments.

In conclusion, remote ENT specialist assessment screening appears to neither compromise patient safety nor decrease self-reported hearing aid treatment benefit and satisfaction in adult potential first-time hearing aid users. Nonetheless, maintaining high-quality data is crucial for achieving accurate remote screening, and further testing of this routine in a broader context is recommended to fine-tune the model and its elements, ensuring a responsible parallel implementation alongside current practices.

DANSK RESUMÉ

Aldersbetinget høretab hos ældre kan mindske livskvaliteten markant ved at medføre social isolation, fremme tidlig pensionering fra arbejdsmarkedet og bidrage til psykologiske lidelser. Alligevel medfører organisatorisk ineffektivitet i Danmarks høresundhedsvæsen - herunder lange ventetider og kompleks lovgivning - at nødvendig behandling af denne befolkningsgruppe ofte forsinkes unødigt. Dette problem forventes at intensiveres, da den globale befolkning på over 60 år forudses at næsten fordoble fra 12% til 22% mellem 2015 og 2050, hvilket lægger betydeligt pres på de eksisterende sundhedsydelser.

I Danmark gennemgår førstegangsbrugere af høreapparater traditionelt en fysisk øre-næse-hals (ØNH) specialistvurdering for at screene for svære/komplicerede høretab eller alvorlige ørelidelser, der kræver specialiseret behandling på en audiologisk hospitalsafdeling. Selvom denne praksis er i overensstemmelse med de aktuelle nationale retningslinjer og lovgivning, forlænger denne proces det diagnostiske forløb, forsinker behandlingsopstart og nødvendiggør ofte gentagne audiologiske tests. Innovative strategier er derfor nødvendige for at forbedre effektiviteten af behandlingsprocesserne og optimere fordelingen af socioøkonomiske ressourcer inden for høresundhedsvæsenet.

Som reaktion på disse udfordringer introducerede Sundhedsministeriet i 2018 i 'Høreområdet i Fremtiden, en Forbedret Indsats for Borgere med Høretab', seks initiativer til at ruste det danske høresundhedsvæsen til fremtidens behov. Det indledende initiativ omhandler udvikling og afprøvning af en digital fjernvisitationsmodel til at strømline ØNH-specialistvurderinger, reducere diagnostiske forsinkelser og adressere nuværende flaskehalse. De efterfølgende initiativer omfatter levering af transparent behandlingsinformation, implementering af nye nationale kvalitetsstandarder, forbedret ressourceanvendelse, systematiske dataindsamlingsmetoder og strategier for at sikre upartisk behandling.

Denne afhandling omhandler det første initiativ, udvikling og afprøvning af en digital fjernvisitationsmodel i et randomiseret klinisk forsøg, der involverer 751 voksne potentielle førstegangsbrugere af høreapparater. Afhandlingen fokuserer på de centrale spørgsmål om patientsikkerhed, behandlingseffekt og tilfredshed, som kan opstå, når den direkte kontakt mellem læge og patienten udelades i det indledende udredningsforløb.

Manuskript 1 sammenligner præcisionen af digital fjernvisitation og fysisk visitation i diagnosticeringen af svære/komplicerede høretab eller alvorlige ørelidelser. Studiet viser, at den digitale fjernvisitation har en betydeligt højere screeningssensitivitet og dermed ikke kompromitterer patientsikkerheden.

Manuskript 2 fandt ingen signifikant forskel i selvrapporteret behandlingseffekt og -tilfredshed hos patienter, der blev visiteret henholdsvis ved fjernvisitation og ved

fysisk visitation af en ØNH-læge, hvilket antyder, at digital fjernvisitation ikke negativt påvirker patienternes opfattelse af høreapparatbehandlingen.

Manuskript 3 rapporterer oversættelses- og valideringsprocessen for instrumentet Consumer Ear Disease Risk Assessment (CEDRA), der på dansk har fået titlen 'Risikovurdering af Høreapparatbrugere' (RiHab). Dette værktøj, som er integreret i den digitale fjernvisitationsmodel, har til formål at evaluere risikoen for ørelidelser hos voksne førstegangsbrugere af høreapparater.

Manuskript 4 analyserer præcisionen af fire ØNH-specialister, to privatpraktiserende ØNH-læger og to ØNH-læger med medicinsk audiologisk ekspertise. Studiet viser, at begge grupper af ØNH-subspecialister er lige kvalificerede til at udføre digital fjernvisitation.

Overordnet blev det vist, at digital fjernvisitation hverken kompromitterer patientsikkerheden eller forringer patienternes opfattelse af behandlingseffekt og -tilfredshed hos voksne førstegangsbrugere af høreapparater. Ikke desto mindre er det afgørende fremadrettet at sikre data af høj kvalitet og teste modellen yderligere i et større format for at finjustere den og dens elementer, samt sikre en ansvarlig implementering parallelt med nuværende praksis.

ACKNOWLEDGEMENTS

To Morten Høgsbro, my thesis supervisor, who, in my experience, possesses one of the sharpest minds I have encountered. Our collaboration over the past three years has been as rewarding as it has been invaluable. I am deeply thankful for your willingness to embark on this journey with me and for your unfaltering support throughout. I anticipate our future projects with much enthusiasm and am proud to count you as both an ally and a dear friend.

To Henrik Jacobsen, Head of Department of Otolaryngology, Head and Neck Surgery, and Audiology at Aalborg University Hospital, for inviting me to participate in this project and for your unwavering support that followed, which have truly enriched the entire experience. I am grateful for the fresh perspectives generated by our collaboration and eagerly look forward to embarking on new shared ventures.

To Dan Dupont Hougaard, my thesis co-supervisor, your expert knowledge, steadfast support, and friendship over the past three years have been truly valued.

To all the participants, collaborators, supporters, allies, friends, critics, and skeptics, whose contributions have shaped this project, I am honored to have been a part of such an expansive collaboration.

To my colleagues and research fellows at the Department of Otolaryngology, Head and Neck Surgery, and Audiology, Aalborg University Hospital, deserve special recognition for cultivating a vibrant community that I am proud to be a part of. I treasure the friendships I've gained throughout this journey.

To my beloved mother, who, even long after her passing, continues to spark my spirit with her enduring zest for life, her unwavering ambition, and her everlasting love and support. I firmly believe that she would have steadfastly accompanied me throughout this journey, just as she would have in countless other chapters of my life.

Finally, to my closest friends and wonderful family who consistently make me feel more cherished than words can express. The depth of my appreciation for your unconditional support is beyond description. Thank you!

LIST OF MANUSCRIPTS

Manuscript 1

Siggaard, L.D., Jacobsen H., Hougaard D.D., Høgsbro M. Digital vs. physical ear-nose-and-throat specialist assessment screening for complicated hearing loss and serious ear disorders in hearing-impaired adults prior to hearing aid treatment: a randomized controlled trial. *Front. Digit. Health, Volume 5 – 2023*. <https://doi.org/10.3389/fdgth.2023.1182421>

Manuscript 2

Siggaard, L.D., Jacobsen H., Hougaard D.D., Høgsbro M. Effects of Remote Ear-Nose-and-Throat Specialist Assessment Screening on Patient-Reported Hearing Aid Benefit and Satisfaction. Submitted.

Manuscript 3

Siggaard, L.D., Jacobsen H., Hougaard D.D., Khaled M.S., Høgsbro M. Cross-Cultural Translation and Adaptation of the Consumer Ear Disease Risk Assessment (CEDRA) Questionnaire in Danish. In preparation.

Manuscript 4

Siggaard, L.D., Jacobsen H., Hougaard D.D., Høgsbro M. Remote specialist screening for complicated hearing loss: Is specialized audiological experience necessary? Submitted.

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LIST OF ABBREVIATIONS

AC	Air Conduction
BC	Bone Conduction
CEDRA	Consumer Ear Disease Risk Assessment
CG	Control Group
DS	Discrimination Score
EAC	External Auditory Canal
ENT	Ear-Nose-and-Throat
GP	General Practitioner
HA	Hearing Aid
HL	Hearing Loss
IOI-HA	International Outcome Inventory for Hearing Aids
MRI	Magnetic Resonance Imaging
PESA	Physical ENT Specialist Assessment
PREM	Patient-Reported Experience Measures
PTA	Pure Tone Average
RESA	Remote ENT Specialist Assessment
RiHab	'Risikovurdering af Høreapparatbrugere' (the Danish equivalent to CEDRA)
SSQ12	Speech, Spatial and Qualities of Hearing Scale (abbreviated version)
TEDs	Targeted Ear Diseases
TG	Test Group
TG1	Test Group 1
TG2	Test Group 2
THI	Tinnitus Handicap Inventory
UK	United Kingdom
US	United States

CHAPTER 1. INTRODUCTION

Hearing loss (HL) can profoundly impact an individual's quality of life, leading to accelerated social isolation, premature retirement, and an increased risk of anxiety, depression, and dementia (Cosh et al., 2019; Dalton et al., 2003; Mahmoudi et al., 2019; Thomson et al., 2017). Despite the capacity of timely and appropriate hearing rehabilitation to counteract these effects, Danish individuals suffering from age-related HL are currently facing the risk of delayed treatment due to inefficiencies and data misalignments within the healthcare system. Such shortcomings are exacerbated by long waiting lists, repetitious examinations, and complex legislation, all of which contribute to patient confusion and unawareness of their entitlements (The Danish Ministry of Health, 2018).

With the population aged over 60 anticipated to nearly double from 12% to 22% between 2015 and 2050 (Steverson, 2021), there will be a concurrent rise in the number of individuals with hearing impairment. This demographic shift is expected to place substantial pressure on the hearing healthcare system, which may struggle to meet the escalating demand for rehabilitation and prevent the detrimental impacts of delayed treatment.

To expedite this process, Danish individuals with no prior experience with hearing aids (HAs) must undergo a physical ear-nose-and-throat (ENT) specialist assessment (PESA) to screen for complicated HL or serious ear disorders requiring specialized hospital care. However, this practice, despite aligning with national guidelines, can result in prolonged diagnostics and treatment delays.

To address the prevailing challenges, the Danish Ministry of Health introduced a publication in 2018, titled 'The Future of Hearing, an Enhanced Effort for Citizens with Hearing Loss' (The Danish Ministry of Health, 2018). The publication proposed several approaches to prepare the Danish hearing healthcare system for future hurdles. This thesis explores the first of these six approaches: the development and testing of a remote ENT specialist assessment (RESA) screening method. The remaining five initiatives recommend the provision of transparent treatment information from private audiological clinics, the establishment of new national quality standards for HA treatment, the enhanced utilization of professional resources in hearing healthcare, the adoption of systematic data collection methodologies for HA treatment benefits and quality analyses across both private and public sectors, and, finally, the implementation of strategies to guarantee a more unbiased treatment and advisory process. This digital and remote approach is anticipated to facilitate ENT specialists in performing assessments digitally, remotely, and without direct patient consultations, thus streamlining the process and reducing diagnostic and treatment delays. Therefore, RESA screening could be a potential resolution to the existing bottlenecks within the Danish hearing healthcare system.

Transitioning to a digitized process, however, might present new challenges, such as the risk of misdiagnosis of severe or complicated HL or serious ear disorders necessitating specialized assessment and treatment in an audiological hospital department. Therefore, to ensure the professional feasibility of the proposed RESA screening method, top priority must be given to patient safety. Overlooking symptoms of severe otological conditions, such as cholesteatoma or vestibular schwannomas requiring surgical intervention, remains a major concern. Besides, numerous middle ear pathologies can cause HL, yet surgical intervention may eliminate the need for HA treatment. Consequently, meticulous documentation of the patient's medical history and symptoms, along with high-quality audiometric and otoscopic examinations possessing proven sensitivity for these otological conditions, are indispensable. Another potential challenge might be the impact on shared decision-making due to the absence of direct patient-physician interaction. Thus, in addition to safety, the proposed model must ensure that the quality and benefits of treatment meet or exceed existing standards.

The primary objective of the RESA screening method is to enhance the productivity of the hearing healthcare system. This is to ensure that the expanding population of individual with hearing impairments receives prompt and effective treatment. Concurrently, the main aim of this thesis is to investigate whether this enhancement can occur without jeopardizing patient safety of diminishing self-reported HA satisfaction and benefit.

CHAPTER 2. BACKGROUND

2.1. STRUCTURE OF HEARING HEALTHCARE IN DENMARK

It is estimated that approximately 500,000 – 800,000 Danes are grappling with varying levels of HL and approximately 300,000 of them are using HAs (The Danish Ministry of Health, 2018). However, exact numbers remain unknown. The fastest-growing demographic in Denmark is individuals aged over 65, presently comprising 18% of the population. By 2040, this proportion is projected to expand to 23% adding around 400,000 individuals to this age group, totaling 1.5 million people. Out of these, nearly 18% will be expected to require treatment for HL with HAs. According to the Danish Ministry of Health an average of 46,000 adults annually received HL-related treatment between 2007 and 2014 (The Danish Ministry of Health, 2018). Approximately a third of these were between 18 and 64 years old, while the rest were aged over 65.

This is supported by a report from 2021 by the supervising government-approved Research and Technology Organization institute FORCE Technology Lab, stating that approximately 140,570 HAs were administered in private and public audiological clinics combined in Denmark in 2018 (Ravn & Jørgensen, 2021). This number rose to 168,402 HAs in 2021 where 37% of them were administered in private audiological clinics and 11% in one of the increasing numbers of private so-called 'pool clinics' that offer HAs on public terms, free of charge to the consumer.

The Danish National Health Service system covers services within the public sector, including consultations, tests, and treatments, ensuring access to care for all Danish citizens. However, Danish hearing healthcare is organized in both private and public sectors, ensuring individuals with HL to have access to both public and private options, and allowing them to choose the providers and services that best suit their needs. This dual-sector approach helps to ensure that a wide range of diagnostic and treatment options are available to individuals with HL throughout Denmark.

In Denmark, individuals with suspected HL may start their journey by consulting either with their general practitioner (GP) or one of the 161 Danish private practicing ENT specialists for further evaluation (*Sundhed.Dk - Private ENT Specialists*, n.d.). The private ENT specialists play a crucial role in the initial screening process of the hearing rehabilitation journey. They conduct comprehensive examinations, including audiological tests, such as pure-tone audiometry, speech audiometry, tympanometry, and objective examinations of the ear canal and tympanic membrane, to assess the nature and extent of the patient's HL, diagnosing and treating potential minor ear disorders and screening for severe/complicated HL or serious ear disorders that need specialized assessment and care at an audiological hospital department. Many ENT specialists collaborate with audiologists to provide a comprehensive diagnosis and develop appropriate treatment plans for patients with HL and may recommend appropriate treatment options based on the individual's specific HL condition. This may include medical management, surgical interventions, or referral to public or private audiology services for HA fittings and rehabilitations programs.

2.2. PUBLIC HEARING AID TREATMENT

When approved for HA treatment by an ENT specialist and granted municipal HA support, patients with hearing impairment can choose public sector HA treatment. Within this system, they can receive treatment at a regional audiological clinic or from a practicing ENT specialist with a regional framework agreement.

If the patient opts for public sector treatment, they receive HA treatment free of charge, irrespective of the cost. The expenses are in this case covered by the region. However, the HA is only loaned, and must be returned once no longer needed, allowing for its parts to be reused.

For patients with severe HL, complex needs, or serious ear disorders, specialized assessment and treatment may be required. Therefore, this patient group is referred directly to one of the 20 audiology or 10 ENT surgical public hospital departments in Denmark by the private ENT specialists (Dansk Selskab for Oto-rhino-laryngologi Hoved og Halskirurgi, 2022). The public audiology and ENT surgical departments are equipped with advanced diagnostic tools and treatment options and offer a wide range of services, including hearing tests, HA fittings, cochlear implant evaluations and surgeries, rehabilitation programs, and follow-up care. Furthermore, public rehabilitation centers offer specialized services such as auditory training, speech therapy, counseling, and support groups. These centers work in collaboration with other healthcare professionals to provide comprehensive care.

2.3. PRIVATE HEARING AID TREATMENT

The private sector subsidy scheme in Denmark includes a 6,502.00 DKK grant, that covers treatment and HA expenses in two ears. A 4,129.00 DKK grant is provided to cover treatment and HA expenses in one ear. The subsidy can only be used at one of the 358 approved Danish private audiological clinics (Technical Audiological Laboratory (TAL), n.d.) that meet specific requirements set by the Ministry of Health's regulation No. 1140 of November 10, 2019 (Executive Order on Hearing Aid Treatment [BEK Number 1140 of November 10, 2019], n.d.). To be approved, a private audiological clinic must meet the following criteria:

- 1) The audiometry must be performed by an audiologist or audiological assistant in accordance with recognized and documented guidelines and standards.
- 2) Audiometric equipment must be calibrated at least one a year.
- 3) A quality manual for audiometry, personnel, and HA treatment (including impressions for ear molds), and handling of any complaints must be in place.
- 4) Selection and adjustment of HAs should be based on the manufacturer's instructions.
- 5) The effect of the HA treatment must be documented through measurement or patient interview and noted in the patient's record.

- 6) FORCE Technology Lab conducts annual announced supervisions in the clinic to ensure requirements are met.

Up until 2021, private clinics have been obliged to report annually to FORCE Technology, including biannual submissions of data based on the seven-item International Outcome Inventory (IOI-HA) (Thunberg Jespersen et al., 2014), focusing on users' benefit from the HAs, and information on staff changes, and the number of HAs distributed etc. Based on these data, mandatory analyses have been conducted in HA recipients in private hearing rehabilitation clinics since 2009, and the results showing high patient satisfaction have been published semi-annually. However, response rates have varied significantly and have usually not reached 50% (Ravn & Jørgensen, 2021). Currently, the analyses do not include HA recipients attending public rehabilitation clinics.

According to results from the 2022 Eurotrak Denmark - a comprehensive study on hearing impairment, HA prevalence and use of HAs in 1,309 Danish hearing-impaired individuals - approximately 26% of the responders were either dissatisfied or neither satisfied nor dissatisfied with their HAs (The European Hearing Instrument Manufacturers Association (EHIMA), 2022). In 2020, Eurotrak results were compared between 11 participating European countries (Laureyns et al., 2020). Although Denmark had the highest HA uptake in individuals with self-reported hearing problems, Danish HA recipients ranked lowest on self-reported HA satisfaction. The report stated that satisfaction was highest in countries with a high freedom of choice. However, we lack data to substantiate this association.

2.4. LEGISLATION GOVERNING HEARING HEALTHCARE IN DENMARK

According to an in-depth investigative report of the Danish HA sector by the Danish Health and Prevention Committee from 2012 (The Working Group for 'Kulegravning af Høreapparatområdet', 2012), HAs are recognized and granted as assistive devices. They can be obtained through the public health care system, or via private audiological clinics, in which case a subsidy to cover treatment and HA expenses is granted. According to the Danish Health Act §74 (Executive Order of the Danish Health Act [LBK Number 1011 of June 17, 2019], 2023), regions are responsible for the organization of HA treatments in public hospitals and audiological clinics.

The rules for assistive devices, including the subsidy scheme, which give the citizen the right to choose private HA treatment, are found in §12 of the Social Services Act Order No. 170 of January 24, 2022, on aid for the acquisition of assistive devices and consumer goods under the service law (Executive Order on the Act of Social Services [LBK Number 170 of January 24, 2022], 2022). The Service Law is under the jurisdiction of the Ministry of Social Affairs and Integration.

Municipal councils are responsible for assessing eligibility and funding HA support, based on a detailed evaluation. A prerequisite for support is that the patient has a permanent HL, and the HA must significantly improve their daily life or be essential for their profession. A 2010 social board decision confirmed citizens' right to subsidized private HA treatment upon specialist referral (The Working Group for 'Kulegravning af Høreapparatområdet', 2012). Consequently, municipalities are obligate to provide subsidies if requested by the citizen.

The Ministry of Health sets rules for the approval of private HA providers, with oversight duties delegated to the FORCE Technology. The Health Authority is tasked with detailing specific guidelines for HA treatment and monitoring approved private providers.

2.5. INTERNATIONAL STRUCTURE OF HEARING HEALTHCARE

2.5.1. HEARING HEALTHCARE IN THE NORDIC COUNTRIES

According to a report published by the Nordic Audiological Society (NAS) in 2014 significant differences were observed in the organization of hearing rehabilitation across the five Nordic countries, Sweden, Norway, Finland, Denmark, and Iceland (Möller, 2016). The report encapsulated a review of various documents related to hearing rehabilitation from each Nordic country, authored by representative authors or designated workgroups. A more recent report is not available. While certain aspects of the report regarding the countries organizational structures in 2014 might be antiquated, the historical overview is likely to remain accurate and relevant.

The documents revealed a shared lineage of hearing rehabilitation among the five Nordic countries. Denmark, establishing an audiology institute in 1892, led the way, with Norway, Sweden, and Finland following suit in the 1900s. Early provisions for the rights of the deaf and hard of hearing were implemented in Denmark by 1929, which expanded to include individuals with hearing impairment in the 1950s. Across the Nordic region, numerous organizations significantly contributed to hearing rehabilitation. The advent of technical devices, such as HAs, occurred in the 1950s, paralleling developments in the United States (US) spurred by war veterans who had acquired HL.

Denmark's early establishment of industry-leading HA companies such as Oticon, Danavox, GN, Resound, and Widex marked it as a forerunner in technical audiology. In the 1950s and 60s, Sweden experienced a healthcare expansion under the strategic leadership of ENT professors who founded audiology clinics across the country.

Over the past 25 years, the approach to hearing rehabilitation in each country has diversified. Denmark led in the private sector with audiology clinics focusing on HAs, whereas Finland relied on lottery funding and user organizations. Norway saw expansion in both public and private ENT clinics. Meanwhile, Sweden and Iceland experienced a trend toward privatization in more recent years.

In regard to the organization of hearing healthcare in Denmark's neighboring Nordic countries by 2014, Norway's hearing rehabilitation infrastructure operated on three

tiers: municipalities, user organizations, and the state. According to the report, the quality of services could significantly vary between municipalities, largely due to differences in population size and economic circumstances. The state played a critical role in facilitating professional practices and minimizing wait times. The state achieved this by partnering with various entities, including private ENT physicians and assistive technology centers.

In Iceland, the state predominantly shouldered the responsibility for hearing rehabilitation, supplemented by private auditory centers that were often tied to specific HA manufacturers. Meanwhile, Finland's audiology healthcare system was somewhat fragmented, with nearly 40 units, some small and others large, providing aural rehabilitation and HA adjustments.

Lastly, Sweden exhibited great variability in audiology healthcare organization depending on geographical area. Some regions offered the so-called free choice of care, with a mix of public and private audiology healthcare providers, while others solely relied on public providers. There were three main models of operation, ranging from county council-run entities to authorized clinics that could handle both county-assigned and self-acquired assignments. Some of these authorized private aural rehabilitation units were affiliated with specific hearing aid manufacturers.

2.5.2. HEARING HEALTHCARE IN OTHER WESTERN COUNTRIES

In the US, ENT physicians handle medical and surgical treatments related to HL and other ear disorders, while audiologists, who have earned a Doctor of Audiology degree, provide most diagnostic and rehabilitative hearing services, conducting comprehensive hearing tests, fit HAs, provide auditory rehabilitation, and treat conditions like tinnitus and balance disorders (Academy of Doctors of Audiology, n.d.; American Academy of Audiology, 2023). Unfortunately, primary treatment for HL is currently not covered by Medicare or many private insurance companies (Centers for Medicare & Medicaid Services, n.d.), why other efforts have been effectuated to increase access to affordable HAs, such as the Over-The-Counter (OTC) Hearing Aid Act of 2017, that aimed to establish a category of OTC HAs for those with mild-to-moderate HL that would be accessible to consumers without a prescription (S.670 - 15TH CONGRESS: Over-the-Counter Hearing Aid Act of 2017, 2017).

In the United Kingdom (UK), HA treatments are predominantly carried out in the public sector, as well as by private providers who have agreements with the public sector. To receive such treatment, a referral from a GP is necessary, whereas an ENT specialist assessment is not required prior to treatment. Entirely private audiological clinics also exist as an option. While public sector HA treatment is free of charge, consumers bear the cost of the treatment in private clinics that do not hold contracts with the public sector. The extent of this personal expense is contingent upon the type of HA chosen, as well as the individual's specific preferences and expectations (National Institute for Health and Care Excellence, 2018; *NHS Choices*, n.d.).

In Germany, HAs can be obtained through statutory health insurance, provided the treatment is cost-effective and aligns with the required quality level for HAs suitable for the specific type of HL in question. In order to receive reimbursement from their insurance for obtaining HAs from one of the insurance company's partners, patients need a referral from their GP or ENT specialist. Should patients opt for different provider, or if they wish to acquire more expensive HAs than those recommended, their personal expenses will increase (Bundesministerium Für Gesundheit, n.d.).

It is clear that diverse approaches exist to balance cost, access, and quality. Despite these disparities, a common thread is the shared challenge of ensuring equitable and efficient care in a field characterized by intricate technological, clinical, and patient-driven factors. The variations across these systems offer opportunities for mutual learning and exploration of innovative, patient-centric strategies for improved hearing healthcare worldwide.

2.6. PRESENT AND FUTURE CHALLENGES IN HEARING HEALTHCARE

The Danish hearing healthcare sector, much like its global counterparts, is confronted with an array of significant challenges that are expected to persist and shape the future of the field. In Denmark's hearing healthcare system, substantial challenges comprise prolonged wait times, particularly in the public sector where waits can extend to 115 weeks, which significantly impacts patients with complicated and severe HL who lack the option to choose private services (The Danish Ministry of Health, 2018). Compounding this issue is the systemic complexity and lack of accessible information, which hinder patients – often older individuals – from understanding their choices, such as potential subsidies for HAs from private providers. The absence of uniform quality control across the public and private sectors further exacerbates the problem, impeding the systematic evaluation of treatment effectiveness and hindering sector-wide improvements. Lastly, transparency concerns about potential financial conflicts of interest among healthcare professionals could undermine patient trust, casting doubt on whether advice given is entirely grounding in professional expertise rather than financial incentives.

General factors impacting hearing healthcare globally include the rising prevalence of HL due to an aging population, noise pollution, and the use of personal audio devices are major contributors to this predicament (Imam & Hannan, 2017; Natarajan et al., 2023). Further complications stem from a general lack of awareness and delayed detection, which inhibit early intervention and thus compromise the efficacy of treatment outcomes. Access to necessary hearing healthcare services, such as ENT specialists, audiological departments, and rehabilitation programs, is also a concern, particularly in rural or underserved areas, and so is the burden of inadequate insurance coverage or limited reimbursement options for hearing healthcare services.

Furthermore, integration and adoption of new technologies into clinical practice also pose challenges, particularly in terms of providing proper training and support for healthcare professionals and patients alike (Boisvert et al., 2023). And lastly, obstacles

in funding and fostering interdisciplinary collaborations, along with issues in translating research findings into practical clinical applications, require urgent attention to stimulate further advancements in diagnostic and therapeutic approaches, and rehabilitative strategies.

To address these complex issues, a comprehensive approach involving policymakers, healthcare providers, researchers, advocacy organizations, and individuals with HL is essential. Concerted efforts to enhance awareness, accessibility, affordability, and quality of hearing healthcare services are vital, and should prioritize prevention, early intervention, and a focus on person-centered care.

2.7. APPROACHES TO ADDRESS CHALLENGES IN HEARING HEALTHCARE

Globally, and within Denmark specifically, several strategies have been proposed, enacted, and examined to tackle the prevailing challenges in hearing healthcare (The Danish Ministry of Health, 2018). These strategies aim to enhance accessibility, affordability, and the quality and outcomes of hearing healthcare services. Examples of these strategies include the implementation of universal newborn hearing screening programs, prevalent in Denmark and many other countries. These initiatives target early identification of HL in infants to expedite necessary interventions, thereby improving long-term outcomes.

Public awareness campaigns have also been instrumental. Organizations and health agencies worldwide have launched numerous initiatives to elevate awareness, mitigate stigma, and advocate for early diagnosis and treatment. A noteworthy Danish campaign 'Don't lose your ears – they have to last a lifetime', initiated by the Danish Association of the Hard of Hearing, targets noise-induced hearing impairment and tinnitus among children and young adults (*The Danish Association of the Hard of Hearing*, n.d.). Internationally, institutions such as the World Health Organization (WHO) (*World Health Organization - Deafness and Hearing Loss*, n.d.), the National Institute on Deafness and Other Communication Disorders (NIDCD) (*National Institute on Deafness and Other Communication Disorders (NIDCD)*, n.d.), the Hearing Loss Association of America (HLAA) (*Hearing Loss Association of America (HLAA)*, n.d.), and the UK-based Royal National Institute for Deaf People (*Royal National Institute for Deaf People (RNID)*, n.d.) have also led significant awareness efforts.

Digital advancements, like hearing apps, tele-audiology, and tele-rehabilitation, have also been notable, particularly during the COVID-19 pandemic (Almufarrij et al., 2022; Bright & Pallawela, 2016; Corona et al., 2020; De Sousa et al., 2021; Jämsä et al., 2022; Smith et al., 2020). These services allow for remote consultations, assessments, and follow-up care, facilitating access to specialized care regardless of geographic constraints. Parallel developments have been observed in other medical fields, with the proliferation of asynchronous tele-healthcare technologies (Chan et al., 2018; Hooper et al., 2001; Mahnke et al., 2008; Rotvold et al., 2003; Shapiro et al., 2004; Thrall, 2007; Yellowlees et al., 2021) and the growing applicability of

artificial intelligence (AI) (Mello-Thoms & Mello, 2023; Srivastava et al., 2023; Subhan et al., 2023; Young et al., 2020). In otology, AI models have shown remarkable accuracy in classifying ear diseases through video-otoscopic images (Habib et al., 2022). Nevertheless, a gap remains, as a 2018 review indicated that merely 10.7% of technology services in hearing healthcare were committed to screening and assessment (Paglialonga et al., 2018).

Additionally, strategies like policy implementation, development of audiological practice guidelines and standards, professional certification requirements, and regulations regarding to HA provision have also been instrumental in safeguarding the quality and safety of hearing healthcare services.

2.8. FUTURE PERSPECTIVES FOR HEARING HEALTHCARE IN DENMARK

In 2018, the 'The Future of Hearing, an Enhanced Effort for Citizens with Hearing Loss' initiative was published (The Danish Ministry of Health, 2018). The enactment of the 2019 Finance Act followed this, setting aside 40 million DKK for 2019 and an annual commitment of 25 million DKK from 2020 to 2022 to reinforce the HA sector.

With the publication, the Danish government envisioned a future hearing healthcare system where patients are at the center of the treatment process, guided clearly and cohesively from start to finish. This approach relies on cutting-edge technology and aims to minimize the risk of patients experiencing confusion or misdirection during their treatment journey. With the focus on providing high-quality, unbiased HA treatment, there is an aspiration to ensure equality of service irrespective of whether a patient chooses a public or private audiological clinic. To eliminate wait times and fully utilize the sectors' capacity, the government plans to promote better transparency and improve information about various treatment options. The treatment quality and its real-world effectiveness remain paramount to avoid unused HAs and ensure patients benefit meaningfully from their treatment. Lastly, to foster patient trust, the government seeks to enforce new regulations ensuring ENT specialists' advice is strictly professional and uncolored by potential financial interests in HAs.

Guided by the government's vision for the hearing healthcare system in both sectors, six principal areas of focus have been identified, majorly emphasizing two critical dimensions: 1) facilitating patient navigation through the system for those requiring HA treatment, and 2) improving the quality of impartial treatment for patients with HL, regardless of their selection of public or private HA providers (The Danish Ministry of Health, 2018).

The first dimension encompasses two focus areas. The initial area promotes clinical testing of a digital, remote ENT specialist assessment technique, while the second advocates for more transparent treatment information from private audiological clinics.

The second dimension is encapsulated by the remaining four focus areas. These encompass the establishment of new National Quality Requirements tailored to HA

treatment, a mandate necessitated by the Executive Order on Authorization of Health Professionals and Health Professional Activity No. 122 of January 1, 2023 (Executive Order on Authorization of Health Professionals and Health Professional Activity [LBK Number 122 of January 1, 2023], n.d.). Further, they emphasize the efficient utilization of professional resources in hearing healthcare, guaranteeing that all hearing care personnel are capable of conducting vital HA treatment. Additionally, they champion a more systematic approach to data collection for comprehensive insights into HA treatment benefits and quality in both public and private sectors. Lastly, they underline efforts to ensure a more impartial treatment and advisory process.

2.9. POTENTIAL CHALLENGES POSED BY REMOTE SCREENING

The introduction of digital and remote assessment tools in hearing healthcare could pose certain challenges. It is crucial to examine and address potential risks when these innovative strategies are brought into supplement or replace current in-person procedures by medical experts. Although benefits such as improved accessibility for remote patients, reduced travel burden, increased convenience, and more efficient resource allocation in the hearing healthcare system are evident from adopting remote assessment procedures, recognizing their limitations is equally important. It is vital to assess the suitability of tools on a case-by-case basis to ensure that they are developed in conjunction with necessary in-person evaluations.

Concerns may emerge regarding the diagnostic accuracy of RESA screenings compared to in-person evaluations. Factors such as internet connectivity, the limitations of remote assessment tools, and potential difficulties in interpreting certain findings remotely can affect assessment accuracy. Misinterpretation of test results or overlooked subtle indicators may potentially lead to misdiagnosis or suboptimal treatment decisions. It seems fair to ask, whether RESA screenings may lack the ability to fully capture the patient's context and nuance? Observable factors like non-verbal cues, body language, and visual cues in the patient's environment might be limited or absent, potentially leading to incomplete assessments and overlooked diagnostic or treatment opportunities.

For instance, RESA screenings may limit ENT specialists' ability to conduct physical examinations. This means that instead of performing the gold standard otomicroscopic examination of the ear canal and the tympanic membrane themselves, the ENT specialists will need to rely on still images depicting the same structures obtained by video-otoscopy but captured by another person. For this process to be feasibly and safe, high-quality equipment, advanced technology, and skilled examiners are essential.

Furthermore, RESA screening might lack the personal interaction that is essential for establishing a robust patient-physician relationship, a crucial element in diagnosing and treating HL. Various factors can influence a patient's perception of their condition and their motivation for treatment. The lack of direct interaction in remote assessment

procedures may impact the trust-building process between the ENT specialist and the patient, making it more difficult to address concerns and provide emotional support. Ultimately, these limitations could adversely affect patients' perception of their HA benefit and undermine their overall satisfaction with the treatment.

Lastly, RESA screening necessitate the transfer and storage of sensitive personal health data, thereby emphasizing the need for privacy and data security to uphold patient confidentiality. Secure communication platforms that adhere to privacy guidelines are vital but may be time-consuming to develop and challenging to implement.

CHAPTER 3. MATERIALS AND METHODS

3.1. PARTICIPANTS

Eligible participants were adults aged 18 years or more who reported subjective HL or difficulty hearing and did not exhibit acute or chronic ear-related symptoms such as ear pain or discharge. Individuals who had previously used HAs, who were unable to read or understand Danish, suffered from severe dementia, or had extensive comorbidities precluding participation, consent, or completion of the study questionnaires were excluded from participation.

To enlist participants, a registration form was made available through a Facebook page maintained by the North Denmark Region. This form, hosted on an online survey software, allowed interested individuals to register their personal and contact information, including full name, home address, phone number, and email address. Following registration, eligible candidates who fulfilled the inclusion criteria were contacted by either one of two study secretaries or a principal study coordinator who provided further information about the study. With oral consent, participants were registered in the project database in REDCap® hosted by Aalborg University (Harris et al., 2009, 2019). Momentarily after, participants received an email with a consent form that needed digital signature.

3.1.1. SAMPLE SIZE

The applicability of RESA screening in hearing-impaired individuals relies on the precise identification of complicated HL and serious ear disorders by ENT specialists. However, some conditions such as cholesteatoma and vestibular schwannoma are relatively rare in Denmark, and otosclerosis presents clinical symptoms in 6-14 individuals per 100,000 in Europe (Svensson et al., 2022). Therefore, achieving sufficient sample sized to test RESA's sensitivity and specificity for these conditions would be impractical, overly expensive, and time-consuming.

Instead, the RESA screening method sought to screen a collective group of participants with complicated HL/and or symptoms of serious ear disorders, where incidences of these rare conditions were presumed to be higher. Based on a 2010 analysis by the National Bord of Social Services (Bengtsson & Røgeskov, 2010), the prevalence of these conditions in Danish adults with hearing impairment was estimated at 5%.

Based on the above assumption and a desired power of 0.80, literature on determining sample size for screening studies (Bujang & Adnan, 2016) recommends a minimum total sample size of 400 individuals to accurately ascertain the sensitivity and specificity of the RESA routine serving as a screening tool for patients with complicated HL and/or serious ear disorders when compared to PESA screening.

Since the RESA screening routine was assessed within both private (Test Group 1) and public (Test Group 2) sectors, each subgroup comprised of a minimum of 200 individuals. Anticipating a potential 20% attrition rate, an additional 50 individuals were included in each test subgroup. For comparative purposes, a control group of 250 individuals was constituted to evaluate the differences between RESA and PESA screenings, 50 of whom were included to compensate for potential loss to follow-up or the need for exclusion in the control group.

3.1.2. RANDOMIZATION

Thus, 750 adult subjectively hearing-impaired and potential first-time HA users were recruited for the trial. After the participants had completed, proved, and digitally signed a participant consent form, they were eligible for randomization. A random assignment sequence was generated using the 'R' statistical software (R Foundation for Statistical Computing, 2021), specifically utilizing the 'REDCapAPI' package (Nutter & Lane, 2020). Block randomization was employed to minimize selection bias, accidental bias, and to ensure balanced participant allocation. The block size was set to 12, chosen for its multiple factorial possibilities of participant assignment without risking repeated blocks. No stratification variables were used. The allocation sequence was uploaded to the REDCap® system and kept confidential from all study staff, including researchers, field workers, and participants, making it impossible to predict or decipher participant allocation. The randomization process was activated in the database for each participant by one of the two study secretaries granted user access to the randomization tool.

3.2. STUDY DESIGN

The InHEAR trial was an open label, randomized controlled trial divided into two arms with a random allocation ratio of 2:1. The intervention arm, constituting 501 participants, was further bifurcated into two test groups: Test Group 1 (TG1) with 251 participants, and Test Group 2 (TG2) with 250 participants. Participants from TG1 were examined and treated in one of 12 collaborating private audiological clinics, whereas those from TG2 were serviced by one of the five public audiological clinics in the North Denmark Region. Notwithstanding the different locations for TG1 and TG2, the intervention techniques and methodologies were consistent across both groups. In contrast, the 250 participants in the second arm, the control group (CG), underwent in-person assessments by private ENT specialists, adhering to the current Danish guidelines and practices (The Danish Health Authority, 2015).

The five public audiological clinics, operating under the Department of Audiology at Aalborg University Hospital, spanned five different cities in the North Denmark Region. Similarly, the 12 participating private audiological clinics were located in or near the same cities, ensuring widespread coverage across the region and thereby facilitating easy access to trial clinics for participants, irrespective of their geographical locations. Private ENT specialists from the region performed PESA screening of CG participants.

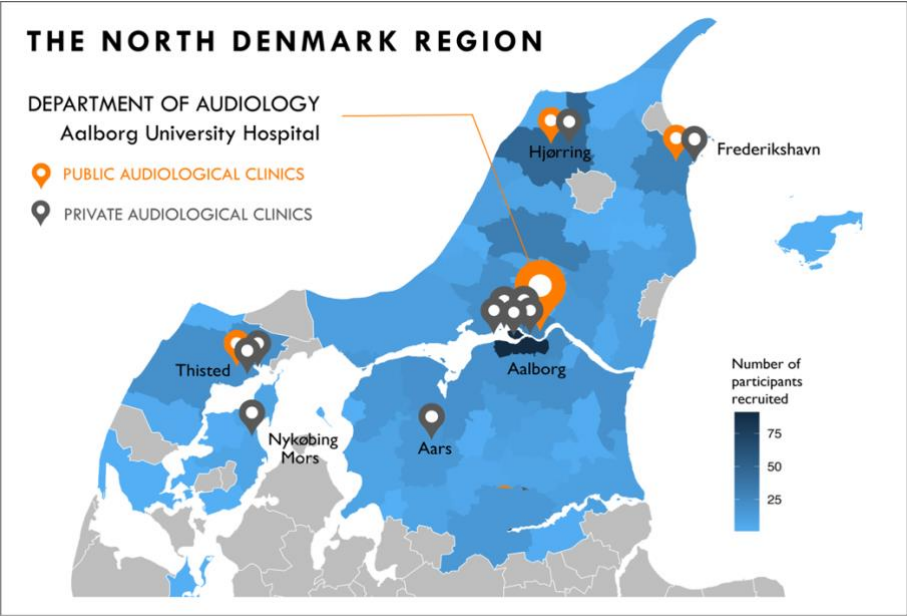


Figure 1. The figure visualizes the geographical distribution of trial participants in the North Denmark Region. The color intensity represents the recruitment rate in different areas, with darker shades corresponding to higher participant counts.

The trial process was divided into three stages: Stage 1, the intervention stage; Stage 2, the treatment stage; and Stage 3, the 'gold standard' reassessment stage conducted by ENT specialists with expertise in medical audiology or otology from the Department of Otolaryngology, Head and Neck Surgery, and Audiology at Aalborg University Hospital.

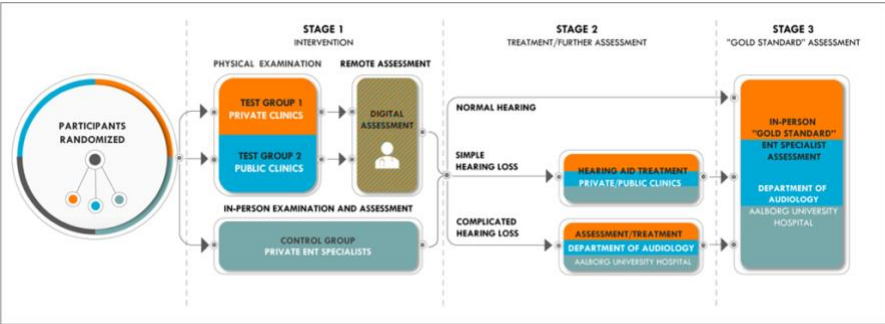


Figure 2. The figure depicts the InHEAR trial study design, outlining the respective stages of intervention, treatment, and the 'gold standard' ENT specialist assessment.

3.2.1. STAGE 1: INTERVENTIONS

While CG participants were examined and evaluated in-person by private ENT specialists as per existing national guidelines at Stage 1, participants in TG1 and TG2 underwent RESA screening in private and public audiological clinics, respectively. RESA screening comprised firstly of a standardized examination conducted by certified audiology assistants with a minimum of two years clinical experience. The standardized examination was a test package comprising of three key elements: 1) a medical history with a focus on ears and hearing, 2) an audiological examination (audiometry and tympanometry), and 3) an objective examination of the external auditory canal (EAC) and tympanic membrane bilaterally performed using a digital otoscope, Otocam 300, from Natus Medical Incorporated (Natus Medical Incorporated, n.d.).

3.2.1.1. MEDICAL HISTORY FOCUSED ON EARS AND HEARING

The study collected medical history data related to ears and hearing using the Danish-adapted electronic version of the Consumer Ear Disease Risk Assessment (CEDRA) questionnaire (Kleindienst et al., 2017; Klyn et al., 2019); a tool developed following the enactment of the Over-The-Counter Hearing Aid Act of 2017 (S.670 - 15TH CONGRESS: Over-the-Counter Hearing Aid Act of 2017, 2017). The CEDRA questionnaire was designed to assist adult potential first-time HA users in self-screening for TEDs before HA acquisition, and aid clinicians in providing hearing rehabilitation advice. The questionnaire comprises 15 items covering hearing, balance, tinnitus, general health, and other symptoms that potentially co-occur with HL, such as vision impairment and recurrent fever episodes. Additionally, the tool produces a score ranging from 0 to 28, which gauges the risk of disease requiring medical intervention. Higher scores suggest a greater likelihood of having one or more TEDs requiring medical attention either before or alongside HA treatment. Previous studies indicate that the CEDRA questionnaire strikes an optimal balance between sensitivity (76%) and specificity (80%) at a cut-off score of four, when used independently without additional information or objective measures (Kleindienst et al., 2017; Klyn et al., 2019). Practically, this implies that a medical assessment is recommended before HA acquisition for scores of four or higher.

Considering the results from previous studies and the context in which CEDRA was utilized – alongside audiological measures, including audiometry and tympanometry, and visual images of the tympanic membranes – the digital ENT specialist assessors were guided to consider the likelihood of serious ear disorders in TG participants scoring eight or above. While this would increase the tool's specificity to approximately 95% at the expense of a decrease in sensitivity to approximately 55% (Kleindienst et al., 2017), it was anticipated that the additional information provided by the audiometry, tympanometry, and visual images of the tympanic membranes would augment the overall sensitivity of the RESA screening method.

3.2.1.2. AUDIOLOGICAL MEASURES

The audiological examination consisted of air and bone conduction (AC and BC, respectively) thresholds masked when needed, a speech discrimination test, acoustic reflex tests, and a 226 Hz standard tympanometry test. The settings, performance, and equipment for the audiology test were in line with the standards prescribed in the Danish Executive Order on Hearing Aid Treatments (Executive Order on Hearing Aid Treatment [BEK Number 1140 of November 10, 2019], n.d.).

3.2.1.3. VIDEO-OTOSCOPY

Still images of the EAC and tympanic membrane were digitally captured using video otoscopy. Despite the increasing acceptance and prevalence of digital video-otoscopic imaging as a diagnostic tool for ear diseases among GPs and ENT specialists (Biagio et al., 2013; Lundberg et al., 2017; Short, 2017), this method was not routinely performed in the participating private and public audiological clinics prior to their involvement in the trial. Therefore, performance guidelines were established and disseminated among examiners, and quality criteria for test results were defined.

3.2.1.4. REMOTE ENT SPECIALIST ASSESSMENT (RESA)

Following the standardized examination, results from the different tests were individually evaluated digitally and remotely by four experienced ENT specialists: two with expertise in medical audiology located in the South and the North Denmark Region, respectively, and two private ENT specialists located in the Central Denmark Region. To account for assessment discrepancies between the four digital ENT specialist assessors, all TG participants were randomly assigned to one of the four, and the decisions made during this assessment were subsequently applied during the treatment stage. The allocation was blinded for both the participants and the digital ENT specialist assessors.

3.2.2. STAGE 2: TREATMENT

All participants irrespective of group affiliation were categorized into three diagnostic subcategories at Stage 1, that would determine the course of treatment at Stage 2: In the first diagnostic subcategory were participants with objectively normal hearing, in the second were participants with 'simple' HL, and in the third were participants with 'complicated' HL and serious ear disorders.

3.2.2.1. PARTICIPANTS WITH NORMAL HEARING

The normal hearing subcategory included participants with a pure-tone average (PTA) hearing level of 20d dB or below, and no symptoms of serious ear disorders. The PTA indicates the mean AC hearing thresholds at 500, 1,000, 2,000, and 4,000 Hz (PTA-4). To ensure no severe ear conditions were overlooked in the intervention groups, TG participants categorized in the normal hearing diagnostic subcategory who underwent RESA screening at Stage 1 were physically reassessed by an ENT specialist with expertise in medical audiology before completing their trial course.

3.2.2.2. PARTICIPANTS WITH 'SIMPLE' HEARING LOSS

The 'simple' HL subcategory included participants with mild HL (21-40 dB hearing level AC thresholds) and moderate HL (41-60 dB hearing level AC thresholds) without any concurrent symptom of serious ear disorders. If participants displayed an asymmetric sensorineural mild or moderate HL of 15 dB or more at two neighboring octave frequencies, they were offered an additional magnetic resonance imaging (MRI) scan of the internal auditory canal to exclude the possibility of tumors in the cerebellopontine angle, such as vestibular schwannoma. In cases where MRI was not an option, brain stem audiometry was utilized. TG1 participants with simple HL had HAs fitted at private audiological clinics, while TG2 participants had the same done at public audiological clinics. CG participants with simple HL could choose between the participating private or public audiological clinics for HA fitting. Regardless of group affiliation, all participants received the required treatment according to the existing national clinical guidelines on HL management (The Danish Health Authority, 2015).

3.2.2.3. PARTICIPANTS WITH 'COMPLICATED' HEARING LOSS AND SERIOUS EAR DISORDERS

The 'complicated' HL subcategory included participants with symmetric and asymmetric HL exceeding the 61 dB hearing level AC thresholds. It also encompassed participants who exhibited mild or moderate HL with pronounced PTA-4 asymmetry surpassing 30 dB in AC thresholds across both ears, or those demonstrating a disparity of 20% or greater in speech discrimination score (DS) between the two ears. Diagnosis of complicated HL was made in accordance with the 2015 Danish national clinical guideline criteria on ENT specialist assessment and referral of patients with HL (The Danish Health Authority, 2015).

In this subcategory were also participants with symptoms and objective signs of serious ear disorders including: 1) EAC pathology (e.g. atresia, exostosis, infection, EAC cholesteatoma), 2) middle ear pathology (e.g., cholesteatoma, otosclerosis, tympanic membrane perforation or retraction, and secretory or acute otitis media), 3) retro-cochlear pathology (e.g., vestibular schwannoma, tinnitus, otogenic vertigo), and 4) cerebral pathology (e.g., infection, tumor, head trauma, vascular disorders, neurological problems) (Siggaard et al., 2023). Irrespective of their group assignment, all participants in the complicated HL subcategory were referred to the Department of Audiology at Aalborg University Hospital for an additional in-person ENT specialist evaluation before initiating treatment.

Categories of complicated hearing loss (Siggaard et al., 2023; The Danish Health Authority, 2015)	
	<ul style="list-style-type: none"> • All patients below 18 years of age*
	<ul style="list-style-type: none"> • Patients in need of assessment and treatment defined as a regional and highly specialized hospital function in accordance with current guidelines
	<ul style="list-style-type: none"> • Patients with significantly reduced speech-reception thresholds regardless of the extent of their hearing loss, corresponding to a speech discrimination score (DS) < 75% measured by speech audiometry (Dantale I)
	<ul style="list-style-type: none"> • Patients with asymmetric hearing loss, where the averaged asymmetry in hearing thresholds at 500, 1,000, 2,000, and 4,000 Hz is more than 30 dB, and/or where the difference in speech DS between the two ears is 20 or higher. Further assessments to disregard retro-cochlear disease may still be indicated at averaged asymmetries below 30 dB
	<ul style="list-style-type: none"> • Patients in whom a hearing aid is considered for an ear with an average hearing of 25 dB hearing level or better at 500, 1,000, 2,000, and 4,000 Hz
	<ul style="list-style-type: none"> • Patients who may be candidates for cochlear implants, bone-anchored hearing aids, or other implantable hearing aid solutions
	<ul style="list-style-type: none"> • Patients with hearing loss and concomitant severely bothersome tinnitus and patients with severely bothersome tinnitus without hearing loss
	<ul style="list-style-type: none"> • Patients with hearing loss in combination with other severe sensory impairment and/or complicating comorbidity and/or severely reduced functional capacity of importance for the treatment of choice*
	<ul style="list-style-type: none"> • Patients with fluctuating or rapidly progressive hearing loss
<p>* Because of study exclusion criteria, these patient categories were not represented in the study population</p> <p>ENT, Ear-nose-and-throat; DS, Discrimination Score</p>	

Table 1. Categories of patient with complicated hearing loss requiring specialized medical ENT specialist assessment at an audiology hospital department according to existing PESA screening guidelines (The Danish Health Authority, 2015).

3.2.3. STAGE 3: 'GOLD STANDARD' ENT SPECIALIST ASSESSMENTS

Irrespective of their group classification, all participants diagnosed with HL, whether simple or complicated, as well as those with serious ear disorders, were subject to a comprehensive reevaluation, referred to as the 'gold standard', 2-4 months after initiating HA treatment or other intervention. Experienced ENT specialists, distinct from the digital ENT specialist assessors performing remote assessments in TG participants at Stage 1, conducted this evaluation at the Department of Audiology at Aalborg University Hospital. These specialists, experts in either medical audiology or otology, dedicated a 30-minute in-person consultation with each participant, evaluated audiological measures, including an audiometry and a tympanometry, and performed an objective otomicroscopic examination of the EAC and the tympanic membranes bilaterally.

The 'gold standard' ENT specialist assessors adhered strictly to existing and relevant audiological clinical guidelines provided by the Danish Health and Medicines Authority and the Danish Society of Otolaryngology, Head and Neck Surgery (DSOHH) (*Danish Society of Otolaryngology, Head and Neck Surgery (DSOHH)*, n.d.). Based on the ENT specialists' expert evaluations, participants were subsequently categorized into the same three diagnostic subcategories identified at Stage 1: normal hearing, simple HL, and complicated HL. This 'gold standard' reassessment and recategorization process served as the benchmark against which all previous ENT specialist assessments, both remote (for TG1 and TG2 participants) and in-person (for CG participants) from Stage 1, were evaluated.

3.3. QUESTIONNAIRES

At key trial stages, participants received digital, disease-specific questionnaires assessing hearing ability, HA efficacy, and satisfaction. They were directed via email to complete the questionnaires, with automatic reminders for uncompleted ones.

3.3.1. THE INTERNATIONAL OUTCOME INVENTORY FOR HEARING AIDS (IOI-HA)

The International Outcome Inventory for Hearing Aids (IOI-HA) was used at Stage 3 to gauge patient-perceived HA benefit. The easy-to-use IOI-HA assesses seven HA treatment outcomes on a five-point scale defining outcomes from worst to best. Although the IOI-HA covers several HA treatment effect parameters, it offers limited patient-perceived hearing ability details and was thus complemented by other questionnaires.

3.3.2. THE SPEECH, SPATIAL, AND QUALITIES OF HEARING SCALE (SSQ12)

The 12-item Speech, Spatial and Qualities of Hearing Scale (SSQ12) was utilized to evaluate hearing disabilities across three domains, scored on a 0-10 scale (Lorentzen et al., 2019; Noble et al., 2013). The questionnaire was administered at Stage 1 to establish baseline of averaged hearing disability severity across groups. A 'benefit' version (SSQ12-B) was employed at Stage 3 for a retrospective self-report of hearing ability and quality post-treatment, scored on a '-5' to '5' scale (Jensen et al., 2009). Comparative analyses were performed on the SSQ12 and SSQ12-B responses to ascertain significant differences across groups.

3.3.3. SATISFACTION QUESTIONNAIRES (PREM18)

To deepen patient satisfaction analysis, generic questionnaires were used throughout the trial. Selected items from the validated 2021 Danish national Patient Reported Experience Measures (PREM) were incorporated at all three trial stages (Center for patient involvement (CPI), 2021). These covered satisfaction with clinical staff, waiting time, information provided, and overall treatment. A five-point Likert scale was used for scoring, with higher scores indicating better outcomes, and with the option of 'unsure' and 'irrelevant for me'. The questionnaire also included an item on clinical errors or malpractice. Furthermore, participants were welcomed to provide additional free-text comments on staff, information, and overall satisfaction if desired.

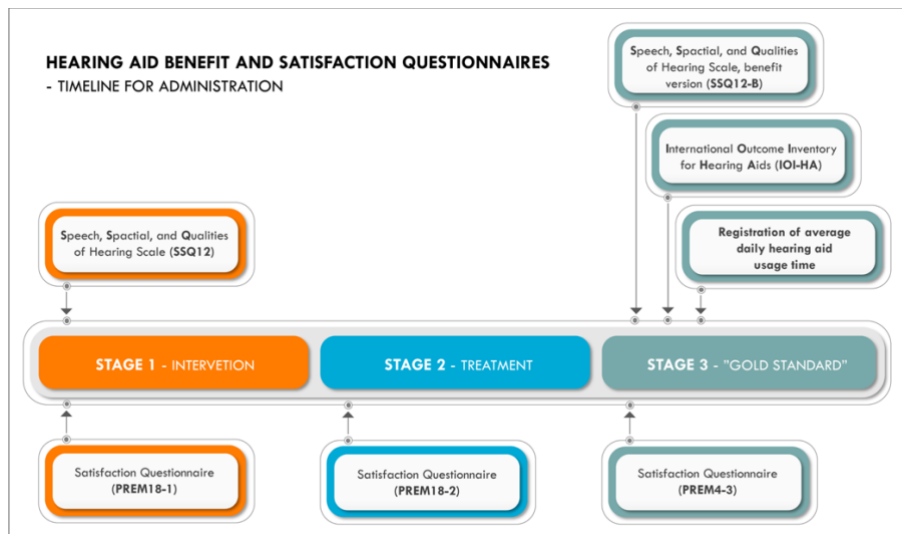


Figure 3. The figure illustrates the timeline for questionnaire administration throughout the course of the trial.

3.4. HEARING AID MODELS

The project placed a premium on providing participants with an array of comparable HA models from various manufacturers. This was to ensure that all participating public and private audiological clinics were equally versed with at least one of the selected devices. While an equitable distribution of the different devices was aspired, clinics were encouraged to familiarize themselves with HA types that best fit the type of HL under investigation.

Following exhaustive dialogues with all private stakeholders involved in the project, a financial framework was established for the involvement of private audiological clinics. This covered the selection of HAs to be used and the setup of a procurement model for the devices. The project deemed mid-range, high-quality devices appropriate as they were capable of treating all potential participants, irrespective of the type, degree, and complexity of their HL.

In partnership with the Danish Supplier Association of Hearing Aids, four comparable mid-range hearing aids were selected from the four different manufacturers. These devices met the project's scientific criteria and catered to the interests of the participating private audiological clinics. For particularly complex cases of severe HL, assessed at the Department of Audiology at Aalborg University Hospital, the usage of HA models outside the pre-determined project-specific selection was allowed if deemed necessary to ensure optimal treatment.

The selected suppliers provided these HAs at a preferential project rate, and the InHEAR project supplemented this with an additional financial subsidy. This co-financing approach eased the cost of the HAs for participating private audiological clinics. Consequently, these clinics could purchase the selected devices through the InHEAR project at a price similar to a basic device, currently dispensed within the public subsidy limit.

The project's procurement model, involving the four selected HA models, ensured all participating private audiological clinics could purchase the devices at the same low project price, thus creating an equal platform. Table 2 outlines the selected HA models used in the project, along with their respective suppliers.

Hearing Aid Model	Hearing Aid Supplier
Marvel M70	SONOVA
Open S2	Oticon
Evoke 330	WS Audiology
Resound Quattro 7	GN Hearing

Table 2. The four selected hearing aid models applied in the InHEAR trial and their respective suppliers.

3.5. PATIENT AND PUBLIC INVOLVEMENT

Members of patient advocacy groups, representatives from both public and private audiological health sectors, collaborators, as well as stakeholders from the HA industry formed a supportive trial committee. Their involvement was crucial in refining the trial design and choosing the outcome metrics before the onset of the trial. Regular meetings held every six months allowed these committee members to contribute valuable feedback and queries during the course of the trial.

3.6. DATA MANAGEMENT

The InHEAR database was developed using the web-based electronic data capture platform, REDCap®. The database housed essential participant details, as well as specific health data related to their ear and hearing health. This also included visual images of the tympanic membranes, audiograms, and tympanograms, which were uploaded to the database as jpeg, jpg, docx, or pdf files.

In addition, the database stored responses from participant surveys, diagnostic annotations made by both the digital and physical ENT specialist assessors at Stage 1, and by the 'gold standard' ENT specialist assessors at Stage 3. Data on the HA usage time, directly obtained from the participants' devices, was also stored in the database. Automated links to surveys were disseminated to participants via a management tool within the REDCap® platform.

All data analyses in the studies were performed using the statistical R v4.1.2 software.

3.7. ETHICAL CONSIDERATIONS

Consistent with Danish regulations, the InHEAR project management group submitted an ethical approval request to the North Denmark Region's Regional Committee on Health Research Ethics (case no. 2020-000992). The committee determined the project did not require a formal notification. Since every manuscript in this thesis originates from the InHEAR project, there was no necessity for additional ethical approval applications.

Before entering the trial, written informed consent was given by all participants, and written trial information were sent by the secure mail system 'e-boks' supplied to all Danish citizens over the age of 15 by the Danish government. All participants were informed of their prerogative to retract their consent and discontinue participation at any juncture, with no need for explanation. All clinical and personal data collected by project staff members, which included secretaries, audiology assistants, hearing consultants, and ENT specialists were kept and stored in the REDCap® project database hosted by Aalborg University Hospital. All private participating audiological clinics in the trial signed a cooperation agreement and all communication concerning

participants were conducted through a secure mail system provided by Aalborg University Hospital.

Treatment of patients adhered strictly to outlined ethical duty which emphasizes the necessity to provide appropriate care for every individual and ensure a fair share of the challenges and advantages associated with project participation (*International Ethical Guidelines for Health-Related Research Involving Humans*, 2016). The single potential barrier to fulfilling this obligation lies in the fact that patients with cognitive difficulties or those who could not comprehend and read Danish were barred from taking part in the project. This exclusion was due to the limitations associated with the study design and the questionnaires employed. This unequal participation is defensible as it safeguards the rights of patients who may not be able to advocate for their own interests, such as when offering informed consent.

CHAPTER 4. AIM AND HYPOTHESIS

The overall aim of the dissertation was to explore, whether RESA screening before treatment in adult potential first-time HA users when compared to existing PESA screening guidelines and practices compromises patients' safety and their self-reported HA benefit and satisfaction. This included translation and validation of the CEDRA questionnaire employed as a sub element in the RESA screening examination package. Finally, the dissertation aimed to explore if ENT specialists with expertise in medical audiology and private practicing ENT specialists were equally qualified to perform RESA screening.

4.1. MANUSCRIPT 1

The primary aim of the first manuscript was to investigate whether RESA screening posed any risks to patient safety. This was achieved by comparing the sensitivity and specificity of RESA screening in the TGs to PESA screening sensitivity and specificity in the CG. Both were evaluated against the 'gold standard' ENT specialist assessments conducted at Stage 3.

We hypothesize that ENT specialists, when equipped with a comprehensive dataset – consisting of a detailed medical history specifically focused on hearing and ear-related conditions, standard-equivalent audiometry and tympanometry measures, and high-resolution images of the tympanic membranes – can competently identify patients with severe and complex HL, as well as symptoms of serious ear disorders that require specialized assessment at an audiological hospital department before initiating HA treatment, even when working remotely, digitally, and without direct patient interaction. We assert that the screening accuracy of this method is at least equivalent to the current standards and practices of PESA screening.

4.2. MANUSCRIPT 2

The main objective of the second manuscript was to evaluate the impact of RESA screening on self-reported HA benefit and satisfaction relative to PESA screening. This was accomplished by comparing questionnaire responses from TG participants, who underwent RESA screening, and CG participants, who underwent PESA screening. The questionnaires assessed participants' hearing ability pre- and post HA treatment, as well as their HA benefit and treatment satisfaction 2-4 months after HA treatment initiation.

The digitization of the ENT specialist assessment process could present novel challenges. For instance, RESA screening omits direct patient-physician interaction, which could potentially influence mutual understanding and decision-making, as well as obscure the ENT specialist's perception of the patient's treatment motivation level. This could, in turn, impact or even undermine overall treatment benefit and satisfaction. Nevertheless, assuming RESA screening does not lead to a significant

increase in misdiagnosed cases in adult potential first-time HA users when compared to PESA screening, we propose that self-reported HA benefit and satisfaction remain largely similar between the two screening approaches.

4.3. MANUSCRIPT 3

The objective of the third manuscript was to report the translation and validation process of the CEDRA questionnaire in Danish. The Danish rendition of CEDRA was termed 'Risikovurdering af Høreapparatbrugere' (RiHab), serving as the Danish equivalent of CEDRA. The process included comprehensive single-person interviews in 30 intended respondents, a test-retest reliability analysis in 154 individuals, and a screening accuracy analysis for TEDs in the 445 InHEAR trial test group participants. The latter analysis aimed to test the Danish-adapted version's ability to correctly identify patients with complicated HL and symptoms of one or more TEDs in the intended population of adult, subjectively hearing-impaired, potential first-time HA users.

Translation and validation of CEDRA including the test-retest reliability analysis was performed prior to trial initiation, whereas the screening accuracy analysis of the tool was performed after trial completion.

4.4. MANUSCRIPT 4

The fourth manuscript aimed to evaluate the RESA screening accuracy among four digital ENT specialist assessors, and to compare proficiency of two sub-specialized ENT specialists in private practice with two ENT specialists with expertise in medical audiology, in executing RESA screening among hearing-impaired adults prior to treatment initiation.

Given that all four digital ENT specialist assessors had conducted RESA screening on all TG participants, both individual screening sensitivity and specificity were juxtaposed among the four assessors and between the two sub-specialized ENT specialist groups. These individual and group assessments were subsequently benchmarked against the 'gold standard' ENT specialist assessments executed at Stage 3.

CHAPTER 5. SUMMARY OF RESULTS

Overall, 782 participants who met the inclusion criteria were invited to participate in the trial. Of these, 751 participants provided informed consent and were suitable for randomization. Out of the randomized participants, 658 (88%) completed the trial and were included in the analysis. Loss to follow-up accounted for 40 participants, while 52 withdrew due to illness or personal reasons. Additionally, one participant passed away during the course of the trial.

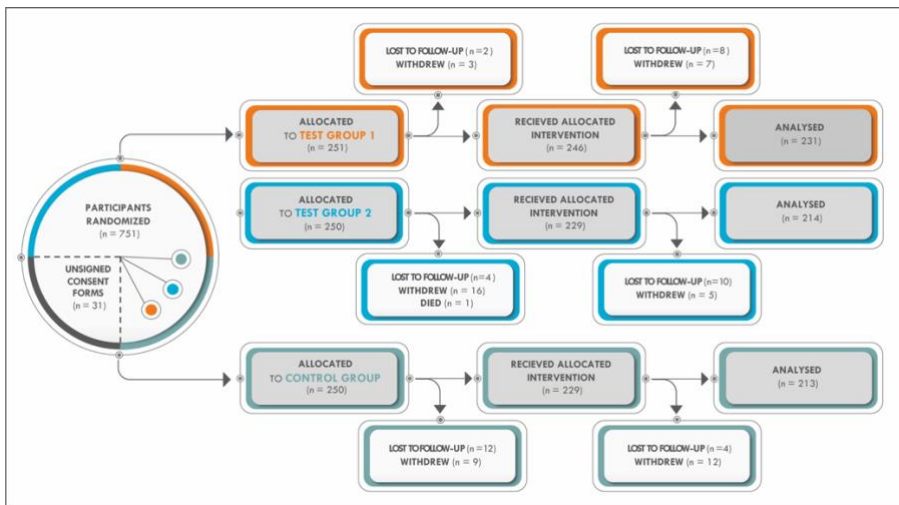


Figure 4. Flowchart depicting the number of participants who were randomized, allocated to each of the three groups, lost to follow-up, withdrew from the study, received their allocated intervention, and were included in the analysis.

5.1. RESA VERSUS PESA SCREENING ACCURACY (MANUSCRIPT 1)

- In a comprehensive assessment, RESA screening sensitivity for complicated HL and/or serious ear disorders was significantly greater than that of PESA screening sensitivity. Figure 5 showcases the overall outcomes from the RESA versus PESA screening accuracy analysis, as well as results from a sub-analysis on RESA screening accuracy among TG1 and TG2 participants. Screening sensitivity was defined as the percentage of participants in the TGs and CG who were correctly identified as having complicated HL and/or serious ear disorders. Similarly, specificity represents the percentage of participants correctly identified as having either normal hearing or simple

HL in the TGs and CG. All measurements are presented with 95% confidence intervals (CI), and a P-value of < 0.05 is deemed statistically significant.

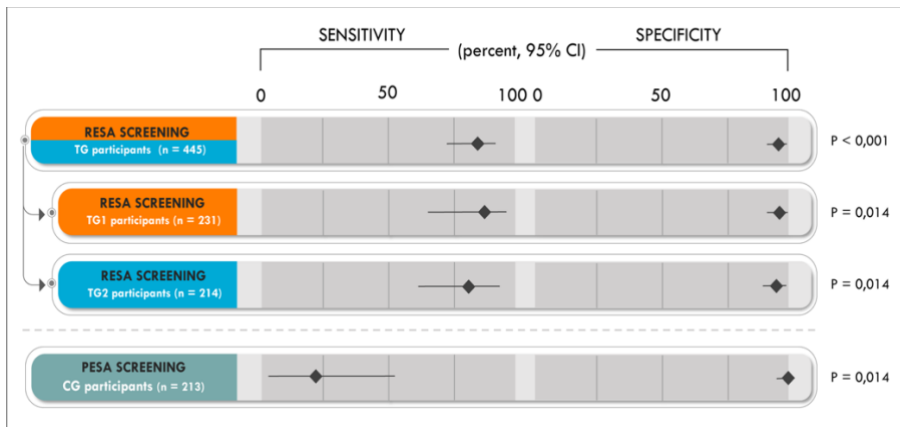


Figure 5. The figure presents overall screening accuracy results comparing the RESA and the PESA screening methods, and also displays the results for each test groups separately. Sensitivity represents the fraction of participants with complicated hearing loss and/or serious ear disorders who were accurately identified. Conversely, specificity denotes the fraction of participants with normal or simple hearing loss who were correctly identified.

- Compared to the definitive 'gold standard' ENT specialist assessment at Stage 3, six TG and eight CG participants were inaccurately identified as 'simple' during the RESA and PESA screenings at Stage 1, respectively.
- When juxtaposed with the definitive 'gold standard' ENT specialist assessment at Stage 3, 12 TG participants and a single CG participant were inaccurately classified as 'complicated' during the initial Stage 1 evaluation. This included eight cases of asymmetric, but otherwise simple, HL, and five instances of tinnitus ranging from mild to bothersome.
- Among the 445 TG participants who completed the study, digital otoscopic images of the tympanic membranes for 130 (29%) were deemed subpar by the digital ENT specialist assessors at Stage 1 due to blurring, earwax blockage, or inadequate tympanic membrane visibility. Of these, 10 cases were found to have varying degrees of ear conditions such as earwax blockage, EAC atresia, OME, tympanic membrane retraction, and cholesteatoma during the otomicroscopic examination at Stage 3. However, none of these 10 TG participants were inaccurately diagnosed at Stage 1, maintaining consistency with the 'gold standard' ENT specialist assessment at Stage 3.

5.2. EFFECTS OF RESA VERSUS PESA SCREENING ON SELF-REPORTED HA BENEFIT AND SATISFACTION (MANUSCRIPT 2)

- The SSQ12 and SSQ12-B survey results shed light on participants' hearing ability and quality before and after HA treatment. Pre-treatment SSQ12 responses indicated no significant variance in self-reported hearing disability across the three groups. However, after adjusting for age, gender, and randomization group, individuals with normal hearing and simple HL had notably higher SSQ12 scores than those with complicated HL. Post-treatment, no significant difference was observed in self-reported hearing ability or treatment benefit across groups via SSQ12-B and IOI-HA assessment.
- PREM survey results revealed patient experiences across the three groups. At the intervention stage, PREM18-1 indicated the CG was less satisfied with the 'Clinical Staff' than the TG1 and TG2. TG1 reported highest satisfaction with 'Waiting Time', followed by TG2, and then CG. Similar trends in 'Waiting Time' were reflected in PREM18-2 at the treatment stage. Despite no significant difference in the distribution of positive/neutral and negative free-text comments across groups, the feedback revealed nuances in patient satisfaction, highlighting scheduling, parking, and high clinical standards as vital for successful treatment. Ultimately, the PREM survey emphasized the importance of efficient logistics and quality staff interactions in hearing rehabilitation.
- The average daily HA usage was similar among participants across the three groups. However, the extensive IQRs suggest substantial variation in HA usage within each group. This variation means that while some individuals may use their HAs considerably less than the median value, others might use them for significantly more hours.

5.3. CROSS-CULTURAL TRANSLATION AND ADAPTATION OF THE CONSUMER EAR DISEASE RISK ASSESSMENT TOOL IN DANISH (MANUSCRIPT 3)

- Rigorous cross-cultural translation and adaptation of CEDRA into Danish was carried out in accordance with field-specific good practice guidelines in translation and validation of hearing-related questionnaires (Hall et al., 2018). The Danish version, RiHab, was field-tested by cognitive debriefing in 30 intended respondents and pilot tested in 600 adult, subjectively hearing-impaired, potential first-time HA users. Semi-structured interviews helped identify any misunderstandings or misinterpretations of specific terms, leading to corrective adjustments aimed at enhancing readability and comprehension. Despite modifications to the self-scoring instructions,

persistent miscalculations of RiHab scores were noted. To remedy these inconsistencies, a digital version of the questionnaire was adopted, offering improved consistency and automatic score calculation.

- The pilot test measured RiHab as a risk assessment tool for TEDs in a sample of 600 adults with subjective HL who were potential first-time HA users. The sample population was diverse, with 93% having either normal hearing, or mild/moderate, or severe HL and no symptoms of TEDs, while the remaining 7% exhibited symptoms of one or more TEDs. RiHab demonstrated good diagnostic accuracy, with its performance yielding an Area Under the Curve (AUC) of 0.82. An optimal balance between the sensitivity (74%) and specificity (62%) of the tool was achieved at a cut-off score of five.
- Psychometric properties of RiHab were tested in a reliability test-retest analysis. A total of 113 (73%) of the 154 respondents in the test-retest analysis completed the RiHab questionnaire twice within the given time limit (3-14 days), with an average response time of 4.91 days. Although responses to certain items regarding hearing changes and symptoms of tinnitus demonstrated some inconsistency over time, overall RiHab scores were highly correlated, with a Pearson correlation coefficient of 0.92, and an Intraclass Correlation Coefficient (ICC) of 0.90, suggesting a strong consistency and reproducibility of the test. The small Standard Error of Measurement (SEM) of 0.90 indicated a relatively minor degree of measurement error, further reinforcing the reliability of RiHab.

5.4. RESA SCREENING ACCURACY OF PRIVATE ENT SPECIALISTS VERSUS ENT SPECIALISTS SUBSPECIALIZED WITHIN MEDICAL AUDIOLOGY (MANUSCRIPT 4)

- The RESA screening accuracy of each of the four ENT specialist assessors was calculated twice against the 'gold standard' ENT specialist assessment, both before and after two specific dataset adjustments. First, it was discovered after RiHab implementation, that cut-off scores of eight or higher did not reliably predict TEDs in first-time HA users, when all audiometric measures and visual tympanic membranes images were normal. Hence, eight participants initially classified as 'complicated' based solely on a high RiHab score, but exhibiting normal conditions in all other data, were reassigned to the 'normal hearing' diagnostic subgroup in the adjusted analysis. Second, an adjustment was made for 15 participants initially classified as 'complicated' due to minor asymmetrical HL, marking them eligible for MRI scan to exclude vestibular schwannoma. Per project protocol and guidelines, these participants should have been categorized as 'simple', resulting in their reclassification in the subsequent post-adjustment analysis. The initial

misclassification stemmed from a misunderstanding between ENT specialist assessors and the trial administration and was rectified early in the study.

- In the individual pre-adjusted analysis, RESA screening specificity and PPV for the two medical audiologists were significantly lower compared to the two private ENT specialists. However, no significant difference was observed in the screening sensitivity across all four assessors. For the subspecialist group analysis, a similar pattern emerged with both screening specificity and PPV being equally lower for the two medical audiologists compared to the private ENT specialists prior to dataset adjustments.

CHAPTER 6. DISCUSSION

6.1. DISCUSSION OF STUDY DESIGN

The principal aim of this thesis was to evaluate the practicability of incorporating a RESA screening regimen for subjectively hearing-impaired adults considering HAs for the first time before starting treatment. While a well-established PESA screening procedure already exists for this demographic (The Danish Health Authority, 2015), the advantages of digitalizing and enhancing the screening process are self-evident: an expanding population of adults with HL will profit from swift diagnosis and early hearing rehabilitation, diminishing the risk of associated dementia, depression, and social isolation. Socioeconomic benefits of prompt diagnosis and treatment might also entail prevention of premature retirement due to potentially unresolved hearing-related communication challenges. Moreover, a more expedient diagnostic process will save patients with simple HL from making one or more unnecessary visits to an ENT specialist clinic, while those with complicated HL and symptoms of serious ear disorders needing more thorough physical assessment will receive specialized care and treatment. This will maximize resource allocation and curtail needless expenditure within the hearing healthcare system while meeting the increasing demand for timely treatment among a growing patient population.

In this thesis, we focus on two overarching factors regarding the feasibility for RESA screening in adult HA first-time users: 1) the accuracy of RESA screening in correctly identifying patients with complicated HL and/or severe disorders requiring specialist assessment at treatment, and 2) the effects of RESA screening on self-reported HA benefit and satisfaction. This study also encompasses the translation and validation process of CEDRA in Danish, and comparative analysis concerning the RESA screening accuracy of four ENT specialists to ascertain which ENT subspecialists are competent in performing accurate RESA screening. However, additional variables could have been investigated in the current study to highlight the intricacies of HL and its impact on mental wellbeing, cognition, quality of life, and overall comorbidity in RESA screening context (Baiduc et al., 2023; Samocha-Bonet et al., 2021). To address these aspects, data on participants' educational levels, psychological assessments, and mental status examinations could have been included to evaluate participants' abilities concerning orientation, concentration, language, praxis, memory, and non-verbal psychomotor speed and executive function. This is particularly relevant, as HL has been proven to be independently linked with accelerated cognitive decline (Lin et al., 2013). Although these factors fall outside the scope of the present study, their inclusion could be pertinent for future research focusing on qualifying remote assessment alternatives in hearing healthcare. Furthermore, it may be pertinent to adopt updated objective audiometric measures in the imminent future. For example, the utilization of ambient-pressure wideband tympanometry could be preferred over the standard 226 Hz tympanometry to provide more accurate indicators for conductive HL and middle-ear dysfunctions such as otitis media, otosclerosis, ossicular discontinuity, and tympanic membrane perforation (Keefe & Simmons, 2003). Another emerging methodology involves speech-in-noise

tests that employ phoneme scoring rather than word scoring. This approach might offer potential benefits in comparison to whole word scoring with respect to reducing test time and score variability. Additionally, it could provide insight into specific phoneme perception errors and decrease the influence of the listener's lexicon (Billings et al., 2016).

The study employed a randomized, prospective clinical trial design, a method commonly utilized when examining the effectiveness and safety of a new treatment or intervention if ethically, practically, and economically permissible. This design mitigates the risk of bias, as differences observed in outcomes between groups can likely be attributed to the intervention itself rather than pre-existing known and unknown disparities among participants. Moreover, results from randomized, prospective, clinical trials are typically generalizable to a larger population, which lends the findings particular significance for the implementation of new healthcare policies and practices.

The representation of the current organizational structure in hearing healthcare in Denmark was encapsulated within the cross-sectional scope of the trial, incorporating both private and public audiological clinics. Moreover, should the validation and confirmation of trial findings be required, the structured and controlled framework of the study design facilitates straightforward replication (Vandenbroucke, 2004).

In the present study, the focus of the intervention was the assessment routine at Stage 1, while the treatment at Stage 2 remained consistent for all participants, adhering to current treatment standards and recommendations. To minimize treatment bias arising from differences in HA models used, four specific comparable HA models were selected for use. Only in cases of complicated or severe HL were alternative HA models employed outside the designated selection for the trial.

One point of consideration in this study was the asynchronistic ENT specialist assessments at Stages 1 and 3, which were performed 2-4 months apart. Consequently, there was a risk that some participants could have developed complications during the period between the two trial stages. This risk primarily pertained to cases of EAC and/or middle ear infections or rare instances of acute sudden sensorineural HL. In contrast, it was deemed that cases of cholesteatoma or age-induced HL severity seldom deteriorate significantly over a 2-4-month period.

Another aspect to consider when interpreting the results is the intricacy of the underlying pathophysiology of HL and its associated ear disorders and their varying clinical manifestations. Since the assessment decision often relies on the individual ENT specialist's expertise and the patient's individual needs, it might be impossible to define and apply a definitive 'gold standard' ENT specialist assessment for this patient category. Nonetheless, in this study, assessors were ENT specialists subspecialized in either medical audiology or otology, who undertook a 30-minute in-person consultations with each participant. These specialists conducted objective measurements of hearing, utilizing both audiometry and tympanometry, and executed detailed otomicroscopic examinations of both ear canal and the tympanic membrane bilaterally on all subjects.

A self-selection bias associated with the Facebook-based recruitment strategy employed in the study should be considered. Individuals who volunteered for the study could be younger and healthier, more likely to lead healthier lives, and comply more readily with treatment than older individuals who are less internet-savvy. According to the 2021 Statistics Denmark report on Danes' use of information technology, 95% of the Danish population between the ages of 16 and 74 years were online at least once a day, and 85% were active on social media in 2021, a notable increase from 55% reported in 2011 (Tassy & Berg, 2022). Despite these figures, a synchronous decline in social media use with increasing age is observed. Consequently, this study may underrepresent the elderly population with severe, undiagnosed HL and lower treatment adherence.

6.2. DISCUSSION OF RESULTS

6.2.1. RESA SCREENING ACCURACY (MANUSCRIPT 1)

The RESA screening demonstrated notably higher sensitivity for complicated HL and/or serious ear disorders compared to PESA screening, while both methods displayed high specificity. Within the control group, eight participants presenting with complicated HL and/or serious ear disorders were incorrectly diagnosed as having a 'simple' HL at Stage 1 via PESA screening. Three of these misdiagnoses comprised a small pars flaccida cholesteatoma, a skin impression in the EAC suggesting an early-stage EAC cholesteatoma, and one case of suspected EAC infection and/or malignancy warranting fast-track biopsy. Ironically, these types of ear disorders were initially considered more likely to be missed in the RESA screening setting, where asynchronous assessment without direct patient interaction is central. The significant difference in screening sensitivity between the two methods may be attributed to the inherent difficulty in correctly diagnosing early-stage ear canal and middle ear pathology even when in-person, gold-standard examinations by proficient ENT specialists are employed. Alternatively, the reduced PESA screening sensitivity could reflect limited consultation times within private ENT specialist practices due to high patient turnover and demanding schedules, compared to their public audiological clinic counterparts. Lastly, it is conceivable that the remote ENT specialist assessors, cognizant of the potential risk of misdiagnosis of complicated HL and/or serious ear disorders in a RESA screening setting, might have exercised increased caution in the evaluations. Such prudence could have resulted in them giving more participants the benefit of the doubt and categorizing them as complicated cases if their assessment decisions were equivocal. However, this potential bias is mitigated by the high specificity of RESA screening, which generally suggests that participants with normal hearing or simple HL were not inaccurately classified as 'complicated'.

Also, although the intervention deployed in the control group adhered to the existing guidelines for PESA screening (The Danish Health Authority, 2015), it is important to note, that in certain circumstances, private ENT specialists opt to utilize clinical staff, who operate under their jurisdiction and supervision, rather than certified audiology assistants to perform the audiological examinations on patients. This practice might yield variability in the quality of the resulting audiograms used in the

ENT assessment process, potentially escalating the risk of inaccurate assessments and misdiagnosis. In this study, the sensitivity of PESA screening was impacted by three instances of misdiagnosis due to this factor, reducing the potential screening sensitivity from 50% to 20%.

Tinnitus-related distress emerged as the most frequently misdiagnosed disorder amongst both TG and CG participants. Four TG participants and two CG participants with tinnitus were erroneously diagnosed as 'simple' and five TG participants were misdiagnosed as 'complicated' at Stage 1. The THI score, reflecting the state of self-perceived tinnitus distress over the four weeks preceding questionnaire completion, was the sole measure available for the TG participants' tinnitus severity at Stage 1 of RESA. Conversely, the CG participants' tinnitus diagnoses were based on in-person consultations with private ENT specialists. Ideally, a new THI score could have been obtained for reassessment at Stage 3 2-4 months later. However, this study utilized the Stage 1 THI score for the 'gold standard' ENT specialists assessment conducted at Stage 3 despite the time-gap between the two trial stages. Given that tinnitus often co-occurs with HL, HA treatment may alleviate or entirely remove tinnitus-related symptoms ("Clinical Practice Guideline: Tinnitus," 2014). However, the severity of tinnitus distress can fluctuate over time, influenced by factors such as depression, anxiety, and sleep deprivation (Geocze et al., 2013; Lasisi & Gureje, 2011; Zöger et al., 2006). Consequently, a single self-reported THI score might be insufficient to capture the evaluation of tinnitus distress severity over time. More comprehensive insights into the patient history, acquired through either in-person patient consultations or repeated self-reports may be crucial for accurate diagnose and personalized management. Nevertheless, even if all pertinent subjective information was current and accessible, there would arguably still be discrepancies in the ENT specialists' objective interpretation of the patient's tinnitus severity. Tinnitus, in essences, is a complex condition that challenges categorization and diagnosis within a RESA as well as a PESA screening setting. Nonetheless, RESA could be an effective screening tool for identifying individual with HL and accompanying mild to moderate bothersome tinnitus. In cases where HA treatment does not adequately alleviate symptoms, these individuals may require additional in-person counselling and tinnitus management guidance.

The findings of this study align with those of a British study conducted in 2022, which included 58 adults suffering HL or tinnitus. In that study, ENT specialists employed a remote review platform, consisting of a focused history, audiometric testing, and a smartphone-based application with an otoscope (Forde et al., 2022). The research showed that 75% of patients eliminated one hospital visit from their treatment journey, with 65% avoiding hospital attendance altogether. However, 24% required an additional in-person appointment due to an incomplete view of the tympanic membrane or the need for further tests. Diagnostic concordance between remote-review and in-person consultations was found to be 98% among 12 patients who consented to in-person review. Despite the smaller sample size of that study compared to the current one, its findings endorse the viability of remote assessment services in hearing healthcare, from the triage stage to treatment.

6.2.2. EFFECTS OF RESA SCREENING ON SELF-REPORTED HA BENEFIT AND SATISFACTION (MANUSCRIPT 2)

The SSQ12 and SSQ12-B surveys elucidated participants' pre- and post-treatment hearing capabilities and quality across all three groups. Prior to treatment, no significant discrepancies were detected in self-reported hearing disability; however, after controlling for age, gender, and randomization group, a notable divergence was observed. Individuals with normal hearing and simple HL had significantly higher SSQ12 scores, indicative of superior hearing ability pre-treatment. Post-treatment, no significant group variations in self-reported hearing capability or treatment benefits were discerned, as per the SSQ12-B and IOI-HA analyses. The primary reason appears to be the non-completion of SSQ12-B by participants with untreated normal hearing. However, the uniformity of self-reported HA benefits, irrespective of the screening method used by the ENT specialists, as well as the independence of HA treatment trajectories from the employed screening method, may also be significant.

Insights into patient experiences were garnered via the PREM survey results. At the intervention stage, patient satisfaction with 'Clinical Staff' was lower in the control group (CG) compared to both treatment groups (TG1 and TG2). Moreover, satisfaction regarding 'Waiting Time' was highest for TG1, intermediate for TG2, and lowest for CG. This disparity may stem from the private ENT specialists' constrained time with patients, leading to expedited consultations and extended wait times. Feedback on free-text comments in the survey highlighted factors such as appointment scheduling, parking, and clinical care standards as pivotal to a satisfactory treatment journey.

Lastly, daily HA usage demonstrated no significant differences across groups, but substantial intra-group variation was evident. This study did not explore potential causes for these usage disparities, which might encompass demographic factors, HL severity, and environmental influences. Overall, these findings stress the need to consider both clinical and logistical factors when devising patient-centric strategies for hearing rehabilitation.

6.2.3. TRANSLATION AND VALIDATION OF CEDRA IN DANISH (MANUSCRIPT 3)

The strength of the cross-cultural translation and adaptation of RiHab lies in its structured methodology aligning with established good practice guidelines (Balslev Willert et al., n.d.-a, n.d.-b; Hall et al., 2018). A total of 30 single-person interviews were conducted to validate the cultural adaptation of the questionnaire, and the fact that all interviews were conducted by the same person minimized interviewer bias. Questionnaires for the test-retest reliability analysis were completed online by respondents at home, reducing the potential for influences from clinical staff. Although the potential for assistance, acquiescence, or social desirability biases was not assessed, the risk was deemed minimal due to the question neutrality and non-extreme wording. A minor risk of recollection bias, however, was acknowledged due to the 3-day interval between test and retest (Willert et al., 2015). Most items exhibited

strong consistency over time (Spearman's correlation coefficients of 0.70 or higher in the test-retest). However, some items related to hearing changes and ear fullness/blockage yielded lower coefficients, potentially reflecting daily variations in symptom perception. Overall, the RiHab demonstrated strong correlation and reliability, as evidenced by a Pearson's correlation of 0.92, an ICC of 0.90, and a SEM of 0.90 on the total RiHab score.

This study's additional strength is the pilot testing and screening accuracy analysis, which included a diverse sample of 600 adult, potential first-time HA users without prior TED diagnosis. The sample was representative of the hearing-impaired demographic for who CEDRA was originally developed (Klyn et al., 2019), and for which RiHab, alongside with audiometric measures (audiometry and tympanometry) and bilateral images of the tympanic membranes, was intended for use in a RESA screening setting.

The screening efficacy of RiHab was evaluated at various cut-off scores among respondents grouped by the presence and absence of TEDs irrespective of HL diagnosis or severity. An AUC value of 0.82 on the ROC curve suggests a good discriminative ability of RiHab to differentiate respondents with and without TEDs. RiHab correctly classified 82% of the respondents, which is a better outcome than chance but not perfect. At a cut-off score of five, the most optimal balance was achieved between sensitivity (74%) and specificity of (62%). The original tool was initially assessed using 307 participants, separated into a training group (80%, n = 246) and a validation group (20%, n=61) (Kleindienst et al., 2017; Klyn et al., 2019). The training group facilitated the creation of a scoring algorithm that displayed a balanced sensitivity and specificity – 90% and 72%, respectively – at a cut-off score of four. This score was further substantiated in the validation group, showing a sensitivity and specificity of 76% and 80%. However, it is critical to note that this original sample, may have limited generalizability, especially to populations with lower TED prevalence, such as the one examined in the current study.

6.2.4. RESA SCREENING ACCURACY IN PRIVATE ENT SPECIALISTS AND MEDICAL AUDIOLOGISTS (MANUSCRIPT 4)

In this study, we performed dual analyses: prior to and following two major dataset adjustments. Pre-adjustment analyses revealed that medical audiologists exhibited a notable decrease in screening specificity and PPV compared to private ENT specialists during both individual and grouped RESA screenings. This could be attributed to the extensive expertise of private ENT specialists in handling diverse patient conditions and directing first-time HA users towards appropriate treatment. MAs, generally dealing with more complex cases in specialized audiological hospital departments, might not have comparable experience. However, post-adjustment analyses neutralized these differences, implying potential issues in the design and accuracy of the RiHab tool, or inadvertent symptom over-reporting by participants eager to secure free, high-quality HAs. Discrepancies in screening specificity and PPV might also stem from miscommunications concerning logistical procedures for participants with minor asymmetrical HL.

No significant differences in screening sensitivity were detected between individual ENT specialists or subspecialist groups pre- and post-adjustments, indicating the consistent performance of the RESA routine in identifying complicated HL or serious ear disorders.

As RESA offers a novel alternative to traditional PESA, its application necessitates iterative refinement based on initial findings. Notably, our study highlighted the need for a more nuanced interpretation of the RiHab questionnaire results, especially when other audiological and visual data indicate normal ear and hearing conditions. Therefore, to improve the accuracy of RESA screening among potential first-time HA users, it may be beneficial to develop new instruments for identifying risk factors and symptoms related to serious ear disorders associated with HL.

CHAPTER 7. CONCLUSIONS AND PERSPECTIVES

As global healthcare systems grapple with a myriad of formidable challenges, the necessity for pioneering and inventive solutions to shape the future of healthcare is more pronounced than ever. Demographic shifts brought about by an aging global population amplify these challenges, as they necessitate an accelerated provision of timely diagnostic and treatment strategies for an expanding demographic with complex comorbidities. These demographic trends predictably augment the prevalence of age-related HL, but environmental factors such as noise pollution may also substantively contribute to a surge in HL cases among younger adults.

Specific to the Danish hearing healthcare system, immediate concerns encompass protracted wait times, especially in the public sector. This has a profound impact on patients, especially vulnerable groups such as children, teenagers, and those with intricate and severe HL, who do not have the luxury of opting for private services. Systemic intricacies and lack of comprehensible information often deter elderly individuals from understanding their healthcare options, while the lack of standardized quality control across public and private sectors hinders the evaluation of treatment efficacy, obstructing improvements throughout the sector. Furthermore, a lack of transparency concerning potential financial conflicts of interest among healthcare professionals could erode patient trust.

In regions where access to requisite hearing healthcare services and rehabilitation programs is scarce, especially in rural or underserved areas, or where insurance coverage or reimbursement options for hearing healthcare services are insufficient, the onus of these challenges can be particularly heavy. Hence, it is imperative to approach the development of groundbreaking hearing healthcare technologies and digital practices from a comprehensive, global standpoint rather than resorting to patchwork solutions that serve a limited local benefit.

The assimilation and endorsement of new technologies into clinical practice are just as crucial as their genesis. This highlights the importance of providing thorough training and support for healthcare professionals and patients alike, as well as advancing the digital infrastructure vital for data exchange and digital interaction across sectors, regions, and countries.

Our findings suggest that RESA screening does not compromise patient safety by increasing the risk of misdiagnosis for patients with complicated HL and severe ear disorders requiring specialized assessment or treatment, compared to PESA screening conducted as per existing guidelines and current practices in Denmark. Despite the significant accuracy of RESA screening, it was apparent that diagnosing certain conditions, such as tinnitus associated with HL, could be challenging. This difficulty, however, was pertinent to both screening methods. Tinnitus, inherently complex, often presents a challenge in categorization and diagnosis. Still, RESA could effectively identify individuals with HL and associated mild to moderate bothersome

tinnitus. In instances where hearing aid (HA) treatment fails to adequately alleviate symptoms, these individuals may require additional in-person counselling and tinnitus management guidance.

A prerequisite for high RESA screening accuracy is the quality and adequacy of data. Ideally, only patients with complete data sets should qualify for RESA screening prior to HA treatment initiation. This includes a comprehensive set of audiometric measures acquired by certified hearing healthcare professionals, such as technical audiologists or audiology assistants, and high-quality images of the entire tympanic membrane without blurring or obstructive ear wax. Should these data quality requirements not be met, the patient should resort to PESA screening as per current practice before initiating treatment.

Furthermore, our study demonstrated that RESA screening did not compromise patient-perceived HA benefit and satisfaction compared to PESA screening. As digital solutions are increasingly incorporated into healthcare, they assist chronic disease management and enhance patient feedback collection for research and quality analysis. Though some of the questionnaires utilized in this study are endorsed by the Danish Ministry of Health for public healthcare use, they are not widely used in the private sector, which provides approximately half of Denmark's HA services. Tools like the IOI-HA are underutilized in public clinics, and the SSQ12 remains unused in both sectors. This lack of consistent data collection and quality control across sectors could affect future care quality. We advocate for systematic use of these data across sectors, aligned with forthcoming legislative and clinical guidelines. These guidelines will require clinics to report on HA benefits and patient satisfaction to the Danish Health Data Authority using IOI-HA, SSQ12, and other satisfaction outcome tools. This approach is congruent with evolving practices in Danish hearing healthcare, serving as a valuable model for future quality assurance and data analysis.

While integrating screening components like RiHab into the RESA screening routine could improve diagnostic efficiency and expedite treatment processes, further validation of RiHab and the RESA screening model in a larger, more representative sample is crucial. This will ensure a thorough evaluation of the model's screening accuracy and the performance and interplay of its individual components.

Digital, remote, multi-modal screening techniques such as the RESA screening routine, presented in this dissertation, hold immense potential in Denmark and all developed countries where the standard examination routine necessitates one or more in-person interactions with an ENT specialist. Our research indicates that both private and public ENT specialists within the field of medical audiology are capable of conducting RESA screening with a high degree of accuracy. RESA simplifies the treatment process, mitigates extended diagnostic and treatment delays, and potentially enhances socioeconomic resource distribution within the hearing rehabilitation healthcare system without compromising patient safety or diminishing existing examination standards.

However, these benefits are contingent on the availability of proficient hearing care assistants capable of conducting valid audiological examinations that meet legally

required quality standards, as well as capturing high-quality digital otoscopic images of the tympanic membrane. Consequently, to maintain a necessarily high level of quality standards, it is essential to define professional quality requirements and process guidelines.

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APPENDICES

Appendix A. Manuscript 1

Appendix B. Manuscript 2

Appendix C. Manuscript 3

Appendix D. Manuscript 4

ISSN (online): 2246-1302
ISBN (online): 978-87-7573-639-3

AALBORG UNIVERSITY PRESS