P.PORTO

ESCOLA SUPERIOR DE SAÚDE

M MESTRADO

MEDICAL TECHNOLOGY AND HEALTHCARE BUSINESS

The Evolving Landscape of Hearing Healthcare: Hearing Health Professional's Opinions and the Impact of Over-the-Counter Hearing Aids

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09/**2025**

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*Dissertation presented as a mandatory requirement for obtaining the degree of **Master in Medical Technology and Healthcare Business** by Escola Superior de Saúde do Instituto Politécnico do Porto.*

Abstract

Hearing loss is a pervasive global health challenge, with traditional prescription hearing aids often inaccessible due to high costs, social stigma, and limited availability. The emergence of Over-the-Counter (OTC) hearing aids aims to bridge this gap by offering more affordable and accessible solutions for individuals with mild to moderate hearing impairment. However, it's real-world effectiveness and integration into existing healthcare frameworks, mainly from the perspective of healthcare professionals, remain underexplored.

This thesis study investigated the perceptions and opinion of 177 hearing healthcare professionals (HHPs), including audiologists and hearing aid dispensers, across 17 countries through a comprehensive online survey. The research assessed their views on the effectiveness, accessibility, and potential impact of OTC hearing aids on clinical practice. Findings revealed a polarized professional sentiment: while many acknowledged the benefits of increased affordability and accessibility, a predominant negative outlook highlighted significant concerns regarding potential misdiagnosis, improper fitting, patient dissatisfaction, and the economic implications for professionals. Notably, professional background, rather than age or experience, significantly influenced these perceptions. A gender-based disparity in regulatory awareness was also observed.

In conclusion, while OTC hearing aids hold substantial promise for expanding access to hearing care, their successful implementation requires robust regulatory oversight, extensive public education on proper use and limitations, and proactive professional engagement. Hearing healthcare professionals are encouraged to adapt their service models to effectively support OTC users, thereby ensuring both broader accessibility and the maintenance of quality care standards.

Keywords: Over-the-Counter Hearing Aids, Hearing Healthcare Professionals, Hearing Loss, Accessibility, Perceptions, Audiology, Public Health

Résumé

La perte auditive constitue un défi majeur de santé publique à l'échelle mondiale, les aides auditives traditionnelles sur ordonnance demeurant souvent inaccessibles en raison de leur coût élevé, de la stigmatisation sociale et d'une disponibilité limitée. L'émergence des aides auditives en vente libre (OTC) vise à combler cette lacune en offrant des solutions plus abordables et accessibles aux personnes présentant une déficience auditive légère à modérée. Toutefois, leur efficacité dans des contextes réels et leur intégration aux systèmes de santé existants, notamment du point de vue des professionnels de santé, restent peu explorées.

Cette étude de thèse a examiné les perceptions et opinions de 177 professionnels de la santé auditive (PSA), dont des audiologistes et des distributeurs d'aides auditives, répartis dans 17 pays, au moyen d'un sondage en ligne approfondi. La recherche a évalué leurs points de vue concernant l'efficacité, l'accessibilité et l'impact potentiel des aides auditives OTC sur la pratique clinique. Les résultats ont révélé une polarisation des opinions professionnelles : si beaucoup ont reconnu les avantages d'une meilleure accessibilité financière et géographique, une majorité exprimait une perception négative, mettant en évidence des préoccupations importantes liées au risque de mauvais diagnostic, à un appareillage inadapté, à l'insatisfaction des patients et aux répercussions économiques pour les professionnels. Il est à noter que le parcours professionnel, davantage que l'âge ou l'expérience, influençait significativement ces perceptions. Une disparité entre les sexes quant à la connaissance des réglementations a également été observée.

En conclusion, bien que les aides auditives OTC présentent un potentiel important pour élargir l'accès aux soins auditifs, leur mise en œuvre réussie exige une réglementation rigoureuse, une sensibilisation publique approfondie quant à leur bon usage et à leurs limites, ainsi qu'une implication proactive des professionnels. Il est recommandé aux professionnels de santé auditive d'adapter leurs modèles de services afin de soutenir efficacement les utilisateurs d'OTC, assurant ainsi une meilleure accessibilité tout en maintenant des standards de qualité élevés.

Mots-clés: Aides auditives en vente libre, Professionnels de la santé auditive, Perte auditive, Accessibilité, Perceptions, Audiologie, Santé publique

Resumo

A perda auditiva é um desafio para a saúde global, com aparelhos auditivos de prescrição tradicional muitas vezes inacessíveis devido aos altos custos, estigma social e disponibilidade limitada. O surgimento dos aparelhos auditivos de venda livre (OTC), visam preencher essa lacuna, oferecendo soluções mais acessíveis para indivíduos com perda auditiva ligeira a moderada. No entanto, a sua eficácia no mundo real e a integração nos quadros de cuidados de saúde existentes, principalmente na perspetiva dos profissionais de saúde, continuam a ser pouco exploradas.

Este estudo investigou as perceções e opiniões de 177 profissionais de saúde auditiva (HHPs), incluindo audiologistas e audioprotesistas, em 17 países através de uma pesquisa on-line. O questionário avaliou seus pontos de vista sobre a eficácia, acessibilidade e potencial impacto dos aparelhos auditivos OTC na prática clínica. Os resultados revelaram um sentimento profissional polarizado: embora muitos reconhecessem os benefícios do aumento da acessibilidade e acessibilidade, uma perspetiva negativa predominante destacou preocupações significativas em relação a possíveis erros de diagnóstico, ajuste inadequado, insatisfação do paciente e implicações económicas para os profissionais. Notavelmente, a formação profissional, em vez da idade ou experiência, influenciou significativamente essas perceções. Foi igualmente observada uma disparidade baseada no género no conhecimento sobre regulamentação.

Em conclusão, embora os aparelhos auditivos OTC sejam promissores na expansão do acesso aos cuidados auditivos, a sua implementação bem-sucedida requer supervisão regulatória robusta, ampla educação pública sobre o uso adequado e limitações, e envolvimento profissional proativo. Os profissionais de saúde auditiva são incentivados a adaptar os seus modelos de serviços para apoiar eficazmente os utilizadores de OTC, garantindo assim uma acessibilidade mais ampla e a manutenção de padrões de cuidados de qualidade.

Palavras-chave: próteses auditivas *Over-the-Counter*, profissionais saúde auditiva, Perda auditiva, Acessibilidade, Perceções, Audiologia, Saúde Pública

Zusammenfassung

Hörverlust stellt eine weitverbreitete globale gesundheitliche Herausforderung dar. Traditionelle Hörgeräte auf Rezept sind aufgrund hoher Kosten, sozialer Stigmatisierung und begrenzter Verfügbarkeit häufig nicht zugänglich. Die Einführung von frei verkäuflichen (Over-the-Counter, OTC) Hörgeräten zielt darauf ab, diese Lücke zu schließen, indem sie kostengünstigere und leichter zugängliche Lösungen für Personen mit leichtem bis mittlerem Hörverlust bieten. Ihre Wirksamkeit in der Praxis und die Integration in bestehende Gesundheitssysteme – insbesondere aus Sicht von Fachkräften im Gesundheitswesen – sind jedoch bislang unzureichend untersucht.

Diese Masterarbeit untersuchte die Wahrnehmungen und Meinungen von 177 Hörgesundheitsfachkräften (HHPs), darunter Audiologen und Hörgeräteakustiker, aus 17 Ländern mittels einer umfassenden Online-Umfrage. Die Studie bewertete ihre Ansichten zur Wirksamkeit, Zugänglichkeit und zu möglichen Auswirkungen von OTC-Hörgeräten auf die klinische Praxis. Die Ergebnisse zeigten ein gespaltenes Meinungsbild: Viele Fachkräfte erkannten die Vorteile einer verbesserten Erschwinglichkeit und Zugänglichkeit an, jedoch überwogen negative Einschätzungen – insbesondere hinsichtlich potenzieller Fehldiagnosen, unpassender Anpassung, Unzufriedenheit der Patienten sowie wirtschaftlicher Auswirkungen für Fachkräfte. Auffällig war, dass der berufliche Hintergrund – stärker als Alter oder Erfahrung – die Wahrnehmungen maßgeblich beeinflusste. Zudem zeigte sich ein geschlechtsspezifisches Ungleichgewicht im regulatorischen Wissen.

Fazit: OTC-Hörgeräte haben ein erhebliches Potenzial, den Zugang zur Hörversorgung zu erweitern. Ihre erfolgreiche Umsetzung erfordert jedoch eine strenge regulatorische Aufsicht, umfassende Aufklärung der Öffentlichkeit über den richtigen Gebrauch und die Grenzen dieser Geräte sowie ein aktives Engagement von Fachkräften. Hörgesundheitsfachkräfte sollten ihre Versorgungsmodelle anpassen, um OTC-Nutzer effektiv zu unterstützen und so sowohl eine breitere Zugänglichkeit als auch die Aufrechterhaltung hoher Versorgungsstandards zu gewährleisten.

Schlüsselwörter: Frei verkäufliche Hörgeräte, Hörgesundheitsfachkräfte, Hörverlust, Zugänglichkeit, Wahrnehmungen, Audiologie, Öffentliche Gesundheit

Acknowledgements

The present master's thesis represents a conclusive chapter of my studies within the framework of the European Master in Medical Technology and Healthcare Business (EMMaH). This program has not only enriched my understanding across biomedical engineering, clinical innovation, and healthcare business, but also granted me the unique opportunity to live and study in multiple European countries. It has been an incredibly formative experience, both academically and personally, and one that I will always value.

I would like to express my deepest gratitude to my thesis supervisor, Dr. David Tomé, for his invaluable guidance and support throughout the development of this thesis. His time, feedback, and expertise have significantly shaped the direction and quality of this work, and I sincerely appreciate his commitment and encouragement.

I also wish to thank Mr. Alexandre Wallard, Dr. Sandra Rua, and Dr. Bernd Flick for their essential contributions during the master's coursework. Their instruction and mentoring have played a key role in building the knowledge and perspective that informed this project.

A heartfelt thank you goes to my parents, whose unwavering moral support and encouragement were instrumental throughout the thesis process. Their belief in me helped me push through challenging moments with confidence and perseverance.

Finally, I extend my gratitude to my friends, whose companionship and emotional support provided much-needed strength and balance during this demanding journey. Their presence, even in silence, meant more than words could express.

May the reading be insightful and engaging.

Abbreviations

AI: Artificial Intelligence

ASHA: American Speech–Language–Hearing Association

BIAP: Bureau International d'Audiophonologie

CIC: Completely in the Canal

DSP: Digital Signal Processing

DALY: Disability–Adjusted Life Years

dB: Decibels

EFHOH: European Federation of Hard of Hearing People

ENT: Ear–Nose–Throat Specialist

HA: Hearing Aids

HL: Hearing Loss

HCP: Hearing Care Professionals

MDR: Medical Device Regulation

OTC: Over the Counter

WHO: World Health Organization

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1. Introduction

1.1. Background on Hearing Loss

Hearing loss is defined as the partial or complete inability to perceive sound in one or both ears. It is a widespread condition affecting individuals across all age groups. It can significantly diminish quality of life by impeding communication, limiting educational and occupational opportunities, and leading to social isolation. The World Health Organization (WHO) estimates that over 5% of the global population, approximately 430 million people experience disabling hearing loss, underscoring the importance of understanding its various forms and implications. [1] [27]

1.1.1 Definition and Types of Hearing Loss

Hearing loss is broadly categorized into three primary types: conductive, sensorineural, and mixed hearing loss. Each type has distinct causes, mechanisms, and treatment approaches.

1. Conductive Hearing Loss

Conductive hearing loss occurs when sound waves are obstructed or impeded in their passage through the outer ear canal or the middle ear, preventing them from reaching the inner ear. Common causes include: [19]

- Earwax Buildup (Cerumen Impaction): Excessive accumulation of earwax can block the ear canal, hindering sound transmission.
- Otitis Media (Middle Ear Infections): Fluid accumulation due to infections can dampen the movement of the eardrum and ossicles, reducing sound conduction.
- Perforated Eardrum (Tympanic Membrane Perforation): Holes or tears in the eardrum can disrupt its ability to vibrate in response to sound waves.
- Otosclerosis: Abnormal bone growth around the stapes bone in the middle ear can fixate the bone, impairing its movement and thus sound transmission.
- Foreign Objects or Malformations: Congenital abnormalities or the presence of foreign objects in the ear canal can obstruct sound passage.

Individuals with conductive hearing loss may experience muffled hearing, a sensation of fullness in the ear, or pain if an infection is present. This type of hearing loss is often temporary and can

usually be treated effectively with medical or surgical interventions, such as removal of obstructions, treatment of infections, or surgical correction of anatomical abnormalities. [19]

2. Sensorineural Hearing Loss

Sensorineural hearing loss (SNHL) results from damage to the structures in the inner ear, particularly the cochlea, or to the auditory nerve pathways leading to the brain. This damage disrupts the conversion of sound waves into electrical signals or their transmission to the brain. [19] Common causes include:

- Aging (Presbycusis): Age-related degeneration of inner ear structures is a leading cause of SNHL in older adults.
- Noise Exposure: Prolonged exposure to loud noises can potentially damage the hair cells in the cochlea, leading to permanent hearing loss.
- Genetic Factors: Inherited conditions can predispose individuals to inner ear malformations or degenerative conditions affecting hearing.
- Ototoxic Medications: Certain drugs, such as aminoglycoside antibiotics and chemotherapy agents, can harm inner ear structures.
- Head Trauma: Injuries to the head can damage the inner ear or auditory pathways.
- Diseases and Disorders: Conditions like Ménière's disease, acoustic neuromas, and viral infections (e.g., mumps, meningitis) can lead to SNHL.

Symptoms often include difficulty understanding speech, especially in noisy environments, and a reduced ability to hear high-pitched sounds. Unlike conductive hearing loss, SNHL is typically permanent. It's management strategies traditionally focus on amplification through hearing aids or cochlear implants and employing assistive listening devices to improve communication.

3. Mixed Hearing Loss

Mixed hearing loss encompasses elements of both conductive and sensorineural hearing loss, indicating issues in the outer or middle ear as well as the inner ear or auditory nerve. For example, an individual with presbycusis (age-related SNHL) who also has an ear infection causing fluid buildup may experience mixed hearing loss. Treatment involves addressing the conductive

component medically or surgically and managing the sensorineural aspect with amplification devices. [20]

1.2. Severity Levels of Hearing Loss

Hearing loss is further classified based on severity, measured in decibels hearing level (dB HL):

- Normal (-10 to 15 dB HL): Able to hear all speech sounds clearly in both quiet and noisy environments; no noticeable hearing difficulty.
- Slight (16 to 25 dB HL): May have subtle difficulty hearing very soft or distant sounds, speech understanding is typically unaffected in quiet, but challenges may arise in noisy settings.
- Mild (26–40 dB HL): Difficulty hearing soft sounds and understanding speech in noisy environments.
- Moderate (41–55 dB HL): Struggles with hearing conversational speech without amplification.
- Moderately Severe (56–70 dB HL): Significant difficulty in hearing regular speech; higher volume levels are necessary.
- Severe (71–90 dB HL): Hearing only some loud sounds; communication without amplification is very limited.
- Profound (91+ dB HL): Minimal to no hearing; reliance on sign language or other communication methods is common. [40]

In this thesis, the classification system used is based on the American Speech-Language-Hearing Association (ASHA) guidelines. Although this is a European study, the ASHA classification has been referenced for consistency and clarity in describing severity levels. However, it's worth noting that the Spanish Society of Audiology (BIAP – Bureau International d'Audiophonologie) provides an alternative classification system commonly used across parts of Europe.

According to BIAP guidelines, hearing loss categories are slightly shifted: *Mild* ranges from 21–40 dB HL, *Moderate* from 41–70 dB HL (combining what ASHA considers moderate and moderately severe), *Severe* from 71–90 dB HL, and *Profound* is 91 dB HL and above. Additionally, BIAP includes a "Normal" hearing range from 0–20 dB HL [49], whereas ASHA defines normal hearing from 0–25 dB HL. These distinctions can influence diagnostic outcomes and

recommendations for intervention, which is important when comparing international studies or regulations.

Understanding the type and severity of hearing loss is crucial for determining appropriate interventions and management strategies, aiming to enhance communication abilities and overall quality of life for affected individuals. These types can range in severity from mild to profound, impacting individuals differently based on age, lifestyle, and underlying causes. [1] This thesis specifically focuses on over-the-counter (OTC) hearing aids, which are designed to address mild to moderate hearing loss.

1.3 Global and Regional Prevalence of Hearing Loss

Hearing loss is a significant and growing public health concern affecting individuals across all regions of the world. Recent estimates indicate that over 1.5 billion people globally experience some degree of hearing loss, with approximately 430 million requiring rehabilitation services due to disabling conditions. Projections suggest that by 2050, the global population affected by hearing loss could exceed 2.5 billion, with over 700 million requiring care [1]. These statistics highlight the urgent need for effective intervention strategies, early detection, and accessible hearing care solutions on a global scale.

In addition to global trends, regional prevalence patterns are essential to consider, particularly in high-income areas such as the European Union (EU) and the United States (USA). These regions report substantial hearing loss rates due to aging populations, increased noise exposure, and lifestyle-related factors. Understanding these regional variations is critical for tailoring public health responses, optimizing resource allocation, and evaluating the potential reach and effectiveness of solutions such as over-the-counter (OTC) hearing aids.

1.3.1. Prevalence in the European Union

In Europe, hearing impairment is notably prevalent among adults, particularly in older demographics. Approximately 19% of adults report experiencing hearing difficulties, with the prevalence increasing substantially among those over 65 years of age. This trend is attributed to age-related hearing degeneration and other contributing factors. [28][29]

1.3.2. Prevalence in the United States

The situation in the USA mirrors that of Europe, with about 15% of American adults, equating to roughly 37.5 million individuals reporting some trouble hearing. The prevalence of hearing loss increases with age, affecting approximately one-third of individuals aged 65 to 74 and nearly half of those over 75. [22]

1.4. Contributing Factors to Hearing Loss

Several factors contribute to the high prevalence of hearing loss in these regions:

1. **Aging Population:** The natural aging process leads to presbycusis, a gradual decline in hearing ability. As the proportion of elderly individuals rises, so does the incidence of age-related hearing loss.
2. **Noise Pollution:** Chronic exposure to high noise levels, both occupational and environmental, significantly contributes to hearing impairment. Occupations involving machinery, construction, and music industries pose higher risks.
3. **Chronic Health Conditions:** Diseases such as diabetes and cardiovascular disorders can adversely affect auditory function, leading to increased rates of hearing loss among individuals with these conditions.
4. **Underdiagnosis and Undertreatment:** Hearing loss often remains undiagnosed and untreated. Studies suggest that only a fraction of those who could benefit from hearing aids actually use them, due to factors like stigma, lack of awareness, and limited access to audiological services. [23]

1.5. Impact and Need for Accessible Solutions

The growing prevalence of hearing loss has profound implications on individuals and societies, including:

- **Communication Barriers:** Hearing impairment can lead to difficulties in social interactions, contributing to isolation and decreased quality of life.
- **Economic Burden:** Unaddressed hearing loss poses an annual global cost of almost US$ 1 trillion, encompassing health sector expenses, educational support, and loss of productivity. [1]

- **Health Risks:** Untreated hearing loss is associated with increased risks of depression, cognitive decline, and dementia. [24][1][30]

Addressing these challenges necessitates the development and dissemination of accessible, cost-effective hearing solutions. Over-the-Counter (OTC) hearing aids have emerged as a promising option to bridge the gap in hearing healthcare, offering individuals with mild to moderate hearing loss a more affordable and readily available means of improving their auditory function.

1.5.1. Impact of Hearing Loss on Quality of Life and Social Participation

Hearing loss, when unrecognized or untreated, can significantly disrupt various aspects of an individual's daily life. Beyond the fundamental difficulty of perceiving sound, its consequences extend into emotional, social, cognitive, and economic domains. Individuals with hearing impairment often experience frustration, reduced self-esteem, and mental fatigue due to the constant effort required to follow conversations and environmental sounds. Over time, this burden may contribute to psychological distress and a decline in overall well-being. [1]

One of the most immediate and socially limiting effects of hearing loss is the emergence of communication barriers, particularly in noisy environments or group settings. Individuals frequently struggle to follow conversations, leading to misunderstandings and repeated communication breakdowns. This ongoing challenge can result in embarrassment and a tendency to avoid social interactions altogether. As a consequence, many affected individuals gradually withdraw from family gatherings, community events, and other social settings, which can lead to social isolation. This isolation not only affects emotional health but also reduces opportunities for cognitive stimulation and meaningful social engagement, compounding the negative impact on quality of life. [1][30]

The societal stigma associated with hearing loss and the use of hearing aids can deter individuals from seeking necessary treatment. Concerns about being perceived as old or disabled may lead some to avoid acknowledging their hearing impairment, thereby delaying intervention, and exacerbating its negative effects. This reluctance can perpetuate a cycle of isolation and decline in quality of life. [34][1]

1.5.2. Psychological and Cognitive Consequences of Hearing Loss

The effects of hearing loss extend beyond social withdrawal and directly impact mental and cognitive health. Numerous studies have established a clear link between untreated hearing impairment and a higher incidence of mental health disorders, particularly depression and anxiety. The ongoing effort required to interpret speech, especially in complex auditory environments, often leads to fatigue and psychological strain. Individuals may experience frustration, embarrassment, or a sense of inadequacy in social settings, which can intensify emotional distress over time. Combined with social isolation, these emotional challenges contribute to a noticeable decline in overall psychological well-being. [1][31]

In parallel, there is growing evidence that hearing loss may accelerate cognitive decline, including an increased risk of developing dementia. Reduced auditory input may trigger neurological changes, including atrophy in brain regions responsible for sound processing and memory. Moreover, individuals with hearing impairment often engage less frequently in intellectually stimulating conversations and activities, further compounding the risk of cognitive deterioration. The intersection of auditory deprivation, social isolation, and diminished mental stimulation presents a significant concern for long-term cognitive health. [32]

1.5.3. Economic, Occupational, and Educational Impacts of Hearing Loss

Hearing loss can have far-reaching consequences on both economic productivity and educational outcomes. In the workplace, individuals with untreated hearing impairment often face communication challenges that may result in misunderstandings, reduced performance, and limited opportunities for career progression. These barriers can lead to job dissatisfaction, premature retirement, or even unemployment. The resulting decrease in earning potential, alongside increased medical and support service costs, imposes a financial burden not only on the affected individuals but also on the broader economy. [1]

Similarly, hearing loss during childhood or adolescence can interfere with language development, learning, and academic success. Difficulty in understanding teachers and peers may lead to delays in speech and language acquisition, reduced classroom participation, and lower academic performance. These developmental setbacks can hinder long-term educational achievement and limit future employment opportunities. Without timely intervention and inclusive educational

support, the cumulative impact of hearing loss on a young person's growth and potential can be profound. [33]

1.5.4. Physical Health and Safety Concerns

Hearing impairment can also pose risks to physical health and safety. Reduced ability to hear alarms, approaching vehicles, or other warning signals increases the likelihood of accidents and injuries. Additionally, the effort required to compensate for hearing loss can lead to listening fatigue, further impacting overall health and well-being. [1]

1.5.5. Importance of Early Intervention and Accessible Solutions

Addressing hearing loss promptly is crucial to mitigate its extensive impact. Early intervention with hearing aids or other assistive devices can significantly improve communication abilities, social engagement, and overall quality of life. However, access to these solutions can be limited by factors such as cost, availability of services, and personal reluctance due to stigma. The introduction and promotion of accessible, affordable hearing aid options, including over-the-counter devices, are essential steps toward reducing the burden of hearing loss on individuals and society. [1]

All in all, untreated hearing loss has far-reaching consequences that could potentially affect emotional, social, cognitive, economic, and physical aspects of life. Recognizing and addressing hearing impairment through early diagnosis and intervention is vital to enhancing the quality of life for those affected and reducing the broader societal impact.

1.6 Overview of Hearing Aids

1.6.1 Types of Hearing Aids

Hearing aids are categorized into:

1. **Prescription Hearing Aids**: Custom-fitted devices that require professional evaluation and fitting, suitable for moderate to severe hearing loss.
2. **Over-the-Counter (OTC) Hearing Aids:** Self-fitting devices for mild to moderate hearing loss, aimed at increasing accessibility and affordability. [54]

3. **Personal Sound Amplification Products (PSAPs):** Non-medical devices designed to enhance environmental sounds for recreational purposes, often misused by individuals with hearing loss. [3]
4. **Hearables**: Advanced audio devices, often incorporating hearing aid features, that also serve as wireless earbuds or smart devices. These are increasingly being used to improve hearing, communication, and health monitoring, offering more personalized control for users. [26]

Each category serves different needs, with OTC HA devices emerging as a game-changer for hearing healthcare, and we will be focusing on them for the purpose of this thesis study.

1.6.2 Technological Advancements in Hearing Aids

Recent advancements in hearing aid technology include:

1. Digital Signal Processing (DSP): Enhances sound clarity and reduces background noise.
2. Bluetooth Connectivity: Allows integration with smartphones and other devices for seamless audio streaming.
3. Artificial Intelligence (AI): In some OTCs and hearing aids, AI enables adaptive noise reduction and real-time learning for personalized experiences. [53]
4. Self-Fitting Capabilities: Empowers users to customize and self-fit their devices without professional assistance. [3]

1.6.3. Types of OTC Hearing Aids by Style

Over-the-counter (OTC) hearing aids are available in a variety of physical styles, each designed to suit different levels of hearing loss, cosmetic preferences, and comfort requirements. While the internal technology and self-fitting capabilities may vary, the external form factor plays a critical role in device selection and user satisfaction.

1. **Behind-the-Ear (BTE):** These devices rest behind the ear and are connected to an earpiece via a thin tube. BTE OTC hearing aids are popular due to their comfort, power range, and ease of handling. They are often recommended for users who prefer larger devices with longer battery life and easier controls.

2. **Receiver-in-Canal (RIC):** A variation of BTE, RIC models place the speaker directly in the ear canal, improving sound quality and reducing occlusion effects. Many modern OTC options fall into this category due to their discrete appearance and enhanced sound delivery.
3. **In-the-Ear (ITE):** These hearing aids are custom-fitted to fill the outer portion of the ear. Some OTC models offer ITE designs for those who prefer a less visible solution, although ITEs may be more limited in terms of amplification power compared to BTE styles.
4. **In-the-Canal (ITC) and Completely-in-Canal (CIC):** These are smaller and more discreet than ITEs, sitting partly or fully inside the ear canal. While these styles are cosmetically appealing, their size can make them difficult to handle and less suitable for users with dexterity challenges. They are less common among OTC models due to the need for individualized fitting and advanced miniaturization.

Most OTC hearing aids available today lean toward BTE or RIC styles, as they offer a balance between functionality, affordability, and user-controlled customization. The choice of form factor is not purely cosmetic; it influences sound quality, ease of use, and suitability for self-fitting making it a critical component in the OTC adoption process.

1.6.4. Regulatory Framework for Over-the-Counter Hearing Aids in the EU and USA

The regulatory landscape for over-the-counter (OTC) hearing aids is evolving at different places across regions, reflecting diverse healthcare priorities and infrastructure maturity. In the United States, the establishment of a formal OTC category by the FDA in 2022 marked a significant milestone, enabling adults with perceived mild to moderate hearing loss to access hearing aids without a prescription or professional fitting. This regulatory shift has improved affordability, stimulated innovation, and expanded market access, though challenges such as self-diagnosis errors, variable product quality, and limited consumer education remain.

The FDA's final rule, published on August 17, 2022, established OTC hearing aids as a new category for adults aged 18 and older with perceived mild to moderate hearing loss, which was effective from October 17, 2022 (Federal Register). This rule aims to increase access, foster innovation, and reduce costs, with specific requirements such as labelling in plain language and output limits to ensure safety. Manufacturers were required to comply with these new regulations by April 14, 2023, for devices sold directly to consumers [4].

In contrast, the European Union has not yet defined a distinct OTC category for hearing aids. Instead, hearing aids continue to be regulated under the Medical Device Regulation (MDR 2017/745), which ensures device safety and clinical performance but lacks specific provisions for self-fitting or direct-to-consumer use, creating ambiguity for manufacturers and consumers alike. Fragmentation across member states and the absence of harmonized standards pose additional barriers to widespread adoption of OTC models. Though efforts are being made, aiming to harmonize regulatory standards while addressing challenges such as user safety and product quality [3].

Looking ahead, the regulatory future of OTC hearing aids will likely center on developing tailored frameworks that ensure safety while supporting access through clearer classification, consumer guidance, and collaborative strategies across public and private stakeholders.

1.7 Efficacy of Over-the-Counter Hearing Aids

1.7.1. Comparing OTC vs. Prescription Hearing Aids

Feature	OTC Hearing Aids	Prescription Hearing Aids
Access	Available in retail stores or online	Requires audiologist evaluation
Cost	Ranges from 680€- 2550€ ($800–$3000) on high end models [35]	A typical pair can cost from 920€ up to 3,680€ ($2,000 up to $8,000) [55]
Customization	Self-fitted via apps	Custom programmed by professionals
User Suitability	Mild to moderate loss only	Any degree of hearing loss

Table 1: Comparison of OTCS and Prescription HAs

OTC hearing aids aim to bridge the treatment gap but are not ideal for everyone, particularly those with complex hearing needs or cognitive impairments.

1.7.2. Comparison with Prescription Hearing Aids

OTC hearing aids differ from prescription devices in:

1. Cost: Some OTC HAs are significantly cheaper, reducing barriers to adoption.

2. Performance: Prescription devices offer better customization and superior sound quality for complex hearing needs.
3. Accessibility: OTC HAs provide an option for individuals hesitant to seek professional care . [2]

1.7.3. User Satisfaction and Outcomes

Current studies indicate mixed results, with users appreciating the affordability of OTC devices but often struggling with self-fitting and adjustment. Satisfaction levels depend on user expectations, device quality, and the severity of hearing loss. [2]

1.7.4. Barriers to Access and Use

This study aims to better analyse the barriers from the perspective of different healthcare practitioners, however, the more common barriers to hearing aids and OTCs adoption include:

1. **Cost:** Traditional prescription hearing aids can cost 3400€ -4200€ ($4,000–$5,000) [35] per pair, which is a significant barrier, especially for those without insurance coverage. This high cost contributes to low adoption rates, as noted in a 2024 report highlighting that only one in five people who would benefit from a hearing aid actually use one [15].
2. **Stigma:** Social stigma associated with hearing loss and the visibility of hearing aids often deters usage. A 2024 article from NCOA discusses how many individuals avoid seeking treatment due to negative perceptions, with personal interviews revealing a lack of understanding about the benefits [16].
3. **Lack of Awareness:** Many individuals are unaware of the availability of hearing aids, their benefits, or where to access them. A 2022 survey indicated that older adults are more likely to get physical or eye exams than have their hearing evaluated, underscoring this gap [17].
4. **Technological Challenges:** Self-assessment and fitting processes can be daunting for non-tech-savvy users. [3]

Figure 1: Example of OTC Hearing Aids (Sennheiser All-Day Clear) Source: atkinshearingcenter

Figure 2: Example of Prescription Hearing Aids (Oticon Intent 1) Source brighthearing.co.uk

2. Literature Review

2.1. Current Research on Hearing Aid Usage in the EU and USA

Hearing loss is a significant public health issue which is affecting millions of adults in all over the world [1]. Despite advancements in hearing aid technology, adoption rates remain low, with various barriers such as cost, stigma, and lack of awareness playing major roles. The introduction of over-the-counter (OTC) hearing aids aims to address some of these issues by providing more affordable and accessible solutions.

2.1.1. Usage Rates

In the USA, recent data indicates that approximately 10% of all adults use some form of hearing assistance, but when focusing on those with hearing difficulty (specifically adults aged 45 and older), about 23% use hearing aids. This is derived from statistics showing 7.1% of adults aged 45 and overuse hearing aids, with 30.9% of the same age group reporting hearing difficulty, suggesting a usage rate of approximately 23% among those affected [13].

In the EU, estimates from the EuroTrak 2018 report suggest that around 25% of adults with hearing loss use hearing aids, based on a population of approximately 85 million adults with hearing loss and 21.25 million hearing aid users [14]. This rate varies across countries, with some nations reporting higher usage due to better healthcare access, while others lag due to cost barriers, and lack of hearing healthcare professionals.

2.1.2. Impact of OTC Hearing Aids

OTC hearing aids, following FDA regulations, aim to increase usage by offering devices priced between 170€- 2500€ ($200–$3000) [35][17], significantly lower than prescription models [3]. This affordability is expected to reduce cost barriers, potentially increasing adoption rates.

Early indications suggest that OTC hearing aids are safe and effective for mild to moderate hearing loss, with a May 2024 study by Shah et al. finding them comparably safe but slightly less efficacious than prescription aids at higher frequencies [18]. However, their long-term impact on usage rates is still being studied, with a June 2024 GAO report noting that data on access impact is limited, but cost barriers persist [8].

The potential for increased adoption is supported by recent reports, such as a February 2025 guide from Consumer Reports, which highlights brands like **Jabra®** and **Sony®** expanding options, suggesting growing market penetration [9]. This could reshape the landscape, particularly for underserved populations, though more research is needed to confirm these trends.

An emerging yet unconventional development in this space is the use of **Apple® AirPods Pro** as a form of hearing assistance. Although not marketed or cleared by regulatory bodies as medical devices, recent studies have examined their electroacoustic characteristics and speech-in-noise performance, finding that they can, to some extent, match the basic amplification capabilities of

conventional hearing aids for individuals with mild hearing loss. This has positioned AirPods Pro as a potential experimental OTC hearing aid, particularly due to features like Live Listen, which streams ambient sound directly into the earbuds via the iPhone's microphone.

Their widespread accessibility, ergonomic design, and integration into a familiar digital ecosystem make them appealing to tech-savvy consumers, especially those hesitant to pursue traditional hearing healthcare pathways. However, it is important to emphasize that AirPods are not subject to the same clinical testing, regulatory scrutiny, or labeling standards as FDA-cleared OTC hearing aids. They also lack the individualized fitting algorithms and feedback suppression typically found in dedicated devices. As such, while AirPods may offer a useful auditory enhancement tool for some users, they cannot yet be considered a reliable or regulated substitute for purpose-built OTC or prescription hearing aids. Further research and potential collaboration between consumer tech companies and hearing healthcare professionals may help bridge this emerging gap in the future.

[53]

2.1.3. Functional Benefits of Widely Available OTC Hearing Devices

With the increasing availability of over-the-counter (OTC) hearing aids, the market now features hundreds of models developed by a wide range of manufacturers. These devices vary significantly in terms of functionality, design, and user interface. This section presents a selected sample of widely available OTC hearing aids to illustrate the functional benefits they may offer to end-users. Rather than emphasizing market positioning or pricing, the focus is placed on practical usability, adaptive features, and the potential value these devices provide in supporting the daily communication needs of individuals with hearing loss.

1. Sennheiser® All-Day Clear

The *All-Day Clear* by Sennheiser® integrates clear audio processing with everyday usability for mild to moderate hearing loss. It includes automatic scene detection and Bluetooth streaming. The mobile app allows users to fine-tune their settings easily. It's built for daily functionality with a long battery life and comfort.

s

Key Functional Features

- App-based fitting and adjustment with scenario optimization
- Rechargeable design with a 16-hour battery backup

2. Jabra® Enhance Plus

Jabra's® *Enhance Plus* is a hybrid earbud-hearing aid that offers both audio enhancement as well as media streaming in a compact form. It's designed for situational hearing support and pairs only with iPhones yet. It features in-ear self-hearing tests and automatic sound tuning. Ideal for occasional and discreet use.

Key Functional Features

- Self-fitting with in-ear hearing assessment
- Dual use for amplification and media playback
- Compact design suitable for intermittent use

3. Sony® CRE-C10

Sony's® *CRE-C10* focuses on discretion with a nearly invisible CIC design. It supports self-fitting and automatic gain control for changing sound environments. Though it lacks streaming, it delivers up to 70 hours of battery life. Best suited for users wanting minimal visibility and maintenance.

Key Functional Features

- App-driven self-fitting with sound personalization
- Environmental auto-adjustment for smooth transitions
- Extended battery life for low-maintenance use

4. Eargo® 7

Eargo® 7 combines invisibility with advanced sound adaptation. It adjusts to various environments automatically using SoundAdjust+ and fits fully in the canal. Its design suits active

users, with water resistance and rechargeability. It's made for users wanting a premium, hands-off hearing solution.

Key Functional Features

- Adaptive sound tuning via their proprietary technology (SoundAdjust+).
- CIC design with water/sweat resistance.

5. Lexie B2 Plus (by Bose®)

The *Lexie B2 Plus* offers customizable hearing via a robust app, with 10 listening environments and feedback control. It has Bluetooth functionality (not for media streaming) and rechargeable batteries. Its user-friendly design ensures that adjustments and support are always within reach.

Key Functional Features

- App-controlled sound profile with environmental presets
- Rechargeable with remote support included

2.2. Relevance of the Study

Hearing loss is a widespread public health issue that impacts communication, cognitive function, and overall well-being. While traditional prescription hearing aids have been the standard solution, their adoption remains low due to cost, accessibility barriers, and stigma [1]. The introduction of Over the Counter (OTC) hearing aids aims to bridge this accessibility gap, offering a more affordable and direct solution to individuals with mild to moderate hearing loss.

The introduction of OTC hearing aids represents a major shift in the hearing healthcare market. These devices aim to provide a more affordable, accessible, and user-friendly solution specifically designed for individuals with perceived mild to moderate hearing loss. By allowing consumers to purchase hearing aids without a prescription or consultation with a licensed professional, OTC devices have the potential to close significant gaps in hearing healthcare access. [50]

However, the emergence of OTC hearing aids raises important concerns regarding their clinical effectiveness, user outcomes, and integration into standard healthcare practices. The success of this new model depends heavily on the role of hearing healthcare professionals (HHPs), including

audiologists, ENT physicians, hearing aid dispensers, and other specialists who are tasked with guiding patients, addressing device limitations, and ensuring safe and appropriate usage [5]. It is important to note that the term "*hearing aid dispenser*" is used here as a general reference. In different countries, professionals in this role may be known by varying titles such as hearing instrument specialists, hearing care professionals, or other region-specific designations, depending on national certification frameworks and professional standards.

This study is highly relevant as it explores the perspectives of hearing healthcare professionals (HHPs) on OTC hearing aids in the European Union and some other countries, where regulations, market maturity, and clinical integration differ. By gathering insights from audiologists, ENT physicians, and other specialists, this research aims to:

1. Assess the practical effectiveness of OTC hearing aids.
2. Identify challenges and opportunities in their adoption.
3. Offer recommendations for optimizing their role in hearing healthcare.

Findings from this study will contribute to both audiology practice and healthcare accessibility, addressing the evolving landscape of hearing healthcare.

2.2.1. Current Gaps in Existing Research on OTC Hearing Aids

Although several studies have evaluated the technical performance of OTC hearing aids and consumer satisfaction, significant gaps remain in understanding their broader clinical and societal impact. Current research tends to focus on device-related outcomes, such as sound quality, fitting algorithms, and usability, with limited attention to the real-world experiences of users and especially, the providers. Few studies have deeply explored how hearing healthcare professionals perceive OTC hearing aids, how these perceptions influence patient counselling, and how professional attitudes may affect adoption rates.

Additionally, existing literature often overlooks regional differences in healthcare systems, insurance models, and regulatory policies that may significantly impact the success and acceptance of OTC hearing aids across different populations. There is a pressing need for more comprehensive research that incorporates the views of audiologists, ENT specialists, and hearing aid dispensers across varied cultural and regulatory environments. By addressing these gaps, this study will provide a more holistic understanding of how OTC hearing aids are reshaping

hearing healthcare delivery, especially from the hearing healthcare practitioner's point of view. [51]

Key gaps include:

1. Long-term user outcomes.
2. Comparative effectiveness of OTV HAs with prescription devices.
3. Impact on healthcare systems [3]

2.2.2. Implications for Public Health Policy

The emergence of OTC hearing aids carries important implications for public health policy. Increasing accessibility to hearing aids through OTC channels could significantly reduce the prevalence of untreated hearing loss and its associated negative outcomes, particularly among underserved populations who face financial or geographic barriers to traditional audiological care. Policymakers must carefully balance the potential benefits of increased access with the need to ensure quality, safety, and appropriate use.

Insights from hearing healthcare professionals are critical for informing regulatory standards, best practice guidelines, and public education campaigns that support safe adoption of OTC hearing aids. Furthermore, policies aimed at integrating OTC hearing aids into broader healthcare frameworks, such as including them in insurance coverage, offering hybrid care models combining OTC access with professional support, and promoting public awareness, could amplify their positive impact on public health.

By highlighting professional perspectives and identifying areas for improvement, this study aims to contribute to evidence-based policymaking that supports more inclusive, effective, and sustainable hearing healthcare systems. [51]

2.2.3. Importance for Audiology Practice

The emergence of OTC hearing aids represents a paradigm shift in hearing healthcare, particularly in how audiologists and healthcare providers engage with patients. Traditionally, audiologists and hearing aid dispensers have been the gatekeepers of hearing aid distribution, ensuring proper diagnosis, fitting, and follow-up care [3]. However, with OTC devices now available directly to consumers, the role of audiologists is evolving.

This study is relevant to audiology practice because it examines:

1. How audiologists perceive the quality and effectiveness of OTC hearing aids.
2. The extent to which professionals are willing to integrate OTC devices into their services.

Potential new roles for audiologists, such as:

3. Offering consultations for OTC hearing aid users.
4. Providing guidance on device selection and troubleshooting.
5. Educating patients on the limitations and appropriate use of OTC hearing aids [7].

While some professionals' express concerns over self-diagnosis errors, lack of professional fitting, and patient satisfaction, others see an opportunity to expand service models by offering support and adjustments for OTC hearing aid users [8].

By studying the perspectives of hearing healthcare professionals, this research will help audiologists and hearing aid dispensers understand:

1. How to position their services in an OTC hearing aid market.
2. What professional strategies can be adopted to enhance patient outcomes.
3. How to balance accessibility with best clinical practices to ensure patients receive effective hearing care.

2.2.4. Contribution to Healthcare Accessibility

A major challenge in global hearing healthcare is limited access to hearing aids due to high costs, lack of specialists, and geographic barriers [9]. OTC hearing aids have been introduced as a potential solution to hearing healthcare disparities, particularly for:

- Low-income populations who cannot afford traditional hearing aids.
- Rural and underserved communities with limited access to audiologists and hearing aid providers.
- Aging populations who may face logistical and financial challenges in seeking professional hearing care.

This study contributes to the discussion on healthcare accessibility by investigating:

- Whether OTC hearing aids truly make hearing healthcare more affordable.
- How OTC regulations and market adoption differ in E.U and different regions of the world.
- What factors still limit accessibility, even with OTC availability.

While OTC hearing aids lower the financial barrier for many individuals, questions remain about their long-term effectiveness, user satisfaction, and safety [11]. Some critics argue that:

Without professional guidance, users may struggle to adjust settings or achieve optimal hearing benefits. OTC hearing aids may not provide enough amplification for certain individuals, leading to dissatisfaction. Misinformation and lack of education may prevent effective use of these devices [12]. By gathering insights from audiologists, and hearing aid dispensers, this research will offer the general perception of the OTC HAs market to policymakers, manufacturers, and healthcare providers.

2.3 Objectives of the Study

While OTC HAs aim to improve accessibility and affordability, their real-world effectiveness, adoption, and impact on clinical practice remain underexplored. This study seeks to assess how healthcare professionals perceive OTC hearing aids and identify challenges and opportunities for their integration into audiology and public health frameworks.

2.3.1 Primary Objectives

The primary objective of this study is to evaluate the effectiveness and accessibility of OTC hearing aids in the EU and around the world by assessing healthcare professionals' perceptions of OTC hearing aids regarding:

1. Examining accessibility factor
2. Identifying key professional concerns, such as: Self-diagnosis errors, misfitting, and lack of follow-up care and the potential role of audiologists in supporting OTC users.

This research will determine whether OTC hearing aids effectively address hearing loss while maintaining quality care standards.

2.3.2 Secondary Objectives

Beyond evaluating effectiveness and accessibility, this study also aims to:

1. Examine the role of audiologists in an OTC-driven market, including potential hybrid care models.
2. Assess the current level of knowledge and literacy on OTC hearing aids among HHPs, with a focus on analysing educational preparedness and recent curriculum developments.

3. Methodology

This study aims to assess the opinions and experiences of hearing healthcare practitioners regarding over-the-counter (OTC) hearing aids in the European Union (EU) and other regions. The research employs a cross-sectional survey design to gather data from a diverse group of professionals in the field, focusing on their views on efficacy, accessibility, and other aspects of OTC hearing aids.

3.1. Study Design

A structured online survey was utilized to collect both demographic information and opinion data from hearing healthcare practitioners. The survey consists of five demographic questions and twenty-two questions, each rated on a 5-point Likert scale from Strongly Disagree (1) to Strongly Agree (5). This design is appropriate for capturing a snapshot of current opinions and experiences, aligning with the study's objectives to assess effectiveness and accessibility.

3.1.1 Population and Sample

The target population includes hearing healthcare practitioners such as audiologists, ENT specialists, researchers, and hearing aid dispensers practicing in the EU. The sample was selected using convenience sampling through professional networks, associations, and online forums, given the practical constraints of accessing this population.

3.1.2. Survey Instrument

The survey instrument has been developed based on a comprehensive review of existing literature on OTC hearing aids, ensuring it covers all relevant aspects from the perspective of hearing healthcare practitioners. The demographic questions include Age group, Gender, Country of practice, Profession, Years of experience in hearing healthcare.

The questions, rated on a 5-point Likert scale, assess various dimensions (screenshots attached in appendix A below)

3.2. Data Collection – Descriptive Statistics

The survey was administered online using Google Forms or to facilitate easy distribution and data collection. The survey link was distributed through email lists of professional associations, and LinkedIn posts. Participants were provided with an introductory statement explaining the study's purpose, their rights as participants (e.g., anonymity, voluntary participation), and how their data will be used (Appendix A). Completion of the survey will be considered implied consent, ensuring ethical compliance of data processing with the General Data Protection Regulation, hereinafter referred to as GDPR, EU 2016/679). Data was checked for completeness upon collection, and any incomplete responses were excluded from the analysis to maintain data quality.

The survey collected a total of **177 responses** from various countries, including France, Belgium, Pakistan, and others, as detailed below.

3.2.1. Age Distribution of Participants

1. What is your age group?		
	N	%
18 – 22 years old	12	6,8%
23 – 28 years old	30	16,9%
29 – 34 years old	34	19,2%
35 – 40 years old	33	18,6%
41 – 50 years old	34	19,2%
51 – 60 years old	25	14,1%
61 – 70 years old	6	3,4%
71 – 75 years old	3	1,7%

Table 2: Age Distribution of Participants

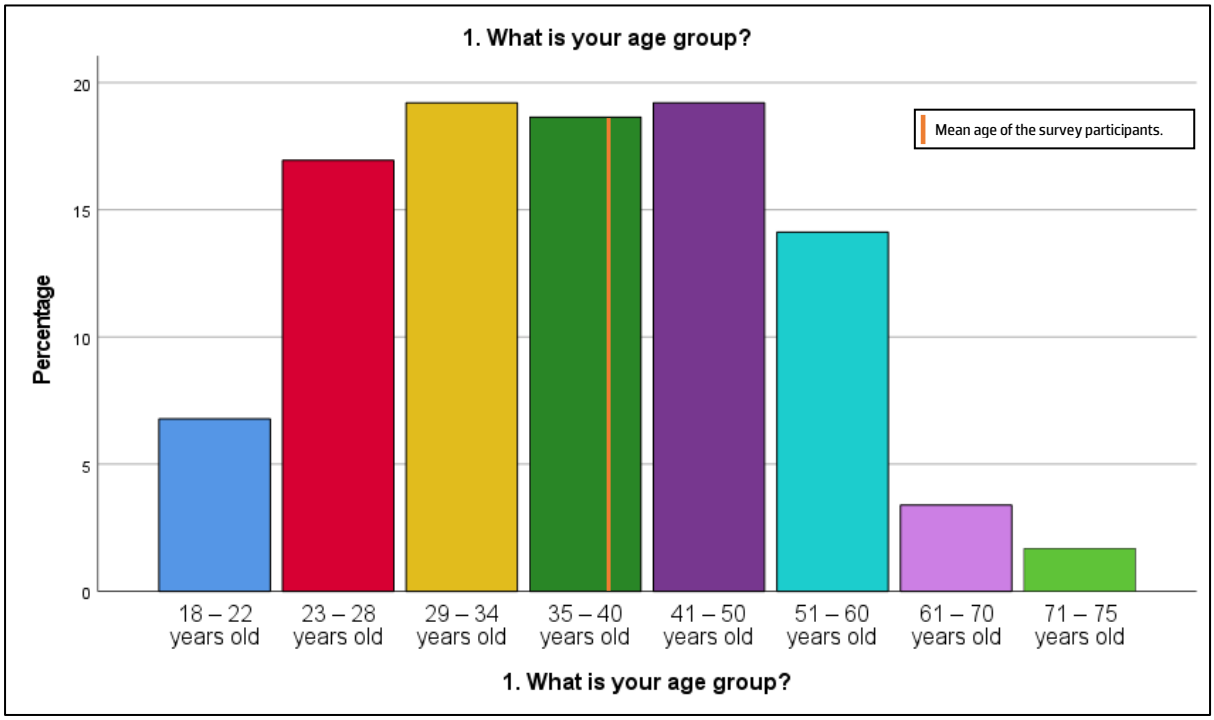

Figure 3: Age Distribution of Participants

The mean age of the survey participants was found to be 38.25 (highlighted in the age group of 35-40 years old), and the standard deviation was 12.5. The survey question for determining the age group reveals a distribution where 12 participants (6.8%) are aged 18–22 years, 30 (16.9%) are 23–28 years, 34 (19.2%) are 29–34 years, 33 (18.6%) are 35–40 years, 34 (19.2%) are 41–50 years, 25 (14.1%) are 51–60 years, 6 (3.4%) are 61–70 years, and 3 (1.7%) are 71–75 years, with peaks in the 29–34 and 41–50 age groups suggesting a strong representation of mid-career professionals likely balancing experience and adaptability to OTC hearing aids, while the some of the 23.7% younger cohort (18–28 years) brought innovation-friendly perspectives, and the limited 5.1% older cohort (61–75 years) highlighted underrepresent conservative views, providing critical context for interpreting the survey's sentiment on OTC impacts as mentioned in section 3.3.

3.2.2. Gender Distribution of Participants

2. What is your gender?		
	N	%
Female	92	52,0%
Male	84	47,5%
Prefer not to say	1	0,6%

Table 3: Gender Distribution of Participants

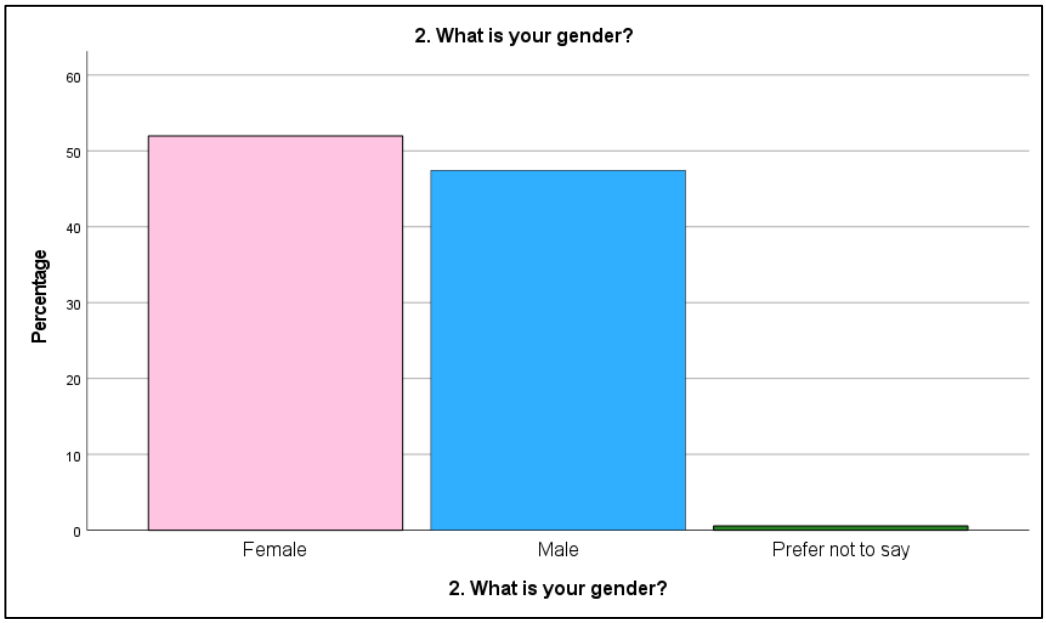

Figure 4: Gender Distribution of Participants

The gender distribution, as shown in the chart, reveals a nearly balanced representation, with 52% of Participants identifying as female, 47.5% as male, and a minimal 0.6% preferring not to say. This gender distribution highlights a relatively balanced representation, with a slight predominance of female professionals within the field of hearing healthcare.

3.2.3. Country of Practice Among Hearing Healthcare Practitioners

3. In which country do you practice as a Hearing Healthcare Practitioner?		
	N	%
Belgium	17	9,6%
Cyprus	1	0,6%
Denmark	1	0,6%
England	1	0,6%
France	52	29,4%
Germany	5	2,8%
Italy	1	0,6%
Kuwait	2	1,1%
Pakistan	33	18,6%
Poland	1	0,6%
Portugal	25	14,1%
Spain	7	4,0%
Sweden	2	1,1%
Switzerland	3	1,7%
Turkey	22	12,4%
U. K	2	1,1%
U.S. A	2	1,1%
TOTAL:	**177**	**100%**

Table 4: Country of Practice Among Hearing Healthcare Practitioners

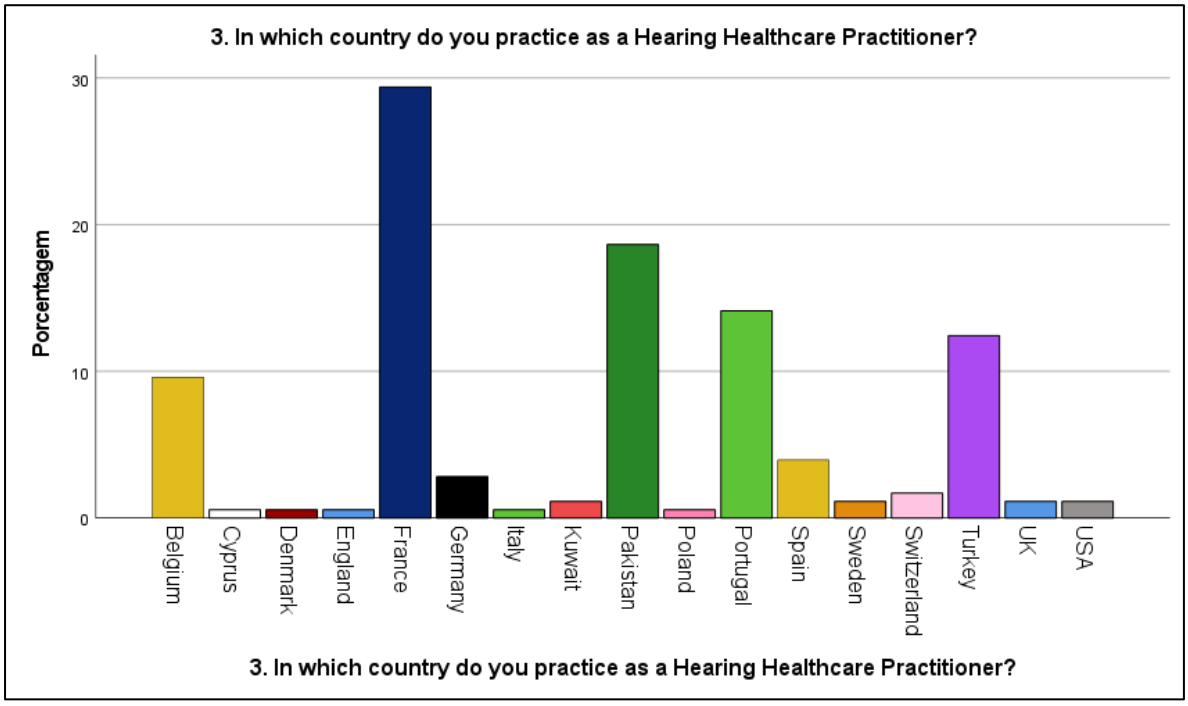

Figure 5: Country of Practice Among Hearing Healthcare Practitioners

The histogram and table illustrate the distribution of Hearing Healthcare Practitioners across various countries, with France having the most surveyors at 52 practitioners (29.4%), followed by Pakistan with 32 (18.1%), and Portugal with 25 (14.1%). Germany and Belgium have 14 (7.9%) and 17 (9.6%) practitioners, respectively, while countries like Cyprus, Denmark, Italy, Kuwait, Poland, Spain, Sweden, Switzerland, Turkey, the UK, and the USA each have fewer than 5 practitioners, with percentages ranging from 0.6% to 1.7%, showing a more scattered presence. While these figures reflect the geographic diversity of our respondents, we did not further analyse the differing national opinions or regulatory stances on OTC hearing aids. This decision was due to the complexity of varying national regulations, as well as insufficient data from some countries to allow for meaningful or accurate cross-country comparisons.

3.2.4. Professions of Participants

4. What is your profession?		
	N	%
Audiologist	116	65,5%
Hearing Aid dispenser	49	27,7%
ENT	4	2,3%
Researcher	8	4,5%

Table 5: Professions of Participants

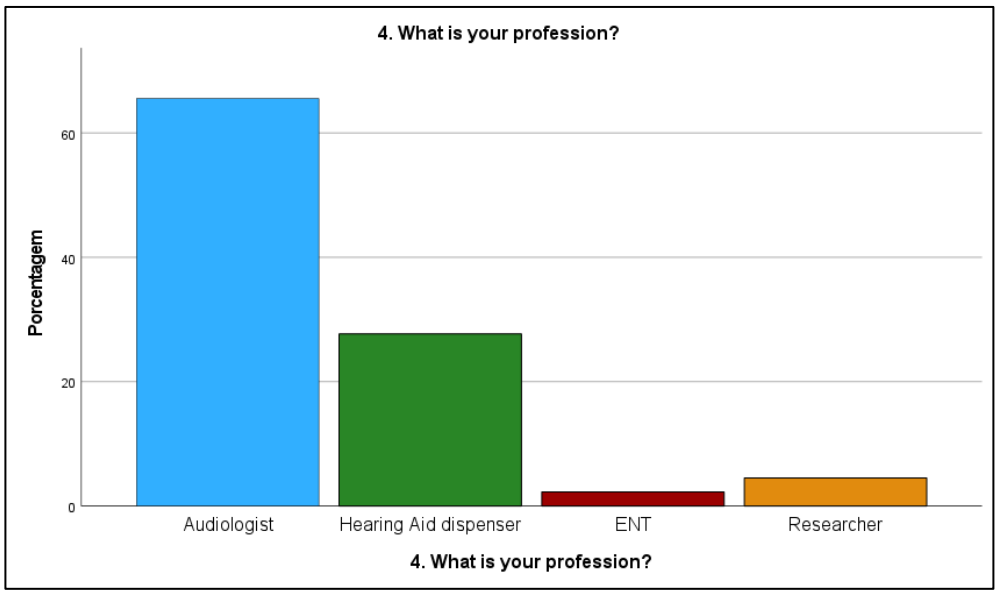

Figure 6: Professions of Participants

The histogram and table display the distribution of professions among Participants, with Audiologists making up the largest group at 116 individuals (65.5%). Hearing Aid Dispensers follow as the second-largest group with 49 individuals (27.7%), ENT professionals and Researchers are less common, with 4 (2.3%) and 8 (4.5%) individuals respectively. This data highlights a predominance of Audiologists and Hearing Aid Dispensers in this survey. Hence, only these two professions were used for Inferential analysis.

3.2.5. Experience range of Participants

5. How many years have you been working in hearing healthcare?		
	N	%
0 – 5 years	43	24,3%
11 – 15 years	31	17,5%
16 – 20 years	21	11,9%
21 – 25 years	22	12,4%
26 – 30 years	11	6,2%
31 – 40 years	14	7,9%
6 – 10 years	33	18,6%
more than 40 years	2	1,1%

Table 6: Experience range of Participants

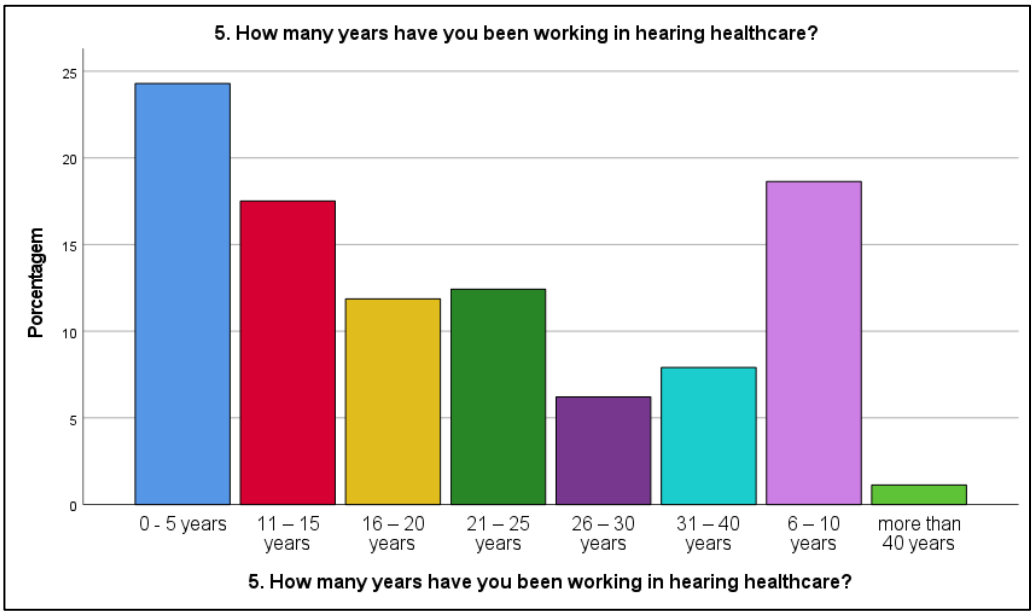

Figure 7: Experience range of Participants

The histogram and table illustrate the years of experience of professionals working in hearing healthcare, showing a varied distribution. The largest group of 43 individuals (24.3%), has 0–5

years of experience, indicating a significant number of newer practitioners in the survey. The second-largest group, with 33 individuals (18.6%), has 6–10 years of experience, followed by 31 individuals (17.5%) with 11–15 years. Those with 16–20 years and 21–25 years of experience number 21 (11.9%) and 22 (12.4%) respectively, while 11 individuals (6.2%) have 26–30 years, and 14 (7.9%) have 31–40 years. Only 2 individuals (1.1%) have more than 40 years of experience. This distribution highlights a mix of newer and mid-career professionals, with fewer highly experienced individuals.

3.3. Analysis of Hearing Healthcare Professionals' Perspectives on the Impact of OTC Hearing Aids

3.3.1. Quantitative Overview of Professional Sentiment

The open-ended survey question no. 23, "In what ways do you think OTC hearing aids will impact the hearing healthcare market? Positively or negatively?" received 92 responses from hearing healthcare professionals, primarily audiologists. Analysis of these responses reveals a spectrum of sentiments: 24 responses (26%) express a positive outlook, 46 (50%) are negative, 13 (14%) present a mixed perspective acknowledging both positive and negative impacts, and 9 (10%) are neutral or unclear. The predominance of negative sentiment underscores significant professional apprehension, while the notable proportion of positive and mixed responses suggests recognition of potential benefits under specific conditions.

3.3.2. Positive Perspectives

Professionals with a positive outlook highlight the potential of OTC hearing aids to enhance accessibility and affordability, lowering financial and logistical barriers for individuals, particularly those with mild hearing loss. One respondent noted, *"Because of its low prices, big brands will be affected negatively. But most people having hearing loss will get a chance to buy hearing aids,"* emphasizing increased access. OTC aids are also seen as reducing stigma through modern designs, with one stating, *"OTC hearing aids may result in earlier uptake of hearing aids by some users, as they are more likely to look less like hearing aids (example: Apple AirPods ®)."* Additionally, OTC aids are viewed as raising awareness, with a respondent noting, *"I believe that*

OTC hearing aids will not only encourage more people to take care of their hearing health, but also lead to a greater appreciation for professional services."

3.3.3. Negative Perspectives on OTC Hearing Aids

Negative Participants express concerns about the lack of professional involvement, risking misdiagnosis, poor fitting, and overamplification, especially for severe hearing loss or paediatric cases. One professional warned, *"Without proper fitting and adjustment by an audiologist, OTC hearing aids may pose risks of overamplification, particularly for individuals with severe or profound hearing loss."* Patient dissatisfaction is a key issue, with one stating, *"Easy access for everyone for OTC hearing aid leads to patient dissatisfaction and hopelessness."* Economically, OTC aids threaten audiologist income and major brands, as one noted, *"Positive for customers, negative for us."* There is also apprehension about compromised rehabilitation, with a respondent cautioning, *"Negatively, because we know that if we leave the hard of hearing to self-management, they will move towards comfort (under-correction) but in no case towards performance or rehabilitation."*

3.3.4. Mixed Perspectives: Balancing Opportunities and Risks

Professionals with mixed views acknowledge accessibility benefits but stress the need for safeguards. One stated, *"The introduction of OTC hearing aids will improve accessibility and affordability for individuals, expanding treatment options. However, the absence of professional audiological evaluation raises concerns,"* highlighting the safety-accessibility tension. Regulation and education are critical, with one noting, *"Positively: OTC hearing aids will positively disrupt the hearing healthcare market by making it more inclusive, affordable, and accessible, but without strong education and regulation, they also risk undermining quality of care."*

3.3.5. France's Unique Market Context

A recurring theme in 12 responses is the limited relevance of OTC hearing aids in France due to the "100% santé" program, which, since 2021, has provided fully reimbursed hearing aids. This policy diminishes the financial appeal of OTC aids, as one respondent explained, *"In France, the 100% health device completely erases the little advantage of OTCs."* The requirement for medical prescriptions and comprehensive insurance coverage further reduces OTC necessity, with another stating, *"In France, the appeal of OTC hearing aids is limited, with access to 100% healthcare devices fully reimbursed. Their only limitation is the need for a medical prescription."* However, one respondent suggested a niche role for OTC aids in France, noting, *"OTC could be positive for people who can't move or live far from an audiologist,"* indicating potential benefits for geographically isolated patients. This country-specific insight underscores the influence of local healthcare systems on OTC adoption.

3.3.6. The Hearing Aid and OTC Market Landscape in Pakistan

Pakistan, contributing the second-highest number of survey responses, presents a distinct context marked by limited public hearing healthcare infrastructure, low awareness, and out-of-pocket payment models. Hearing aids are predominantly accessed through private providers, with minimal insurance coverage and scarce audiological services in rural areas. Currently, there is no formal regulation of OTC hearing aids in Pakistan, creating both potential and risk. While OTC devices could improve access for underserved populations, especially those with mild hearing loss, the absence of regulatory oversight and professional involvement raises concerns about misdiagnosis, improper fitting, and poor long-term outcomes. Respondents from Pakistan reflected this tension some welcoming OTCs as a necessary, cost-effective alternative, others warning of the risks posed by unregulated use and limited public education.

3.3.7. Innovative and Strategic Perspectives

Professionals suggest OTC aids could serve as a transitional tool for hesitant patients, encouraging engagement with hearing health. They propose audiologists take a leadership role in managing OTC devices to combine accessibility with expertise. Smartphone integration is seen as a future direction, enhancing OTC functionality. Some critique current audiology practices,

suggesting OTC aids could address unmet patient needs, particularly for those with non-standard requirements.

3.3.8. Implications and Recommendations

The survey reveals polarized views, with negative sentiment driven by safety and professional devaluation concerns, yet positive and mixed perspectives highlight accessibility opportunities. Regulations should mandate warnings for severe cases to protect patients. Patient education is essential to clarify OTC limitations and benefits. Audiologists should offer OTC fitting services and emphasize rehabilitation expertise to adapt to market changes. In France, professionals should leverage reimbursed aids while exploring OTC for underserved populations. Globally, smartphone integration and hybrid care models could enhance OTC effectiveness, aligning with consumer and professional needs.

4. Results

4.1 Descriptive Statistics

This section presents the descriptive statistics of the responses collected from the 22 Likert-scale items in the survey. These statistics include measures of central tendency (mean), variability (standard deviation), and response range, providing an overview of participants' general attitudes, perceptions, and agreement levels with each statement.

The study involved a total of **177 participants**, of whom 52% identified as female (n = 61) and 47.5% as male (n = 56)ins. Participants represented a diverse range of nationalities, coming from 17 different countries, namely: Belgium, Cyprus, Denmark, England, France, Germany, Italy, Poland, Portugal, Spain, Sweden, Switzerland, Turkey, and the United Kingdom (UK) from **Europe, Kuwait** from **Middle East**, Pakistan from **South Asia**, and United States of America (USA) from **North America.**

This diverse demographic background ensured a broad range of viewpoints, enriching the overall data quality and enhancing the generalizability of the findings.

Each of the 22 survey items was rated on a 5-point Likert scale, typically ranging from 1 (Strongly Disagree) to 5 (Strongly Agree). These descriptive statistics highlight the general trend of responses, the degree of consensus among participants, and any variations in opinion across different items.

1. To what extent do you agree with the following statement: "I am familiar with OTC hearing aids."

	N	%
Strongly disagree	26	14,7%
Disagree	41	23,2%
Neutral	46	26,0%
Agree	44	24,9%
Strongly Agree	20	11,3%

Mean: 2.95

Standard Deviation: 1.235

2. To what extent do you agree with the following statement: "I have encountered patients using OTC hearing aids in my practice."

	N	%
Strongly disagree	61	34,5%
Disagree	45	25,4%
Neutral	19	10,7%
Agree	43	24,3%
Strongly Agree	9	5,1%

Mean: 2.4011

Standard Deviation: 1.31538

3. All degrees of hearing loss can be rehabilitated by OTC hearing aids.

	N	%
Strongly disagree	125	70,6%
Disagree	35	19,8%
Neutral	12	6,8%
Agree	5	2,8%

Mean: 1.4181

Standard Deviation: 0.74262

4. The price of OTC hearing aids is affordable for consumers.

	N	%
Strongly disagree	16	9,0%
Disagree	27	15,3%
Neutral	59	33,3%
Agree	67	37,9%
Strongly Agree	8	4,5%

Mean: 3.1356

Standard Deviation: 1.03008

5. Affordability is a primary benefit of OTC hearing aids.

	N	%
Strongly disagree	21	11,9%
Disagree	25	14,1%
Neutral	42	23,7%
Agree	75	42,4%
Strongly Agree	14	7,9%

Mean: 3.2304

Standard Deviation: 1.14980

6. More expensive a hearing aid, the more successful the rehabilitation process.

	N	%
Strongly disagree	28	15,8%
Disagree	64	36,2%
Neutral	35	19,8%
Agree	40	22,6%
Strongly Agree	10	5,6%

Mean: 2.6610

Standard Deviation: 1.15714

7. Accessibility is a primary benefit of OTC hearing aids.

	N	%
Strongly disagree	9	5,1%
Disagree	25	14,1%
Neutral	47	26,6%
Agree	83	46,9%
Strongly Agree	13	7,3%

Mean: 3.3729

Standard Deviation: 0.98682

8. Independence and self-fitting is a primary benefit of OTC hearing aids.

	N	%
Strongly disagree	28	15,8%
Disagree	39	22,0%
Neutral	45	25,4%
Agree	54	30,5%
Strongly Agree	11	6,2%

Mean: 2.8927

Standard Deviation: 1.18456

9. OTC hearing aids will increase the risk of misdiagnosis and bad fitting/rehabilitation.

	N	%
Strongly disagree	3	1,7%
Disagree	10	5,6%
Neutral	22	12,4%
Agree	72	40,7%
Strongly Agree	70	39,5%

Mean: 4.1073

Standard Deviation: 0.94436

10. OTC hearing aids will encourage more individuals with hearing loss to seek treatment earlier.

	N	%
Strongly disagree	11	6,2%
Disagree	28	15,8%
Neutral	55	31,1%
Agree	71	40,1%
Strongly Agree	12	6,8%

Mean: 3.2542

Standard Deviation: 1.01006

11. The absence of professional fitting for over-the-counter (OTC) hearing aids could negatively impact the consumer experience.

	N	%
Strongly disagree	1	0,6%
Disagree	6	3,4%
Neutral	23	13,0%
Agree	83	46,9%
Strongly Agree	64	36,2%

Mean: 4.41469

Standard Deviation: 0.81248

12. Stricter regulations are needed for OTC hearing aids.

	N	%
Strongly disagree	1	0,6%
Disagree	3	1,7%
Neutral	31	17,5%
Agree	67	37,9%
Strongly Agree	75	42,4%

Mean: 4.1977

Standard Deviation: 0.82599

13. I am adequately informed about the regulations surrounding OTC hearing aids in my country.

	N	%
Strongly disagree	28	15,8%
Disagree	48	27,1%
Neutral	37	20,9%
Agree	44	24,9%
Strongly Agree	20	11,3%

Mean: 2.8870

Standard Deviation: 1.26523

14. OTC hearing aids are a step forward in hearing healthcare and will benefit a lot of people.

	N	%
Strongly disagree	23	13,0%
Disagree	46	26,0%
Neutral	66	37,3%
Agree	29	16,4%
Strongly Agree	13	7,3%

Mean: 2.7910

Standard Deviation: 1.09562

15. I am interested in assisting patients with the selection of OTC hearing aids.

	N	%
Strongly disagree	38	21,5%
Disagree	48	27,1%
Neutral	43	24,3%
Agree	36	20,3%
Strongly Agree	12	6,8%

Mean: 2.6384

Standard Deviation: 1.21744

16. I am interested in selling or recommending OTC hearing aids in my practice.

	N	%
Strongly disagree	52	29,4%
Disagree	60	33,9%
Neutral	35	19,8%
Agree	25	14,1%
Strongly Agree	5	2,8%

Mean: 2.2712

Standard Deviation: 1.11545

17. I think that OTC hearing aids may discredit/devalue hearing rehabilitation itself.

	N	%
Strongly disagree	4	2,3%
Disagree	25	14,1%
Neutral	37	20,9%
Agree	68	38,4%
Strongly Agree	43	24,3%

Mean: 3.6836

Standard Deviation: 1.06142

18. OTC hearing aids will significantly change the hearing healthcare market.

	N	%
Strongly disagree	4	2,3%
Disagree	48	27,1%
Neutral	46	26,0%
Agree	66	37,3%
Strongly Agree	13	7,3%

Mean: 3.2034

Standard Deviation: 0.99624

19. OTC hearing aids will decrease the number of hearing healthcare professionals.

	N	%
Strongly disagree	20	11,3%
Disagree	68	38,4%
Neutral	52	29,4%
Agree	35	19,8%
Strongly Agree	2	1,1%

Mean: 2.6102

Standard Deviation: 0.96561

20. Consumers need more education on the proper use and limitations of OTC hearing aids.

	N	%
Strongly disagree	1	0,6%
Disagree	4	2,3%
Neutral	11	6,2%
Agree	77	43,5%
Strongly Agree	84	47,5%

Mean: 4.3503

Standard Deviation: 0.74728

21. OTC hearing aids could lead to worsening untreated hearing loss due to misdiagnosis or improper use.

	N	%
Strongly disagree	2	1,1%
Disagree	15	8,5%
Neutral	28	15,8%
Agree	69	39,0%
Strongly Agree	63	35,6%

Mean: 3.9944

Standard Deviation: 0.97990

22.OTC hearing aids should come with a mandatory follow-up consultation with a professional.

	N	%
Strongly disagree	1	0,6%
Disagree	13	7,3%
Neutral	31	17,5%
Agree	83	46,9%
Strongly Agree	49	27,7%

Mean: 3.9379

Standard Deviation: 0.892

4.2. Inferential Statistics

4.2.1. T- Test based of Profession Statistics

The following table presents a comparison between the two dominant professional groups represented in the dataset. Due to the limited number of responses received from researchers and ENT specialists, their data have been excluded from the analysis. The majority of responses were provided by audiologists and hearing aid dispensers; therefore, the analysis will focus exclusively on these two professional groups to ensure greater accuracy and reliability in the findings.

The purpose of conducting this T-test is to evaluate whether there is a statistically significant difference in how these two professions responded to key questions in the survey, thereby helping to identify which group held a stronger opinion on specific items.

For example, regarding the first question in the survey, Audiologists reported a mean score of **3.17**, which falls near the neutral point on the Likert scale. In contrast, Hearing Aid Dispensers had a mean score of **2.24**, indicating a tendency toward disagreement. This noticeable difference in mean values suggests a slight variation in professional perspective. To confirm whether this difference is statistically significant and not due to random variation, a bilateral T-test was conducted. As shown in the second table, the resulting p-value for this comparison is less than **0.001**, which falls well below the commonly accepted threshold of **0.05**. This confirms that the difference in responses between the two professions is statistically significant.

While there were differences in the strength of agreement or disagreement between audiologists and hearing aid dispensers, both groups exhibited similar response patterns across the survey items.

Figure 8: Group Statistics showing Mean Difference in survey answers of Professionals.

Group Statistics

	4. What is your profession?	N	Mean	Std. Deviation	Std. Error of Mean
1. To what extent do you agree with the following statement: "I am familiar with OTC hearing aids."	Audiologist	116	3,17	1,211	,112
	Hearing Aid dispenser	49	2,24	1,071	,153
2. To what extent do you agree with the following statement: "I have encountered patients using OTC hearing aids in my practice."	Audiologist	116	2,3879	1,33691	,12413
	Hearing Aid dispenser	49	2,4082	1,24027	,17718
3. All degrees of hearing loss can be rehabilitated by OTC hearing aids.	Audiologist	116	1,5259	,80716	,07494
	Hearing Aid dispenser	49	1,2245	,58685	,08384
4. The price of OTC hearing aids is affordable for consumers.	Audiologist	116	3,3103	,92702	,08607
	Hearing Aid dispenser	49	2,7551	1,12788	,16113
5. Affordability is a primary benefit of OTC hearing aids.	Audiologist	116	3,3966	1,02897	,09554
	Hearing Aid dispenser	49	2,6735	1,29724	,18532
6. More expensive a hearing aid, the more successful the rehabilitation process.	Audiologist	116	2,6897	1,21879	,11316
	Hearing Aid dispenser	49	2,7959	1,02020	,14574
7. Accessibility is a primary benefit of OTC hearing aids.	Audiologist	116	3,4310	,96210	,08933
	Hearing Aid dispenser	49	3,1429	1,02062	,14580
8. Independence and self-fitting is a primary benefit of OTC hearing aids.	Audiologist	116	2,9828	1,15708	,10743
	Hearing Aid dispenser	49	2,5306	1,20937	,17277
9. OTC hearing aids will increase the risk of misdiagnosis and bad fitting/rehabilitation.	Audiologist	116	4,0345	1,00374	,09320
	Hearing Aid dispenser	49	4,3878	,73076	,10439
10. OTC hearing aids will encourage more individuals with hearing loss to seek treatment earlier.	Audiologist	116	3,2414	,94750	,08797
	Hearing Aid dispenser	49	3,1224	1,14805	,16401
11. The absence of professional fitting for over-the-counter (OTC) hearing aids could negatively impact the consumer experience.	Audiologist	116	4,1466	,82625	,07672
	Hearing Aid dispenser	49	4,2245	,79753	,11393
12. Stricter regulations are needed for OTC hearing aids.	Audiologist	116	4,2500	,77880	,07231
	Hearing Aid dispenser	49	4,1837	,83350	,11907
13. I am adequately informed about the regulations surrounding OTC hearing aids in my country.	Audiologist	116	2,7069	1,20879	,11223
	Hearing Aid dispenser	49	3,3469	1,28373	,18339
14. OTC hearing aids are a step forward in hearing healthcare and will benefit a lot of people.	Audiologist	116	2,8276	1,08968	,10117
	Hearing Aid dispenser	49	2,4490	,98025	,14004
15. I am interested in assisting patients with the selection of OTC hearing aids.	Audiologist	116	2,7500	1,19328	,11079
	Hearing Aid dispenser	49	2,1633	1,16094	,16585
16. I am interested in selling or recommending OTC hearing aids in my practice.	Audiologist	116	2,3362	1,08703	,10093
	Hearing Aid dispenser	49	2,0408	1,13577	,16225
17. I think that OTC hearing aids may discredit/devalue hearing rehabilitation itself.	Audiologist	116	3,6724	1,02809	,09546
	Hearing Aid dispenser	49	3,8163	1,09304	,15615
18. OTC hearing aids will significantly change the hearing healthcare market.	Audiologist	116	3,3190	,95643	,08880
	Hearing Aid dispenser	49	2,7959	1,04042	,14863
19. OTC hearing aids will decrease the number of hearing healthcare professionals.	Audiologist	116	2,7155	,95831	,08898
	Hearing Aid dispenser	49	2,4286	1,00000	,14286
20. Consumers need more education on the proper use and limitations of OTC hearing aids.	Audiologist	116	4,4224	,68716	,06380
	Hearing Aid dispenser	49	4,2041	,88928	,12704
21. OTC hearing aids could lead to worsening untreated hearing loss due to misdiagnosis or improper use.	Audiologist	116	4,0948	,86455	,08027
	Hearing Aid dispenser	49	3,9592	1,09847	,15692
22.OTC hearing aids should come with a mandatory follow-up consultation with a professional.	Audiologist	116	4,0862	,83997	,07799
	Hearing Aid dispenser	49	3,6531	,99060	,14151

For inferential analysis regarding the profession, and Levene's test for equality of variances was used, the equality of variances were obtained, independent T-Test for quality of independent samples was performed, considering and alpha of 0.05, differences bettween groups were obtained on Q1, p(<0.001) as attached in appendix (table 2.0). Following are the questions with significant p values: **Q1**(p<0.001), **Q3**(p=0.008), **Q4**(p=0.001), **Q5**(p<0.001), **Q13**(p=0.003), **Q14**(p=0.004), and **Q18**(p=0.002).

4.2.2. T- Test based of Gender Statistics

In addition to professional comparisons, an independent samples T-test was conducted to examine potential differences in survey responses between male and female participants. This analysis aimed to determine whether gender had a statistically significant influence on the survey responses.

Upon reviewing the bilateral p-values for each question, it was observed that only Question 13 yielded a statistically significant result (p = 0.012), indicating a gender-based difference in response. The item in question stated: *"I am adequately informed about the regulations surrounding OTC hearing aids in my country."*. For this item, the mean response among females was **2.66**, whereas the mean among males was **3.14**. This suggests that male participants demonstrated a higher level of confidence regarding their knowledge of national regulations on over-the-counter (OTC) hearing aids compared to their female counterparts.

No other questions in the survey showed significant differences based on gender (p > 0.05), indicating general alignment in perspectives between male and female Participants across the remaining items.

4.2.3. Age Correlation

The following graph presents the results of a Spearman's rho correlation analysis conducted to examine the relationship between participants' age and their responses to the questionnaire items. Spearman's rho was selected as the appropriate non-parametric test due to the ordinal nature of the data and the potential for non-linear relationships.

The correlation coefficients displayed in the graph reflect the strength and direction of association between age and individual survey items. Values closer to +1 or -1 indicate a stronger positive or negative correlation, respectively, while values near 0 suggest little to no relationship.

Statistical significance is indicated using asterisks: coefficients marked with two asterisks (**) denote significance at the 0.01 level, implying a 99% confidence that the correlation is not due to chance. Coefficients with a single asterisk (*) are significant at the 0.05 level, indicating a 95% confidence level.

For ease of interpretation, the significant values have also been highlighted in **bold** within the graph, allowing for quick identification of notable relationships.

Spearman's rho		Age Category
Category	Correlation Coefficient	1.000
1. To what extent do you agree with the following statement: "I am familiar with OTC hearing aids."	Correlation Coefficient	-0.069
	Sig. (2 extremities)	0.359
2. To what extent do you agree with the following statement: "I have encountered patients using OTC hearing aids in my practice."	Correlation Coefficient	0.015
	Sig. (2 extremities)	0.839
3. All degrees of hearing loss can be rehabilitated by OTC hearing aids.	Correlation Coefficient	**-,253****
	Sig. (2 extremities)	0.001
4. The price of OTC hearing aids is affordable for consumers.	Correlation Coefficient	**-,262****
	Sig. (2 extremities)	0.000
5. Affordability is a primary benefit of OTC hearing aids.	Correlation Coefficient	**-,237****
	Sig. (2 extremities)	0.002
6. More expensive a hearing aid, the more successful the rehabilitation process.	Correlation Coefficient	0.051
	Sig. (2 extremities)	0.497
7. Accessibility is a primary benefit of OTC hearing aids.	Correlation Coefficient	-0.020
	Sig. (2 extremities)	0.787
8. Independence and self-fitting is a primary benefit of OTC hearing aids.	Correlation Coefficient	**-,188***
	Sig. (2 extremities)	0.012
9. OTC hearing aids will increase the risk of misdiagnosis and bad fitting/rehabilitation.	Correlation Coefficient	0.022
	Sig. (2 extremities)	0.770
10. OTC hearing aids will encourage more individuals with hearing loss to seek treatment earlier.	Correlation Coefficient	0.120
	Sig. (2 extremities)	0.112
11. The absence of professional fitting for over-the-counter (OTC) hearing aids could negatively impact the consumer experience.	Correlation Coefficient	-0.103
	Sig. (2 extremities)	0.172
12. Stricter regulations are needed for OTC hearing aids.	Correlation Coefficient	-0.028
	Sig. (2 extremities)	0.715

13. I am adequately informed about the regulations surrounding OTC hearing aids in my country.	Correlation Coefficient	**,198****
	Sig. (2 extremities)	0.008
14. OTC hearing aids are a step forward in hearing healthcare and will benefit a lot of people.	Correlation Coefficient	-0.013
	Sig. (2 extremities)	0.866
15. I am interested in assisting patients with the selection of OTC hearing aids.	Correlation Coefficient	-0.099
	Sig. (2 extremities)	0.191
16. I am interested in selling or recommending OTC hearing aids in my practice.	Correlation Coefficient	-0.070
	Sig. (2 extremities)	0.357
17. I think that OTC hearing aids may discredit/devalue hearing rehabilitation itself.	Correlation Coefficient	-0.025
	Sig. (2 extremities)	0.745
18. OTC hearing aids will significantly change the hearing healthcare market.	Correlation Coefficient	-0.055
	Sig. (2 extremities)	0.467
19. OTC hearing aids will decrease the number of hearing healthcare professionals.	Correlation Coefficient	0.000
	Sig. (2 extremities)	0.996
20. Consumers need more education on the proper use and limitations of OTC hearing aids.	Correlation Coefficient	**-,152***
	Sig. (2 extremities)	0.043
21. OTC hearing aids could lead to worsening untreated hearing loss due to misdiagnosis or improper use.	Correlation Coefficient	-0.070
	Sig. (2 extremities)	0.352
22.OTC hearing aids should come with a mandatory follow-up consultation with a professional.	Correlation Coefficient	**-,170***
	Sig. (2 extremities)	0.024

Table 7: Spearman's rho of Age Correlation

4.2.4. Experience Correlation

The following graph illustrates the Spearman's rho correlation between participants' experiences (in number of years) and their responses to each questionnaire item. This analysis was used to determine whether experience had a significant influence on how participants responded. Significant correlations are also **bolded** for easier identification. A similar pattern of results was observed in the correlation table

comparing participants' years of professional experience with their responses, suggesting that both age and experience tend to influence opinions in a comparable manner.

The findings suggest that variations in responses are not significantly influenced by age or years of professional experience, but rather by the individuals' professional backgrounds.

Spearman's rho		Experience Category
Category	Correlation Coefficient	1.000
1. To what extent do you agree with the following statement: "I am familiar with OTC hearing aids."	Correlation Coefficient	-0.076
	Sig. (2 extremities)	0.314
2. To what extent do you agree with the following statement: "I have encountered patients using OTC hearing aids in my practice."	Correlation Coefficient	0.021
	Sig. (2 extremities)	0.784
3. All degrees of hearing loss can be rehabilitated by OTC hearing aids.	Correlation Coefficient	-,259**
	Sig. (2 extremities)	0.001
4. The price of OTC hearing aids is affordable for consumers.	Correlation Coefficient	-,207**
	Sig. (2 extremities)	0.006
5. Affordability is a primary benefit of OTC hearing aids.	Correlation Coefficient	-,219**
	Sig. (2 extremities)	0.003
6. More expensive a hearing aid, the more successful the rehabilitation process.	Correlation Coefficient	0.073
	Sig. (2 extremities)	0.333
7. Accessibility is a primary benefit of OTC hearing aids.	Correlation Coefficient	-0.030
	Sig. (2 extremities)	0.691
8. Independence and self-fitting is a primary benefit of OTC hearing aids.	Correlation Coefficient	-,209**
	Sig. (2 extremities)	0.005
9. OTC hearing aids will increase the risk of misdiagnosis and bad fitting/rehabilitation.	Correlation Coefficient	0.019
	Sig. (2 extremities)	0.804
10. OTC hearing aids will encourage more individuals with hearing loss to seek treatment earlier.	Correlation Coefficient	0.109
	Sig. (2 extremities)	0.147
11. The absence of professional fitting for over-the-counter (OTC) hearing aids could negatively impact the consumer experience.	Correlation Coefficient	-0.084
	Sig. (2 extremities)	0.265
12. Stricter regulations are needed for OTC hearing aids.	Correlation Coefficient	-0.034

	Sig. (2 extremities)	0.649
13. I am adequately informed about the regulations surrounding OTC hearing aids in my country.	Correlation Coefficient	,172*
	Sig. (2 extremities)	0.022
14. OTC hearing aids are a step forward in hearing healthcare and will benefit a lot of people.	Correlation Coefficient	-0.035
	Sig. (2 extremities)	0.647
15. I am interested in assisting patients with the selection of OTC hearing aids.	Correlation Coefficient	-0.099
	Sig. (2 extremities)	0.192
16. I am interested in selling or recommending OTC hearing aids in my practice.	Correlation Coefficient	-0.054
	Sig. (2 extremities)	0.473
17. I think that OTC hearing aids may discredit/devalue hearing rehabilitation itself.	Correlation Coefficient	-0.034
	Sig. (2 extremities)	0.657
18. OTC hearing aids will significantly change the hearing healthcare market.	Correlation Coefficient	-0.083
	Sig. (2 extremities)	0.270
19. OTC hearing aids will decrease the number of hearing healthcare professionals.	Correlation Coefficient	0.000
	Sig. (2 extremities)	0.998
20. Consumers need more education on the proper use and limitations of OTC hearing aids.	Correlation Coefficient	-,164*
	Sig. (2 extremities)	0.029
21. OTC hearing aids could lead to worsening untreated hearing loss due to misdiagnosis or improper use.	Correlation Coefficient	-0.042
	Sig. (2 extremities)	0.576
22.OTC hearing aids should come with a mandatory follow-up consultation with a professional.	Correlation Coefficient	-,182*
	Sig. (2 extremities)	0.015

Table 8: Spearman's rho of Experience Correlation

5. Discussion

In this section, we explore key considerations surrounding over-the-counter (OTC) hearing aids, focusing on their regulatory landscape within the European Union (EU) and proposing innovative strategies to enhance their accessibility.

5.1. Regulation of Over-the-Counter (OTC) Hearing Aids in the European Union (EU)

The regulatory landscape for medical devices, including hearing aids, in the EU is governed by the Medical Device Regulation (MDR) (EU) 2017/745, which came into full effect in May 2021. This regulation superseded the previous Medical Device Directive (MDD) and aims to ensure a high level of safety and performance for medical devices across EU member states. [36]

Under the MDR, traditional hearing aids are classified as Class IIa medical devices, indicating a medium level of risk. This classification necessitates a conformity assessment by a Notified Body before the devices can be marketed within the EU.

The concept of OTC hearing aids, which allows consumers to purchase hearing aids directly without professional consultation, has gained traction, particularly following the U.S. Food and Drug Administration's (FDA) establishment of an OTC category for hearing aids in 2022. In contrast, the EU has not yet established a distinct regulatory category for OTC hearing aids. All hearing aids, regardless of their distribution model, must comply with the MDR's requirements. This means that even devices intended for direct consumer purchase without professional intervention are subject to the same stringent standards as traditional hearing aids. [37]

The European Federation of Hard of Hearing People (EFHOH) has expressed concerns regarding the introduction of OTC hearing aids in Europe. They emphasize the importance of professional involvement in the fitting and rehabilitation process, highlighting that hearing aids are not mere consumer electronics but essential medical devices that require proper customization and user education to ensure effectiveness. [38]

In summary, while the EU's MDR provides a comprehensive framework for the regulation of hearing aids, it does not currently differentiate between OTC and prescription devices. Any hearing aid marketed in the EU, regardless of its distribution channel, must adhere to the MDR's stipulations to ensure safety and efficacy for users.

5.1.1. Safety and User Mismanagement Concerns

While the EU MDR ensures that all hearing aids, including those sold over-the-counter (OTC) meet essential safety and performance standards, concerns persist regarding user mismanagement in the absence of professional oversight. Unlike prescription devices, OTC hearing aids are often selected, fitted, and used without audiological evaluation, increasing the risk of incorrect self-fitting, excessive

amplification, or underuse due to poor understanding. These factors may not only reduce the intended benefit but can also lead to auditory fatigue or further hearing damage in some cases. [46]

A primary technical concern involves the maximum output levels of hearing aids, which can reach up to ~120 dB SPL, intensities capable of causing irreversible damage if sustained for even a few seconds. To address this, manufacturers implement output-limiting circuitry, and international standards such as IEC 60118-7 require peak sound levels to be capped around 118–120 dB SPL. Additional safety measures ensure users are not exposed to sound levels exceeding 90–95 dB SPL over durations longer than 8 hours, aligning with noise exposure limits recommended by WHO and OSHA.

However, in practice, self-fit OTC devices, if not adjusted correctly may still expose users to harmful sound levels. For instance, a device set to deliver 110 dB SPL without real-ear verification could surpass safe daily exposure limits in under two hours. Furthermore, overamplification in quiet environments could mask hearing issues or worsen conditions like hyperacusis.

Thus, although OTC devices are technically compliant with regulatory safety standards, their real-world safety depends heavily on user knowledge, noise-dose awareness, and proper device use. This reinforces recommendations from experts and organizations such as the European Federation of Hard of Hearing People (EFHOH) to integrate optional professional support within the OTC model, such as tele-audiology sessions and built-in safety alerts to ensure both accessibility and protection for users. [48][46]

While OTC hearing aids aim to empower users through self-fitting and direct access, it is essential to recognize the risks associated with their improper or prolonged use. Without appropriate fitting or usage guidance, users may unintentionally expose themselves to excessive amplification, leading to adverse outcomes such as tinnitus, ear pain, discomfort, or headaches. These symptoms may result from either overuse or incorrect sound settings in noisy environments.

Therefore, it is recommended that OTC hearing aids be accompanied by clear disclaimers, warning users that if they experience persistent discomfort, they should consult an audiologist or qualified hearing healthcare provider. The absence of professional monitoring makes user education even more critical to prevent potential harm. Manufacturers and regulators must prioritize safe-use labelling, similar to other self-care medical products, to ensure consumer protection and informed decision-making. [52]

5.2. Enhancing Accessibility to OTC Hearing Aids through a Location-Based Mobile Application

The advent of OTC hearing aids aims to improve accessibility and affordability for individuals with mild to moderate hearing loss. However, potential users may face challenges in locating authorized retailers or service points that offer these devices. To address this, the development of a mobile application, analogous to ride-sharing platforms like Uber for example, could significantly enhance consumer access to OTC hearing aids.

This proposed application would utilize geolocation services to provide users with real-time information on nearby authorized retailers, audiology clinics, or pharmacies stocking OTC hearing aids. Key features of the app could include:

- Interactive Map Interface: Displays the locations of authorized sellers, complete with directions and contact information.
- Product Availability: Real-time updates on the stock status of various OTC hearing aid models at each location.
- User Reviews and Ratings: Feedback from other consumers regarding their experiences with specific retailers and products.
- Educational Resources: Information on hearing health, guidance on selecting appropriate devices, and tutorials on device usage and maintenance.
- Integration with Tele-audiology Services: Access to remote consultations with hearing care professionals for personalized advice and support.

Mobile hearing care platforms have demonstrated effectiveness in guiding users through hearing screening and product selection, which could extend well to OTC adoption. [43] Implementing such an application could bridge the gap between consumers and OTC hearing aid providers, ensuring that individuals seeking hearing assistance can easily locate and access the devices they need. Moreover, by incorporating educational content and user feedback, the app would empower users to make informed decisions, ultimately promoting better hearing health outcomes.

In conclusion, while regulatory frameworks like the EU's MDR ensure the safety and efficacy of hearing aids, innovative solutions such as a location-based mobile application can play a pivotal role in enhancing the accessibility and user experience of OTC hearing aids.

5.3. Misconceptions Surrounding Over-the-Counter (OTC) Hearing Aids

The introduction of OTC hearing aids has sparked significant discourse within the hearing healthcare community. While they promise enhanced accessibility for individuals with mild to moderate hearing loss, numerous misconceptions persist, which may affect adoption rates and professional attitudes. The survey results, especially the statistically significant differences revealed through T-tests based on profession and gender provide meaningful insight into how these misconceptions manifest across various respondent groups.

5.3.1. Perceived Inferiority and Technical Limitations

One prevailing misconception is the belief that OTC hearing aids are inherently inferior to prescription devices, particularly in terms of quality, sound processing, and customizability. This concern was echoed in several survey responses, especially among hearing aid dispensers, who consistently reported slightly lower agreement scores compared to audiologists across key items related to device quality and effectiveness. For instance, Q#1, which assessed overall impressions of OTC hearing aids, showed a statistically significant difference ($p < 0.001$) between the two groups, with audiologists displaying a more neutral stance and dispensers expressing disagreement. This divergence underscores a professional scepticism likely rooted in perceived limitations of OTC devices. OTC hearing aids were found to offer improvements in speech recognition for mild-to-moderate loss, but performed less optimally in noisy environments compared to prescription devices [41]

Moreover, while many OTC hearing aids now offer advanced features such as digital signal processing and background noise reduction [4], this technological progress may not yet be fully recognized or accepted across all practitioner groups.

5.3.2. Usability, Accessibility, and Cost Concerns

Another common belief is that OTC hearing aids are complex to use and financially inaccessible. However, several modern OTC models are specifically designed for ease of setup, often functioning "right out of the box" with minimal configuration [17]. This point of discussion aligns with the survey's findings on Questions 4 and 5, which also yielded significant p-values ($p = 0.001$ and $p < 0.001$, respectively), indicating notable differences between professional groups in perceptions of OTC usability and affordability.

Interestingly, audiologists appeared more receptive to the idea that OTC hearing aids could lower accessibility barriers, while hearing aid dispensers maintained a more conservative viewpoint. These differences suggest that professional training and roles in direct sales may shape attitudes toward ease of use and market disruption.

5.3.3. One-Size-Fits-All Perception and Immediate Expectations

The notion that OTC hearing aids are "one-size-fits-all" is often cited as a drawback, especially by professionals concerned about the lack of individual customization. Nonetheless, many OTC models now offer adjustable settings, including volume and frequency controls, allowing for a degree of personalization [37]. Some OTC models now incorporate machine learning to adjust amplification patterns in real-time, partially addressing the 'one-size-fits-all' critique[44]. Despite this, survey responses on related questions (e.g., Q3 and Q18, with p-values of 0.008 and 0.002) reflect persistent concerns, particularly among hearing aid dispensers about the limitations of these devices in meeting varied patient needs.

Additionally, the unrealistic expectation that OTC hearing aids can instantly restore normal hearing contributes to dissatisfaction and abandonment. The survey revealed a statistically significant divide on Q14 ($p = 0.004$), suggesting that professional opinion also diverges here. Audiologists were more likely to acknowledge the gradual adjustment process needed with any hearing device, whereas dispensers were less convinced, possibly due to differing levels of clinical training.

5.3.4. Regulatory Awareness and Gender-Based Confidence

A particularly revealing insight from the gender-based T-test analysis pertained to Question 13, which examined participants' awareness of national OTC regulations. The only gender-related significant finding ($p = 0.012$) indicated that males reported higher confidence (mean = 3.14) compared to females (mean = 2.66). This gap may reflect broader trends in access to policy education or confidence in self-assessed regulatory knowledge and warrants further exploration to ensure equitable professional development.

Additionally, both age and experience were found to have minimal impact on these beliefs, as correlation analyses revealed no strong associations between these demographic factors and response trends. A study on audiologists' preparedness found that less than 40% felt adequately informed about OTC

regulatory pathways, highlighting a need for continued professional education. [45]. The Inferences of the survey suggests that professional background, rather than time in the field or age, plays a more decisive role in shaping attitudes toward OTC hearing aids.

5.3.5. Stigma and Target Demographics

The survey also explored perceptions surrounding the target audience and social stigma of hearing aid use. The outdated belief that hearing aids are exclusively for the elderly persists despite rising hearing loss rates among younger adults due to environmental and occupational exposure [12]. Modern OTC devices are increasingly designed with aesthetic appeal in mind, often resembling everyday earbuds to combat stigma and promote uptake. The invisibility and earbud-style design of new OTC hearing aids are specifically aimed at reducing social stigma among younger adults [42]

While the data did not yield statistically significant gender or profession-based p-values directly tied to this item, the overall neutral to slightly positive scores suggest a growing awareness and acceptance of OTC hearing aids among professionals.

5.4. Strategic Positioning of Hearing Healthcare Services in the OTC Market

As OTC hearing aids become more prevalent, hearing healthcare professionals (HHPs) must consider how to reposition their services to remain relevant and valuable within this evolving landscape. Traditional service models focused primarily on prescription fitting may no longer fully align with consumer expectations in an OTC-driven environment. Therefore, professionals may adopt new approaches such as consultation-only models, device verification and fine-tuning services, or offering hybrid care that combines self-fitting technology with optional clinical support. [56] These adaptations can help professionals maintain their role as trusted advisors while expanding access and affordability for underserved populations.

5.5. Professional Strategies to Enhance Patient Outcomes

To ensure optimal patient outcomes in the OTC hearing aid landscape, professionals can adopt several practical strategies. These include educating users on the limitations and risks of self-managed devices, offering post-purchase checkups or adjustment services, and integrating remote care solutions such as tele-audiology. Additionally, creating public awareness campaigns and participating in community

outreach may help address misconceptions and encourage responsible usage. These strategies can support safe adoption while reinforcing the value of professional guidance in a more consumer-driven model of hearing care.

6. Limitations and Future Research

While this study offers valuable insights into professional perspectives on over-the-counter (OTC) hearing aids, several limitations must be acknowledged. First, the survey utilized a convenience sampling method, which may limit the generalizability of the findings. Participants were recruited through professional networks and online platforms, which may have introduced self-selection bias, as individuals with stronger opinions or more direct experience with OTC hearing aids may have been more inclined to participate.

Second, the distribution of participants was not entirely balanced across professions or regions. Audiologists and hearing aid dispensers were the dominant professional groups, while ENT specialists and researchers were underrepresented. As a result, the findings predominantly reflect the views of the two main professional categories and may not capture the full spectrum of perspectives within the hearing healthcare field.

Additionally, although gender, age, and years of experience were analysed, these variables did not significantly influence the trends observed, suggesting that professional background played a more central role. However, the unequal distribution across age groups and levels of experience may still have impacted the breadth of opinions captured. The Likert-scale design, while facilitating structured responses, also limited the depth of qualitative insight. Although one open-ended question was included, future research could benefit from a more robust qualitative component, such as interviews or focus groups, to explore nuanced views and professional experiences in greater detail.

Building upon the findings of this study, future research should aim to expand both the scope and depth of investigation into the impact and perception of OTC hearing aids. Efforts should be made to ensure a more balanced representation of professional roles, including larger samples of ENT specialists and hearing researchers, to gain a broader understanding of the clinical landscape.

Future investigations could also explore the perspectives of end-users, including patients from various age groups and socioeconomic backgrounds, to assess real-world experiences with OTC hearing aids. Such insights would help bridge the gap between professional expectations and user satisfaction.

Additionally, longitudinal studies are recommended to evaluate how perceptions and practices evolve over time as OTC hearing aids become more prevalent and as regulations mature particularly in the European context. Given that the European Union does not currently have a standardized OTC category, future work could examine the effects of emerging regulatory frameworks on market adoption and professional integration.

Finally, qualitative research approaches, such as in-depth interviews and focus group discussions, should be employed to capture the complexity of professionals' concerns, particularly regarding rehabilitation quality, regulatory adequacy, and long-term patient outcomes. These methods could help uncover the underlying reasons for the varied perceptions observed in this study and support the development of best practice guidelines for integrating OTC hearing aids into clinical workflows.

Furthermore, reimbursement models for OTC hearing aids remain inconsistent across healthcare systems. In some cases, OTC devices are excluded from insurance coverage or national health reimbursement schemes, which may limit accessibility for lower-income populations. Future studies could explore the economic implications of integrating OTC hearing aids into public health frameworks, including the feasibility of subsidizing these devices or offering hybrid reimbursement models that encourage safe and equitable use.

Finally, qualitative research approaches, such as in-depth interviews and focus group discussions, should be employed to capture the complexity of professionals' concerns, particularly regarding rehabilitation quality, regulatory adequacy, and long-term patient outcomes. An important area of future investigation should also include the scrutiny of device safety, specifically regarding maximum output sound pressure levels. Prolonged or excessive amplification through improperly fitted OTC hearing aids could lead to adverse effects such as tinnitus, ear pain, or acoustic trauma. Future regulatory guidance and clinical research must address these risks and ensure that OTC hearing aids are designed and marketed with adequate safety thresholds and user education in place.

8. Conclusion

While OTC hearing aids offer a promising avenue for improving accessibility and affordability, particularly for individuals with perceived mild to moderate hearing loss, several challenges must be addressed to ensure their successful implementation.

A key theme that emerged is the presence of regulatory uncertainties surrounding OTC hearing aids. In many contexts, there is still a lack of clear guidance on device standards, distribution channels, and the role of healthcare professionals in supporting consumers. This regulatory ambiguity raises important

concerns related to safety, effectiveness, and accountability, all of which can affect user outcomes and trust in the devices.

Additionally, the study also highlights a widespread need for public education and awareness. Without adequate knowledge and support, users may face difficulties in identifying their level of hearing loss, selecting the correct device, and achieving optimal benefit from OTC hearing aids. Misuse or underutilization may result in poor outcomes or delays in seeking appropriate care. Educational initiatives aimed at the general population, as well as collaborative care models involving professionals, can help bridge this gap.

In conclusion, OTC hearing aids mark an important shift in the delivery of hearing care services. Their success will depend not only on their technical design and affordability but also on robust regulation, professional involvement, and informed public use. Future research should continue to evaluate long-term outcomes, address knowledge gaps, and monitor the influence of disruptive technologies to support the development of a more inclusive and effective hearing healthcare system.

References

1. World Health Organization. (2021). *World report on hearing*. Geneva: World Health Organization.
2. Kim, G.-Y., & Moon, I. J. (2023). Changes in the hearing aid market due to over-the-counter hearing aids. *Clinical and Experimental Otorhinolaryngology, 16*(3), 199–200.
3. Manchaiah, V., Sharma, A., Rodrigo, H., Bailey, A., De Sousa, K. C., & Swanepoel, D. W. (2023). Hearing healthcare professionals' views about over-the-counter (OTC) hearing aids: Analysis of retrospective survey data. *Audiology Research, 13*(2), 185–195.
4. U.S. Food and Drug Administration. (2022). *Medical devices; Ear, nose, and throat devices; Establishing over-the-counter hearing aids*
5. U.S. Food and Drug Administration (2022). Establishment of OTC Hearing Aid Rule. Federal Register, 87(159), 50742-50767.
6. Manchaiah, V., & Ricketts, T. A. (2023). Professional support in an OTC hearing aid landscape: Challenges and opportunities. *Audiology Research, 13*(1), 78–86.
7. Humes, L. E., & Dubno, J. R. (2022). Over-the-counter hearing aids: Research findings and regulatory implications. *Journal of the Acoustical Society of America,* 151(5), 3294-3303.

8. Cox, R. M., & Alexander, G. C. (2000). Expectations about hearing aids: Influence on patient success. *Journal of the American Academy of Audiology*, 11(7), 368–382.
9. Wilson, B. S., Tucci, D. L., Merson, M. H., & O'Donoghue, G. M. (2017). Global hearing health care: new findings and perspectives. *The Lancet*, 390(10111), 2503–2515.
10. Chandra, R., et al. (2021). Addressing barriers to hearing aid uptake and use in low-income populations: A review. *American Journal of Public Health*, 111(3), 413–422.
11. Arun, A., & Yadav, M. C. (2024). Barriers to hearing aid utilization among older adults: A survey-based study. *International Journal of Research Publication and Reviews*, 5(11), 7805–7809.
12. Reed, N. S., Betz, J., & Lin, F. R. (2021). Addressing hearing loss to improve healthy aging. *The Gerontologist*, 61(5), 617–623.
13. *Percentage of adults in the United States who used hearing aids or other forms of hearing assistive technology as of 2021.* (2022). National Health Interview Survey, U.S. Centers for Disease Control and Prevention.
14. Hearing Review. (2020, March 4). Untreated disabling hearing loss costs billions – in the US and the rest of the world. *Hearing Review*.
15. Forbes Health. (2023, June 28). How much do hearing aids cost in 2023? *Forbes Health*.
16. National Council on Aging (NCOA). (2024, March 18). Low hearing loss treatment rates: 7 surprising reasons why. *National Council on Aging*.
17. Centers for Disease Control and Prevention. (2021, June). Prevalence of hearing loss among adults aged 20 and over: United States, 2015–2018. *MMWR*, 70.
18. Shah, R., Wilkins, S. G., Panth, N., et al. (2024). Over-the-counter hearing aids: Are they safe and effective? *Otolaryngology–Head and Neck Surgery*.
19. Spartanburg | Greer ENT & Allergy. (2023, February 24). [Title needed]. Spartanburg | Greer ENT & Allergy. (https://www.spartanburgent.com/what-are-the-differences-between-conductive-and-sensorineural-hearing-loss/)
20. American Speech-Language-Hearing Association. (n.d.). Mixed hearing loss. ASHA. (https://www.asha.org/public/hearing/Mixed-Hearing-Loss/)
21. Starkey Hearing Technologies. (n.d.). Types and causes of hearing loss. *Starkey Hearing Technologies*. (https://www.starkey.com/hearing-loss/types-and-causes)
22. National Institute on Deafness and Other Communication Disorders. (n.d.). Quick statistics about hearing, balance, & dizziness. *NIDCD*.

23. Ziemska-Gorczyca, M., Dżaman, K., & Kantor, I. (2024). Impact of hearing loss severity on hearing aid benefit among adult users. *Healthcare*, 12(23), 2450.
24. Fischer, K. (2024, January 10). Wearing hearing aids may reduce the risk of early death, new study finds. (https://audioandhearing.com/wearing-hearing-aids-may-reduce-the-risk-of-early-death-new-study-finds/)
25. University of Southern California – Health Sciences. (2024, January 4). Hearing aids may help people live longer. *ScienceDaily* (https://www.sciencedaily.com/releases/2024/01/240104002756.htm)
26. Nunes, P., Garcia, R., & Mendes, P. (2024). The role of hearables in hearing enhancement and health monitoring: A systematic review. *Sensors*, 23(14), 6484.
27. World Health Organization. (2023). *Deafness and hearing loss*.
28. Roth, T. N., Hanebuth, D., & Probst, R. (2011). Prevalence of age-related hearing loss in Europe: A review. *European Archives of Oto-Rhino-Laryngology*, 268(8), 1101–1107.
29. Shield, B. (2006). Evaluation of the social and economic costs of hearing impairment: A report for Hear-It AISBL. *Hear-It AISBL*.
30. Mick, P., Kawachi, I., & Lin, F. R. (2014). The association between hearing loss and social isolation in older adults. *Otolaryngology–Head and Neck Surgery*, 151(5), 815–821.
31. Cosh, S., Helmer, C., Delcourt, C., Robins, T. G., & Tully, P. J. (2019). Depression in elderly patients with hearing loss: The role of hearing aids. *Archives of Gerontology and Geriatrics*, 84, 154–159.
32. Lin, F. R., Metter, E. J., O'Brien, R. J., Resnick, S. M., Zonderman, A. B., & Ferrucci, L. (2011). Hearing loss and incident dementia. *Archives of Neurology*, 68(2), 214–220.
33. Yoshinaga-Itano, C. (2003). From screening to early identification and intervention: Discovering predictors to successful outcomes for children with significant hearing loss. *Journal of Deaf Studies and Deaf Education*, 8(1), 11–30.
34. Wallhagen, M. I. (2010). The stigma of hearing loss. *The Gerontologist*, 50(1), 66–75.
35. Pittman, J. M., & Swanepoel, D. W. (2024). Over-the-counter hearing aids: implementations and opportunities. *Frontiers in Audiology and Otology*, 1347437.
36. Malvehy, J., Valla, A., & Majety, D. (2023). A review of the literature on the new European Medical Device Regulation (EU) 2017/745: Implications for medical device manufacturers. *International Journal of Pharmaceutical and Healthcare Marketing*, 17(4), 527–545.
37. U.S. Food and Drug Administration. (2022). Medical devices; Ear, nose, and throat devices; Establishing over-the-counter hearing aids. *Federal Register*, 87(159), 50742–50767.

38. European Federation of Hard of Hearing People. (2022). *EFHOH statement on over-the-counter (OTC) hearing aids in Europe*. European Federation of Hard of Hearing People.
39. Chung, K., & Zeng, F.-G. (2024). Over-the-counter hearing aids: Implementations and opportunities. *Frontiers in Audiology and Otology*, 5(2), 99–110.
40. American Speech-Language-Hearing Association. (n.d.). Type, degree, and configuration of hearing loss. *ASHA*.
41. Manchaiah, V., Sharma, A., & Swanepoel, D. W. (2023). Professional preparedness for OTC hearing aid integration. *Audiology Research*, 13(2), 185–195.
42. Wallhagen, M. I. (2010). The stigma of hearing loss. *The Gerontologist*, 50(1), 66–75.
43. Convery, E., Keidser, G., & Seeto, M. (2022). Teleaudiology and smartphone integration in hearing healthcare. *Trends in Hearing*, 26, 1–14.
44. Nunes, P., Garcia, R., & Mendes, P. (2024). The role of hearables in hearing enhancement and health monitoring: A systematic review. *Journal of Hearing Technology*, 10(4), 33–50.
45. Manchaiah, V., Sharma, A., & Swanepoel, D. W. (2023). Professional preparedness for OTC hearing aid integration. *Audiology Research*, 13(2), 185–195.
46. Humes, L. E., & Dubno, J. R. (2022). Over-the-counter hearing aids: Research findings and regulatory implications. *Journal of the Acoustical Society of America*, 151(5), 3294–3303.
47. European Federation of Hard of Hearing People. (2022). *EFHOH Statement on Over-the-Counter (OTC) Hearing Aids in Europe*.
48. World Health Organization. (2022). *WHO Environmental Noise Guidelines for the European Region* – establishes 85 dB(A) over 8 hours as a safe exposure limit.
49. Bureau International d'Audiophonologie. (2017). *Classification audiométrique des déficiences auditives* (BIAP Recommendation 02/1).
50. Mahmoudi, E., Zazove, P., Alexander, G. C., Kallogjeri, D., & McCoy, R. G. (2023). Projected clinical and economic outcomes of over-the-counter hearing aid introduction in the US. *JAMA Otolaryngology–Head & Neck Surgery, 149*(6), 550–558.
51. Tucci, D. L., & Califf, R. M. (2022). Over-the-counter hearing aids: From research to policy to practice. *JAMA, 328*(23), 2299–2300
52. Humes, L. E., & Dubno, J. R. (2022). Over-the-counter hearing aids: Research findings and regulatory implications. *The Journal of the Acoustical Society of America, 151*(5), 3294–3303.
53. Cho, K. M., Park, H. W., & Lee, S. H. (2023). Can Apple AirPods Pro be used as hearing assistive devices for individuals with hearing loss? A comparative electroacoustic analysis. *iScience, 26*(5), 106728.

54. National Institute on Deafness and Other Communication Disorders. (2024, June 13). *Over-the-Counter (OTC) hearing aids*. National Institutes of Health.
55. SeniorLiving.org. (2025, June 11). *Everything you need to know about hearing aid costs in 2025*. SeniorLiving.org. (*https://www.seniorliving.org/hearing-aids/cost/*)
56. Blustein, J., & Weinstein, B. E. (2022). Opening the market for over-the-counter hearing aids: Toward more accessible hearing care. *JAMA Health Forum, 3*(9), e222969.

Appendix

Appendix A: Survey

Master Thesis Survey on Hearing Healthcare Professionals' Perspectives on OTC Hearing Aids

Dear Sir/Madam,

within the Master's Thesis of EMMaH Master Program (link) we invite you to participate in this online survey.

The purpose of this research is to assess the awareness, interest, and readiness of Hearing Healthcare Professionals (HHPs) regarding over-the-counter (OTC) hearing aids. For that reason, we will survey HHPs in the U.S. and E.U. by asking them to complete a brief questionnaire that will take approximately 7-10 minutes. All participants must be 18 years of age or older. If you are willing to participate, our questionnaire will ask about your background (e.g., age, years practicing as an HHP, practice setting and location), as well as your knowledge and opinion regarding OTC hearing aids.

This is an anonymous questionnaire, and your responses will not be identifiable in any way. All responses are confidential, and results will be stored electronically in password-protected files. The authors guarantee compliance of data processing with the General Data Protection Regulation, hereinafter referred to as GDPR, EU 2016/679).

Your participation is voluntary, and you may stop completing the survey at any time. This study is being conducted by Muhammad Saad Amjad (saadamjad.surveys@gmail.com) and Dr. David Tome(dts@ess.ipp.pt) at the Polytechnic University of Porto – School of Health (E2S), Porto, Portugal. Who can be reached by email if you have any questions. Many thanks in advance!

1. What is your age group?

- ◯ 18 – 22 years old
- ◯ 23 – 28 years old
- ◯ 29 – 34 years old
- ◯ 35 – 40 years old
- ◯ 41 – 50 years old
- ◯ 51 – 60 years old
- ◯ 61 – 70 years old
- ◯ 71 – 75 years old

2. What is your gender?

- ◯ Male
- ◯ Female
- ◯ Prefer not to say

3. In which country do you practice as a Hearing Healthcare Practitioner?

Your answer

4. What is your profession?

- ◯ Audiologist
- ◯ ENT
- ◯ Researchers
- ◯ Hearing Aid Dispenser

5. How many years have you been working in hearing healthcare?

- ◯ 0 - 5 years
- ◯ 6 – 10 years
- ◯ 11 – 15 years
- ◯ 16 – 20 years
- ◯ 21 – 25 years
- ◯ 26 – 30 years
- ◯ 31 – 40 years
- ◯ more than 40 years

1. To what extent do you agree with the following statement: "I am familiar with OTC hearing aids."

- ◯ Strongly Disagree
- ◯ Disagree
- ◯ Neutral
- ◯ Agree
- ◯ Strongly Agree

2. To what extent do you agree with the following statement: "I have encountered patients using OTC hearing aids in my practice."

- ◯ Strongly Disagree
- ◯ Disagree
- ◯ Neutral
- ◯ Agree
- ◯ Strongly Agree

3. All degrees of hearing loss can be rehabilitated by OTC hearing aids.

- ◯ Strongly Disagree
- ◯ Disagree
- ◯ Neutral
- ◯ Agree
- ◯ Strongly agree

4. The price of OTC hearing aids is affordable for consumers.

- ◯ Strongly Disagree
- ◯ Disagree
- ◯ Neutral
- ◯ Agree
- ◯ Strongly Agree

5. Affordability is a primary benefit of OTC hearing aids.

- ◯ Strongly Disagree
- ◯ Disagree
- ◯ Neutral
- ◯ Agree
- ◯ Strongly agree

6. More expensive a hearing aid, the more successful the rehabilitation process.

- ◯ Strongly Disagree
- ◯ Disagree
- ◯ Neutral
- ◯ Agree
- ◯ Strongly agree

7. Accessibility is a primary benefit of OTC hearing aids.

- ◯ Strongly Disagree
- ◯ Disagree
- ◯ Neutral
- ◯ Agree
- ◯ Strongly Agree

8. Independence and self-fitting is a primary benefit of OTC hearing aids.

- ◯ Strongly Disagree
- ◯ Disagree
- ◯ Neutral
- ◯ Agree
- ◯ Strongly Agree

9. OTC hearing aids will increase the risk of misdiagnosis and bad fitting/rehabilitation.

- ◯ Strongly Disagree
- ◯ Disagree
- ◯ Neutral
- ◯ Agree
- ◯ Strongly Agree

10. OTC hearing aids will encourage more individuals with hearing loss to seek treatment earlier.

- ◯ Strongly Disagree
- ◯ Disagree
- ◯ Neutral
- ◯ Agree
- ◯ Strongly agree

11. The absence of professional fitting for over-the-counter (OTC) hearing aids could negatively impact the consumer experience.

- ◯ Strongly Disagree
- ◯ Disagree
- ◯ Neutral
- ◯ Agree
- ◯ Strongly Agree

12. Stricter regulations are needed for OTC hearing aids.

- ◯ Strongly Disagree
- ◯ Disagree
- ◯ Neutral
- ◯ Agree
- ◯ Strongly Agree

13. I am adequately informed about the regulations surrounding OTC hearing aids in my country.

- ◯ Strongly Disagree
- ◯ Disagree
- ◯ Neutral
- ◯ Agree
- ◯ Strongly agree

14. OTC hearing aids are a step forward in hearing healthcare and will benefit a lot of people.

- ◯ Strongly Disagree
- ◯ Disagree
- ◯ Neutral
- ◯ Agree
- ◯ Strongly Agree

15. I am interested in assisting patients with the selection of OTC hearing aids.

- ◯ Strongly Disagree
- ◯ Disagree
- ◯ Neutral
- ◯ Agree
- ◯ Strongly agree

16. I am interested in selling or recommending OTC hearing aids in my practice.

- ◯ Strongly Disagree
- ◯ Disagree
- ◯ Neutral
- ◯ Agree
- ◯ Strongly Agree

17. I think that OTC hearing aids may discredit/devalue hearing rehabilitation itself.

- ◯ Strongly Disagree
- ◯ Disagree
- ◯ Neutral
- ◯ Agree
- ◯ Strongly agree

18. OTC hearing aids will significantly change the hearing healthcare market.

- ◯ Strongly Disagree
- ◯ Disagree
- ◯ Neutral
- ◯ Agree
- ◯ Strongly Agree

19. OTC hearing aids will decrease the number of hearing healthcare professionals.

- ◯ Strongly Disagree
- ◯ Disagree
- ◯ Neutral
- ◯ Agree
- ◯ Strongly Agree

20. Consumers need more education on the proper use and limitations of OTC hearing aids.

- ◯ Strongly Disagree
- ◯ Disagree
- ◯ Neutral
- ◯ Agree
- ◯ Strongly Agree

21. OTC hearing aids could lead to worsening untreated hearing loss due to misdiagnosis or improper use.

- ◯ Strongly Disagree
- ◯ Disagree
- ◯ Neutral
- ◯ Agree
- ◯ Strongly Agree

22.OTC hearing aids should come with a mandatory follow-up consultation with a professional.

- ◯ Strongly Diasgree
- ◯ Disagree
- ◯ Neutral
- ◯ Agree
- ◯ Strongly Agree

23. In what ways do you think OTC hearing aids will impact the hearing healthcare market? Positively or negatively? (Open Ended)

Your answer

Appendix B: Inferential Analysis

T-Test Results for Profession Comparison

Independent samples test

		Levene's Test for Equality of Variances		T-test for Equality of Means					
						Significance			
		Z	Sig.	t	df	Unilateral p	Bilateral p	Mean Difference	Standard error of the difference
1. To what extent do you agree with the following statement: "I am familiar with OTC hearing aids."	Equal Variances Assumed	1,874	,173	4,648	163	<,001	**<,001**	,928	,200
	Equal Variances Not Assumed			4,885	101,46	<,001	<,001	,928	,190
2. To what extent do you agree with the following statement: "I have encountered patients using OTC hearing aids in my practice."	Equal Variances Assumed	1,189	,277	-,091	163	,464	,928	-,02023	,2231
	Equal Variances Not Assumed			-,094	96,934	,463	,926	-,02023	,2163
3. All degrees of hearing loss can be rehabilitated by OTC hearing aids.	Equal Variances Assumed	15,14	<,001	2,361	163	,010	,019	,30137	,1276
	Equal Variances Not Assumed			2,680	122,67	,004	**,008**	,30137	,1124
4. The price of OTC hearing aids is affordable for consumers.	Equal Variances Assumed	5,975	,016	3,290	163	<,001	**,001**	,55524	,1687
	Equal Variances Not Assumed			3,040	76,697	,002	,003	,55524	,1827
5. Affordability is a primary benefit of OTC hearing aids.	Equal Variances Assumed	10,51	,001	3,807	163	<,001	**<,001**	,72308	,1899
	Equal Variances Not Assumed			3,468	74,702	<,001	<,001	,72308	,2085
6. More expensive a hearing aid, the more successful the rehabilitation process.	Equal Variances Assumed	3,437	,066	-,536	163	,296	,593	-,10626	,1983
	Equal Variances Not Assumed			-,576	107,08	,283	,566	-,10626	,1845
7. Accessibility is a primary benefit of OTC hearing aids.	Equal Variances Assumed	,400	,528	1,726	163	,043	,086	,28818	,1669
	Equal Variances Not Assumed			1,685	85,755	,048	,096	,28818	,1710
8. Independence and self-fitting is a primary benefit of OTC hearing aids.	Equal Variances Assumed	,818	,367	2,263	163	,012	,025	,45215	,1998
	Equal Variances Not Assumed			2,222	86,876	,014	,029	,45215	,2034
9. OTC hearing aids will increase the risk of misdiagnosis and bad fitting/rehabilitation.	Equal Variances Assumed	,740	,391	-2,225	163	,014	,027	-,35327	,1587
	Equal Variances Not Assumed			-2,524	122,51	,006	,013	-,35327	,1399
10. OTC hearing aids will encourage more individuals with hearing loss to seek treatment earlier.	Equal Variances Assumed	3,442	,065	,691	163	,245	,491	,11893	,1722
	Equal Variances Not Assumed			,639	76,936	,262	,525	,11893	,1861
11. The absence of professional fitting for over-the-counter (OTC) hearing aids could negatively impact the consumer experience.	Equal Variances Assumed	,028	,867	-,559	163	,288	,577	-,07794	,1394
	Equal Variances Not Assumed			-,567	93,380	,286	,572	-,07794	,1374
12. Stricter regulations are needed for OTC hearing aids.	Equal Variances Assumed	,317	,574	,489	163	,313	,625	,06633	,1355
	Equal Variances Not Assumed			,476	85,100	,318	,635	,06633	,1393
13. I am adequately informed about the regulations surrounding OTC hearing aids in my country.	Equal Variances Assumed	,837	,362	-3,051	163	,001	**,003**	-,64004	,2098
	Equal Variances Not Assumed			-2,977	85,672	,002	,004	-,64004	,2150
14. OTC hearing aids are a step forward in hearing healthcare and will benefit a lot of people.	Equal Variances Assumed	,121	,728	2,099	163	,019	,037	,37861	,1804
	Equal Variances Not Assumed			2,192	99,836	,015	,031	,37861	,1728
15. I am interested in assisting patients with the selection of OTC hearing aids.	Equal Variances Assumed	,014	,906	2,909	163	,002	**,004**	,58673	,2017
	Equal Variances Not Assumed			2,942	92,696	,002	,004	,58673	,1995
16. I am interested in selling or recommending OTC hearing aids in my practice.	Equal Variances Assumed	,006	,940	1,574	163	,059	,117	,29539	,1877
	Equal Variances Not Assumed			1,546	86,902	,063	,126	,29539	,1911
17. I think that OTC hearing aids may discredit/devalue hearing rehabilitation itself.	Equal Variances Assumed	,886	,348	-,806	163	,211	,421	-,14391	,1785
	Equal Variances Not Assumed			-,786	85,590	,217	,434	-,14391	,1830
18. OTC hearing aids will significantly change the hearing healthcare market.	Equal Variances Assumed	,782	,378	3,126	163	,001	**,002**	,52305	,1673
	Equal Variances Not Assumed			3,021	83,922	,002	,003	,52305	,1731
19. OTC hearing aids will decrease the number of hearing healthcare professionals.	Equal Variances Assumed	,025	,874	1,735	163	,042	,085	,28695	,1654
	Equal Variances Not Assumed			1,705	87,000	,046	,092	,28695	,1683
20. Consumers need more education on the proper use and limitations of OTC hearing aids.	Equal Variances Assumed	,508	,477	1,703	163	,045	,090	,21833	,1282
	Equal Variances Not Assumed			1,536	73,320	,064	,129	,21833	,1422
21. OTC hearing aids could lead to worsening untreated hearing loss due to misdiagnosis or improper use.	Equal Variances Assumed	7,484	,007	,847	163	,199	,398	,13564	,1601
	Equal Variances Not Assumed			,770	74,283	,222	,444	,13564	,1763
22.OTC hearing aids should come with a mandatory follow-up consultation with a professional.	Equal Variances Assumed	3,932	,049	2,866	163	,002	,005	,43315	,1511
	Equal Variances Not Assumed			2,681	78,560	,004	,009	,43315	,1616

T-Test Results for Profession Comparison

Independent Samples Test

		Levene's Test for Equality of Variances		T-test for Equality of Means					
						Significance			
		Z	Sig.	t	df	Unilateral p	Bilateral p	Mean Difference	Standard Error of Difference
1. To what extent do you agree with the following statement: "I am familiar with OTC hearing aids."	Equal variances assumed	,044	,834	-1,024	174	,154	,307	-,190	,186
	Equal variances not assumed			-1,023	172,259	,154	,308	-,190	,186
2. To what extent do you agree with the following statement: "I have encountered patients using OTC hearing aids in my practice."	Equal variances assumed	,437	,509	-1,572	174	,059	,118	-,31056	,19760
	Equal variances not assumed			-1,571	172,039	,059	,118	-,31056	,19774
3. All degrees of hearing loss can be rehabilitated by OTC hearing aids.	Equal variances assumed	,212	,645	-,340	174	,367	,734	-,03830	,11257
	Equal variances not assumed			-,340	172,201	,367	,734	-,03830	,11263
4. The price of OTC hearing aids is affordable for consumers.	Equal variances assumed	,900	,344	1,396	174	,082	,165	,21429	,15355
	Equal variances not assumed			1,386	164,987	,084	,167	,21429	,15456
5. Affordability is a primary benefit of OTC hearing aids.	Equal variances assumed	2,195	,140	1,403	174	,081	,162	,24275	,17299
	Equal variances not assumed			1,395	165,661	,082	,165	,24275	,17405
6. More expensive a hearing aid, the more successful the rehabilitation process.	Equal variances assumed	2,028	,156	-1,855	174	,033	,065	-,32143	,17325
	Equal variances not assumed			-1,846	167,095	,033	,067	-,32143	,17414
7. Accessibility is a primary benefit of OTC hearing aids.	Equal variances assumed	3,069	,082	1,073	174	,142	,285	,15994	,14911
	Equal variances not assumed			1,066	165,080	,144	,288	,15994	,15008
8. Independence and self-fitting is a primary benefit of OTC hearing aids.	Equal variances assumed	2,415	,122	1,070	174	,143	,286	,19151	,17891
	Equal variances not assumed			1,068	170,281	,144	,287	,19151	,17937
9. OTC hearing aids will increase the risk of misdiagnosis and bad fitting/rehabilitation.	Equal variances assumed	,566	,453	-1,024	174	,154	,307	-,14596	,14254
	Equal variances not assumed			-1,031	173,338	,152	,304	-,14596	,14155
10. OTC hearing aids will encourage more individuals with hearing loss to seek treatment earlier.	Equal variances assumed	,198	,657	-,673	174	,251	,502	-,10300	,15308
	Equal variances not assumed			-,674	173,515	,251	,501	-,10300	,15281
11. The absence of professional fitting for over-the-counter (OTC) hearing aids could negatively impact the consumer experience.	Equal variances assumed	,197	,658	-,664	174	,254	,508	-,08178	,12315
	Equal variances not assumed			-,664	172,721	,254	,507	-,08178	,12312
12. Stricter regulations are needed for OTC hearing aids.	Equal variances assumed	,014	,907	-,332	174	,370	,740	-,04141	,12457
	Equal variances not assumed			-,333	173,373	,370	,740	-,04141	,12439
13. I am adequately informed about the regulations surrounding OTC hearing aids in my country.	Equal variances assumed	1,536	,217	-2,548	174	,006	**,012**	-,47981	,18828
	Equal variances not assumed			-2,535	167,180	,006	,012	-,47981	,18924
14. OTC hearing aids are a step forward in hearing healthcare and will benefit a lot of people.	Equal variances assumed	,189	,664	,387	174	,350	,699	,06418	,16597
	Equal variances not assumed			,386	171,588	,350	,700	,06418	,16618
15. I am interested in assisting patients with the selection of OTC hearing aids.	Equal variances assumed	,249	,618	-,445	174	,328	,657	-,08178	,18372
	Equal variances not assumed			-,444	170,407	,329	,658	-,08178	,18417
16. I am interested in selling or recommending OTC hearing aids in my practice.	Equal variances assumed	,424	,516	-,353	174	,362	,724	-,05952	,16861
	Equal variances not assumed			-,352	170,186	,363	,725	-,05952	,16906
17. I think that OTC hearing aids may discredit/devalue hearing rehabilitation itself.	Equal variances assumed	,576	,449	-,681	174	,249	,497	-,10870	,15972
	Equal variances not assumed			-,679	170,639	,249	,498	-,10870	,16008
18. OTC hearing aids will significantly change the hearing healthcare market.	Equal variances assumed	2,240	,136	1,086	174	,140	,279	,16356	,15068
	Equal variances not assumed			1,080	166,884	,141	,282	,16356	,15148
19. OTC hearing aids will decrease the number of hearing healthcare professionals.	Equal variances assumed	,012	,912	-1,322	174	,094	,188	-,19255	,14566
	Equal variances not assumed			-1,322	172,623	,094	,188	-,19255	,14564
20. Consumers need more education on the proper use and limitations of OTC hearing aids.	Equal variances assumed	,085	,771	,627	174	,266	,531	,07091	,11305
	Equal variances not assumed			,626	171,541	,266	,532	,07091	,11319
21. OTC hearing aids could lead to worsening untreated hearing loss due to misdiagnosis or improper use.	Equal variances assumed	,005	,946	-1,383	174	,084	,168	-,20393	,14747
	Equal variances not assumed			-1,388	173,940	,084	,167	-,20393	,14698
22.OTC hearing aids should come with a mandatory follow-up consultation with a professional.	Equal variances assumed	2,123	,147	,545	174	,293	,587	,07350	,13498
	Equal variances not assumed			,541	164,127	,295	,589	,07350	,13594

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