Factors affecting outcomes in children with cochlear implants in Chile considering the Latin American Context

Mario Andres Bustos-Rubilar

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Division of Psychology and Language Sciences
Department of Language and Cognition
University College London

Declaration

“I, Mario Andres Bustos Rubilar confirm that the work presented in my thesis is my own. Where information has been derived from other sources, I confirm that this has been indicated in the thesis.”

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One does not solve the problem of childhood without solving, in its midst, the social problem.

No se resuelve el problema de la infancia, sin resolver en su mitad el problema social.

Gabriela Mistral, Paris, December of 1927

This project has been mainly supported under the guidance of women. While childhood and its demands know no boundaries, remarkable women with extensive experience and profound expertise have always been there to offer integrated solutions and comprehensive insights for the most vulnerable. I extend my heartfelt thanks to all of you, especially my supervisors Dr Merle Mahon and Dr Fiona Kyle, my mother Teresa, my family, friends, and especially who those supported me in this revelatory journey.

Abstract

In Chile, one of the most developed countries in Latin America, the incidence of congenital deafness in children is approximately 2.8 per 1000 newborns. This represents a significant challenge for the public health system in terms of intervention. Deaf children with permanent, severe, or profound hearing loss face multiple communication challenges, which can be addressed through the use of sign language, spoken language, or a mixed communication. When it comes to spoken language development, equipping deaf children with cochlear implants (CI) has proven to be beneficial, especially when the implantation occurs at an early age. Rehabilitative interventions for deaf children in Chile are implemented within the framework of the Explicit Healthcare Guarantees (GES) policy. However, up to the present time, no study has been published to evaluate the effectiveness of the national policies incorporated in this plan. Furthermore, there is a need for local measures of expected outcomes with CI and the factors influencing these outcomes in Chile and Latin America. This is particularly important given the shared challenges in the region, such as inequalities and social determinants of health.

Thus, the aim of this thesis was to determine the factors affecting spoken language outcomes in children with CI in Chile, taking into account the Latin American context. The project involved multiple investigations, including the transcultural adaptation of instruments into Chilean Spanish, the characterisation of the national population of children and adults with CI (n=107), and a longitudinal follow-up study on the progress of spoken language in a sub-sample of children with CI in Chile (n=49). The results of these studies were consistent with previous research, highlighting that influencing factors depend on the child, the family, and the local context. These factors encompass early identification, additional challenges, social determinants of health, the daily CI use, family involvement, and the use of spoken language in educational environments.

The thesis also offers significant insights into the underdevelopment of spoken language skills among our sample of children with CI in Chile and the role of social inequalities in hindering their progress. Additionally, they shed light on the lack of policies directed toward minority groups, such as children with disabilities, which are issues specific to Chile and the Latin American region.

Impact statement

The findings of this thesis offer valuable insights into the early intervention pathways for children with CI in Chile and the Latin American region. These insights consider the various challenges these children may encounter in contexts of high levels of inequality and a lack of intervention services. Moreover, the evidence presented in this thesis underscores the importance of evaluating spoken language outcomes and their progression in low and middle income regions, where nearly 80% of children worldwide reside. Findings describe underdeveloped results with the CI, which are commonly unreported by international evidence.

This thesis contributes to the field of children with CI intervention in several ways. It introduces a new instrument designed to measure the expected outcomes of children with CI in Chile. It also characterises 70% of children and 80% of adults in Chile who have used CI between 2017 and 2020. Moreover, it presents findings from a longitudinal follow-up study of children with CI in Chile. These findings make specific contributions to the international evidence of factors influencing outcomes for children with CI in the country. Highlighted are the positive impact of early implantation, absence of additional difficulties, higher well-being and access to services in boroughs, favourable social determinants of health, extensive daily use of CI, high confidence in CI among parents/caregivers, and the role of spoken language in educational environments.

From a policy perspective, this thesis advocates for a comprehensive approach to address the reported findings, aligning with the principles of sustainable development. It suggests integrated policies to enhance interventions for children with CI. Central to this approach is establishing a sensitive social protection system designed to address the specific challenges parents/caregivers face when dealing with children with CI, especially in low and middle income regions characterised by inequality and limited access to services.

Table of Contents

Table of Figures

Table of Tables

Glossary & Abbreviations

Term	**Definition**
A	
Aetiology	Health condition provoking hearing loss in deaf children
Additional Difficulties (Add Diff)	Comorbidity or conditions with cognitive or behavioural compromise.
B	
Borough Development Index (BDI)	In Chile, this is an index variable showing a composite number related to well-being and access to services in boroughs. It ranges from 0 (low) to 1 (high) in relation to each territory's socioeconomic outcomes, living deprivation, and urbanisation.
C	
Categories of Auditory Performance (CAP II)	Instrument for auditory and speech perception performance evaluation in children with CI.
Child with CI Survey 1 (C1 Survey)	Survey to parents/caregivers used in Study 1 (Characterisation study)
Child with CI Short Survey 1 (C1 short Survey 1)	Survey to parents/caregivers used in Study 2 (Longitudinal study)
Child with CI Survey 2 (C2 Survey)	Survey to parents/caregivers evaluating spoken language outcomes in Study 2 (Longitudinal Study)
CI Age	Chronological age at CI surgery.
CI Condition	Variable about the cochlear implant condition, considering operativity and technical device issues.
CI Confidence	Parental Engagement variable measuring the parents/caregiver confidence in the intervention for children with CI.
CI Training	Parental Engagement variable measuring their previous training about the CI in parents/caregivers of children with CI.
Cochlear Implant (CI)	Surgically implanted electronic device providing sense of sound
Communicative Development Inventories (CDI)	Instrument for language evaluation including versions for understanding and production of gestures, words and sentences.
D	
Children with CI	Deaf or hard of hearing children using a unilateral or bilateral cochlear implant due to severe to profound hearing loss.
E	

English Expert Committee	Committee supporting decisions about translation during the thesis project, which was composed of English-speaking professionals.
F	
Family Highest Education (FHE)	Highest education completed by the closest parent/caregiver of a child with CI.
G	
Geers and Moog scale (GeersM)	The Geers and Moog Scales of Early Communication Skills for hearing-impaired children.
GES	The Chilean “Explicit Healthcare Guarantees” policy number 56 and 77 for CI. In Spanish “Garantías Explicitas en Salud”.
H	
Hearing age	In children with CI, hearing age is calculated as their age in years after switching on the CI.
L	
Late Hearing Loss	Hearing loss acquired after the period of spoken language acquisition.
Ley Ricarte Soto (LRS)	High-cost policy providing cochlear implants to children and adults with late hearing loss.
O	
Opinio	Platform provided by UCL to complete surveys online.
Open Science Framework (OSF)	Initiative of open science providing an online platform for completing research pre-registrations.
P	
Programa MINSAL policy	Chilean evidence-based policy providing cochlear implants to deaf children and adults.
S	
School and nursery placement attendance (SNPA)	Variable evaluating rich or less rich spoken language education environment for children with CI
Social Health Insurance (SHI)	Chilean socioeconomic health insurance given by the national public health system to each insured person according to their income. In Spanish, Fondo Nacional de Salud (FONASA).
Socio Determinants of Health	Conditions in which people are born, grow, live and work together with a set of forces and systems shaping the conditions of daily life.
Speech Intelligibility Rating Scale (SIR)	Instrument for rating intelligibility and spoken language production in children with CI.
T	
The Chilean Ministry of Health (TCMH)	Chilean government division in charge of the national health system.

Introduction

This research aims to characterise children with cochlear implants (CI) in Chile and to explore the factors that may affect their spoken language outcomes expected with the device. Understanding these factors and the Chilean and Latin American context is crucial for developing effective local interventions and improving integrated policies that optimise the spoken language development and well-being of deaf children in Chile. In this project, children with CI refers to children with permanent, severe to profound bilateral deafness using CI. Although the thesis also contains clinical terms about deafness and will refer in some sections more widely to groups using the term 'deaf or hard of hearing children', children with CI will be the primary concern of this research. Moreover, it is essential to note that this thesis not specifically considering deaf children and parents for whom sign language is the main means of communication, although this will be considered in discussions where the approach might be relevant.

In terms of thesis composition, this project is divided into eight consecutive chapters. Chapter 1 provides a literature review that examines deaf children's characteristics, challenges, and needs, with a specific focus on cultural and societal factors in Chile and Latin America. It highlights the importance of language development and explores how audiological, clinical, and social factors affect outcomes. The chapter emphasises the vital role of research in CI interventions and policy assessments.

Chapters 2 to 6 examine the research aims, objectives and hypotheses through two studies, namely Study 1 and Study 2.

Chapter 2 provides a general introduction for Study 1 and Study 2, which are reported in detail from Chapters 3 to 6. Chapter 3 presents an account of the methods employed in Study 1, aiming to characterise children with CI in Chile who received the CI within the national public services between 2017 and 2019. This chapter outlines the research design, adaptation of the study during the pandemic, collaborative efforts with the Chilean Ministry of Health, participant selection criteria, data collection procedures, and the employment of relevant assessment instruments.

In Chapter 4, the results of Study 1 are presented, providing an in-depth characterisation of children with CI in Chile. This shaped the research methods employed in Study 2, which aimed to explore the influential factors affecting spoken language in children with CI in Chile. Thus, Chapter 5 outlines the longitudinal data collection procedures, the assessments used, and the variables scrutinised within Study 2. Finally, Chapter 6 presents the findings of Study 2, presenting an analysis and interpretation of the results. This chapter explores the intricate relationships between various factors and specific spoken language outcomes to address the research questions and hypotheses.

In Chapter 7, the results and interpretation of the findings from both studies are discussed. The discussion of Study 1 and Study 2 focus on the complex interplay of factors influencing outcomes in children with CI in Chile within the Latin American context. In this chapter the implications of the research outcomes for interventions and policymaking are also explored. It highlights the significance of socioeconomic factors, educational support systems, and social protection interventions in promoting optimal results and well-being for this vulnerable population. The chapter also critically evaluates the limitations of the current studies, identifies avenues for future research, and argues for continued efforts to improve the policies and public services for deaf children and families.

Finally, a concluding summary of the entire project is presented. It combines the key findings from the literature review, Study 1, and Study 2, emphasising their implications for practice and policy. This final section reaffirms the significance of evidence-based research in guiding interventions and policymaking, particularly in addressing the unique challenges of children with CI. It underscores the importance of considering cultural and societal factors within Latin American policy to ensure equitable development and well-being opportunities.

Chapter 1: Background and Literature Review

1.1. Background

1.1.1. Worldwide and Latin American Incidence of Deafness

Deafness from birth represents a substantial challenge for children’s language acquisition and general well-being. The condition, also named in health as severe to profound bilateral hearing loss, affects more than 430 million people worldwide and impacts their daily lives in many ways. This accounts for over 5% of the world population, with the majority residing in low and middle-income countries (WHO, 2022). The prevalence of moderate or more severe levels of deafness differs around the globe. According to the World Health Organization (2021), zones such as the African region present an incidence of 3.6%, this rises to 6.2% in the European and Americas territories.

Latin America, as part of the Americas, shows a prevalence of 6.18% (WHO,2018), with around 16 million deaf and hard of hearing children below 14 years of age (WHO, 2017). The region is vast and diverse, where Spanish and Portuguese are the primary spoken languages, sharing a common cultural heritage alongside various political and economic challenges (De Garcia et al., 2011). In Chile, one of the most high income countries with pronounced inequalities in Latin America (Flores et al., 2020), the incidence of a congenital condition causing hearing loss in children is around 2.8 per 1000 newborns (Nazar et al., 2009). Moreover, the prevalence of this condition in school-aged children in the country varies among areas between 0.2% and 7.8% (Torrente et al., 2023), representing a challenge to the health and education systems to provide timely intervention.

In terms of cochlear implantation for children in Chile, public regulations providing the devices have been available since 2013 (Minsal, 2016). The latest policy established in 2018 includes the provision and treatment for children diagnosed before the age of four (Minsal, 2018) with a subsequent policy covering from four year of age up to older ages (Minsal, 2022). Although the exact number of children implanted per year in the country is not specified, the program operates in seven different hospitals nationwide with stable CI teams, including ENT doctors, audiologists, speech-language therapists, psychologists, and social workers. In term of cost of the CI in the public sector, the intervention is free once the diagnosis is completed. From 2022, a defined pathway was established thanks to the universal screening regulation in the country, whereby all children are evaluated in the newborn units with immediate referral in case of potential conditions of hearing loss. At the regional level, countries with similar coverage through public health services, such as Mexico and Argentina, have been identified (CSG México, 2010; Ministerio de Salud, 2016).

1.1.2. The context for this study within Latin America

Chile is the southernmost country in Latin America and the longest worldwide, with an extension of more than 2600 miles with a truncated geography secluded by the Andes mountain range (Precht et al., 2016). Its population, of which 99.3% speak Spanish without a broad ethnic diversity, is around 19 million, with a denser population in the country's centre (World Bank, 2022). The Capital, Santiago de Chile, and three regional cities, including Concepcion in the south, Antofagasta in the North and Valparaiso at the central coast, represent the densest population areas in the country (Precht et al., 2016). The country has a national public health system covering approximately 82% of the population, with the remaining 18% served by the private sector (World Bank, 2022). According to the OECD, the country is classified as a high-income country, providing extensive coverage in maternal care with 99% of newborns at hospitals. From their birth children also have access to health services throughout their life cycle. In addition, 99.8% of the population has access to drinking water, and the country presents the highest life expectancy in the region at 79.6 years post-pandemic (Minsal, 2022). The literacy rate in the country stands at 97.6% among individuals aged 15 and above (UNESCO, 2022).

Although the high classification of the country in economy, health provision, and other dimensions (OECD, 2022), it faces similar challenges in early intervention and healthcare access as does the rest of the Latin American region (De Garcia et al., 2011). There are common issues in access to services and policies for children with disabilities, including deaf children, for example, limited essential services such as healthcare, education, and rehabilitation. Insufficient infrastructure, a shortage of specialised professionals, and long waiting lists also contribute to treatment barriers. In addition, according to UNICEF (2021), the lack of high-quality support services and coordination between different sectors involved in supporting children with disabilities can worsen the intervention opportunities for this group. Latin America also presents tremendous challenges in providing required services for children in rural and remote areas, exacerbating disparities in health interventions and social development.

Challenges in Latin America must be added to the current conditions faced by children with disabilities worldwide. According to Wickenden (2018), disabilities in children are part of some "*types of human diversity, but they are denied citizenship and inclusion in a range of ordinary activities as a result of society's habitually negative response to them*" (p.158). This raises essential topics concerning significant intervention and development challenges for children in Chile and the Latin American region.

The Sustainable Development Goals (SDGs) are a set of global aims established by United Nations member states to address the world's most pressing social, economic, and environmental challenges. Adopted in 2015, the SDGs consist of 17 interconnected goals that guide governments, organisations, and individuals towards achieving a more sustainable and equitable future by 2030 (Moore, 2015). Sustainable Development Goal 10 (SDG 10) aims to reduce inequalities, recognising that disparities in income and access to services can perpetuate and exacerbate social and economic inequalities within societies. SDG 10 emphasises the need to ensure that people, in this case, deaf children, regardless of their background or circumstances, have equitable access to quality healthcare services and inclusive education systems (Oestreich, 2018).

In line with SDG 10, the research on social determinants of health tackling health inequalities has been extensively addressed (Friedman, 2021; Sokol et al., 2019; Wolbring, 2011). Social determinants of health are the conditions in which people are born, grow, live and work together with a set of forces and systems shaping the conditions of daily life (Bonner, 2017). These determinants include socioeconomic status, education, employment, social support networks, healthcare and education services access, and the physical environment (Marmot, 2005). They significantly influence an individual's health outcomes and overall well-being. Children with disabilities face unique challenges and experiences that can impact their health, which can be worsened by their age and disability condition (Sokol et al., 2019).

Therefore, it is relevant to consider the inequalities and social determinants of health in research on deaf children in Chile, taking into account the Latin American context. Bringing together these two concepts provides a comprehensive understanding of the common issues deaf children might face at a population level, establishing a baseline of challenges regarding the inequalities and determinants they need to address as a group, in addition to the individual considerations they will need to address from an early stage. In this field, previous findings have reported particular challenges in intervention for deaf children. Bright et al. (2019) have suggested ongoing comparable challenges for deaf children and adults in terms of economics and access to healthcare, characterised by the unequal distribution of professionals and their concentration in urban areas. This can affect deaf children's interventions at early ages, limiting the possibilities of implementing the recommendations in early child development given by professionals and institutions.

The next section will review studies concerning interventions for deaf children. Most of the evidence comes from studies in English-speaking and high income countries.

1.2. Literature review

1.2.1. Cochlear implants as an early intervention for deaf children

Deaf children, who present with a severe-profound level of deafness and are deaf from birth or an early age, can experience difficulties in language development. This can cause communicative issues, which in turn can limit their social inclusion and communication modes, using sign language, spoken language or mixed modalities (Knoors & Marschark, 2018).

In the case of spoken language, early intervention is required to support deaf children and families with the provision of technical and professional assistance. Early intervention in deaf children has been marked in the last decades by two different models of disability. First, a medical model of disability, focused on hearing stimulation and spoken language development (Ha'am, 2017). Second, a socio-anthropological model aimed to recognise deaf people as a group with their own culture and language, which must be respected and promoted from early childhood (Ladd & Lane, 2013).

In this sociocultural understanding of deafness, there is a comprehensive model encompassing health, education, and social considerations for this cultural group, which has been overshadowed by orally focused interventions. Considering access to rights, the United Nations Convention on the Rights of Persons with Disabilities (UNCRPD) offers a comprehensive declaration about the expanded requirements that deaf people and people with disabilities deserve, including access to sign language, inclusive education, social and labour inclusion, and other comprehensive measures for development. Therefore, in case of deaf children, it is recommended that they must be assessed under the medical and socio-anthropological models (Grosjean, 2001; Hall & Dills, 2020; Hall et al., 2019; Harris, 2012; Long et al., 2021). However, considering the focus in the main outcome of CI in relation with spoken language development, this project is mostly aligned with the medical model of intervention.

In the medical model, intervention for deaf children is generally based on a timely diagnosis starting with a newborn screening, which in high income countries has been well stablished. Later, treatment consisting of the provision of amplification aids, either hearing aids (HA) or cochlear implants (CI) is considered (Peterson et al., 2010; World Health Organization, 2021; Yoshinaga-Itano et al., 2018). International audiology recommendations delineate general actions and critical timeframes for early intervention. One general recommendation for deaf children and hard of hearing children is the Early Hearing Detection and Intervention 1-3-6 guidelines. This specific intervention proposes a timely neonatal screening at the first month of age, coupled with confirmation of the diagnosis at the third month. Later, by the age of six months, interventions such as HA and specialised treatments, which are necessary for better language outcomes in deaf children, are suggested. (Yoshinaga-Itano et al., 2020; Yoshinaga-Itano et al., 2018).

In the case of CI as a subsequent intervention for deaf children, implantation at an early age is highly recommended. Recent studies have suggested implantation from nine months of age (Park, Gagnon & Brown, 2021) rather than twelve months (Nikolopoulos, Archbold & Gregory, 2005). In regional regulations, Chile and other Latin American countries such as Mexico and Argentina still have guidelines for implantation after 12 months of age (CSG México, 2010; Ministerio de Salud, 2016; MINSAL, 2013). However, while early implantation at a very young age can facilitate early access to spoken language, it may inadvertently overlook the importance of a more comprehensive approach that includes stimulation through sign language. Adhering solely to the medical model perspective, which posits that spoken language development in children with CI can only be achieved through early auditory stimulation, may indicate a limited understanding of the intricate nature of language development.

Therefore, after receiving a CI, a multidimensional intervention must be provided among highly qualified professionals, including social, educational, and healthcare services (Holzinger, 2022). Following this line, efforts should be directed towards promoting language acquisition, social inclusion, and overall well-being of the child and family (Constantinescu-Sharpe et al., 2017; Grosjean, 2001; Hall & Dills, 2020; Killan et al., 2022; Niparko et al., 2010). Lastly, education-related recommendations underscore the need for specific adjustments and supportive measures to unlock the maximum potential for learning in children with CI (Choo et al., 2021).

At the political level, each country's early child development and health policies commonly include recommendations as technical guidance for professionals. Policies for CI intervention in children differ by country, with packages including specific services and coverage. In high income countries, many services are included as part of the universal health coverage, encompassing integrated services for health services, social protection and education (NHS, 2015; Sorkin & Buchman, 2016). Additionally, most published evidence of children with CI comes from these countries, where there would be optimal conditions offering results that, in many cases, only apply to similarly high income countries.

In the case of middle or low-income countries, where most deaf children live, challenges regarding early services, policy coverage, and cost efficiency of the CI intervention could limit the possibility of following international recommendations (Bright et al., 2019; Madriz, 2000). Regarding the policies providing CI to deaf children in Latin America, each country presents its own policy from its national health services. This is the case in Mexico (CSG México, 2010), Argentina (Ministerio de Salud, 2016), and Brazil (Magalhães Barbosa et al., 2014). However, no wide national monitoring has been reported in the last five years in these countries.

In Chile, policies and interventions for deaf and hard of hearing people have only recently been enshrined in law. Hearing loss was included in the 2013 regulation “Explicit Healthcare Guarantees - GES” (Minsal, 2016), in which standard criteria for diagnosis and treatment for children are defined. In 2018, the regulation “Ricarte Soto Law (LRS)” included CI provision and subsequent interventions for adults and children not included in other regulations. The Chilean public health system currently covers the cost of various early services, including national screening programs in public hospitals (Minsal, 2022). In cultural understanding of a deaf person as a person with disability, Chile ratifies the UNCRPD with regulations emanating from the Ministry of Social Development and Family without integration with health policies, provoking in many cases contradictory practices for deaf people, but also stigmatized beliefs around the deaf community and sign language (Bustos-Rubilar et al., 2022). In health also there remain some challenges children with CI and their families, which are specific to the country context, namely:

1) Early diagnosis because the national newborn hearing screening was introduced only in 2020 (Minsal, 2020).
2) Distance from the public health treatment centre.
3) Socioeconomic burden on the children’s families.
4) Lack of diversity in professionals, treatments and outcomes (Bustos Rubilar et al., 2018).

These challenges in Chile, and the Latin American region, together with policies not covering every needed aspect of health, education and social services, could influence the expected deaf children's trajectories.

1.2.2. Language development in deaf children.

Although language development in deaf children cannot be understood as a single trajectory, it is possible to draw a parallel between their pathway and that followed by typically developing hearing children. Thus, while typically developing hearing children show consistent milestones in spoken language development during their first years of age, deaf children face diverse options for language development with different outcome results. In the case of children with CI, several factors could affect their spoken language development (Yoshinaga-Itano et al., 2018). Nevertheless, before addressing any factors that affect the spoken language development of children with CI, it is essential to describe how language development evolves in deaf children by considering typical language development as a reference.

1.2.2.1. Typical language development from a Social Cognitive perspective

Considering language development as an outcome requires understanding how social contexts frame and support its development. From a Social Cognitive perspective, language development represents a cognitive process requiring a social-communicative context (Lieven & Tomasello, 2008; Rowe & Weisleder, 2022). According to Hoff (2006) and Hoff et al. (2022), although language is based on innate human capacities, environmental conditions with communicative interaction are necessary for language acquisition. In this context, variables at a macro level, such as culture, socioeconomic status, and ethnicity, might directly influence language development. At a micro-level, children's social environment variables, such as multilingualism, maternal age, childcare and school, can shape good or poor language development, which might not apply to all children. Evidence suggests the importance of how rich the language input is and how favourable the communicative interaction is experienced by the child, which might depend on these micro and macro-level variables (Hall et al., 2019; Hoff, 2006; Lederberg et al., 2013).

Therefore, innate potential and communication interaction contribute to language development in typically developing hearing children. In the first 12 months, children use pointing and babbling to communicate what happens around them, showing imperative, declarative, and informative interactions. This time represents the beginning of social interaction. First-word production will mark a new stage from one year of age with constantly increasing vocabulary, word combinations, and better sentence comprehension and production (Tomasello, 2015).

Around 18 months of age, children start word combinations, pivot schema and item-based constructions. For instance, children could use the expression “toy table!” to reference some games with cards on the table. Later, a pivot schema appears as the first systematic pattern of productions, using sorted syntactic symbols and an active role in the communicative context. For example, a child could use “now” as a permanent word used but with different meanings; “now puppy” (I want to see the puppy!),” now toy” (Give me the toy), “now you” (It is your turn). Finally, item-based constructions appear after pivoting as a construction with some syntactic rules from the native language (Hirsh-Pasek & Golinkoff, 1996). Children would commonly say “mom playing” rather than “playing mom” to describe a mother’s action.

Children between 2 and 3 years of age start to use abstract constructions, which have different functions depending on the context, such as identificationals, possessives, datives, locatives and questions. However, more complex structures will be necessary to adapt the children’s language to adults’ expressions. By about five years of age, most typically developing hearing children will have developed complex language comprehension and expressive constructions.

1.2.2.2. Language Development for Deaf Children from the Socio-Cognitive Perspective.

It is essential to recognise that language development in deaf children should not be described from an ableist perspective based on an absence of auditory stimulation. While typically developing hearing children have a fully formed cochlea by 3-4 months gestation and start to hear various sounds, deaf children’s first language steps will begin after birth, perceiving their surroundings in a visual mode (Knoors, 2019). This distinguishes the development and milestones expected from deaf children. Nevertheless, according to Lederberg (2013), in the first months, similar to typically developing hearing children, babbling represents the first vocalisation in deaf children.

From seven months of age, phonological expressions in the family’s native language emerge. This is canonical babbling, which seems to be the first difference between typically developing hearing and deaf children. Canonical babbling will allow typically developing hearing children to produce syllable duplications and strings of sound creations. For deaf children, on the other hand, depending on their degree of deafness, vocalisation and sound combination will be varied. For example, studies have shown that deaf children using CI from a prelinguistic stage of development increase the variety of combinations they develop across the babbling period, which is a predictor of their spoken language (Ching et al., 2018; Lederberg et al., 2013; Moeller, 2000). After this period, between 7 to 18 months of age, in typically developing hearing children, prelinguistic communication and cognitive skills work together to produce the first words expressed by the child. In deaf children, this period will depend on language stimulation using formal sign language or spoken language using hearing (Lederberg et al., 2013).

In the next stage of language development, from one to five years of age, language differences between typically developing hearing children and deaf children can be more pronounced depending on the input received. After the first word in typically developing hearing children, from 18 to 24 months of age, there is a rapid increase in expression and interaction. For deaf children, the development of spoken language will depend on the stimulation given by their parents and the use of HA or CI. Children with CI might improve their vocally responsive communication after implantation (Lederberg et al., 2013), achieving, in some cases, better-spoken language comprehension and production when they reach school age.

Conversely, deaf children without technical amplification or previous sign language input might develop gestures and ‘multi-element’ turns, which might be semantic referents using words and gestures. Therefore, gestures might be an essential communication tool in this context (Mahon et al., 2009). Nevertheless, communication without a consistent modality might not be sufficient to have functional language development.

It is important to consider that while deaf children’s language development depends on the richness of their communication environment, it also must include non-verbal communication (Knoors, 2019). Offering visual communication and the possibility to access communication through sign language might benefit language development even for children with CI. This is significant because regardless of the modality of language used, it is imperative at an early age to establish proficient communication, whether through visual (sign language), spoken or mixed methods using signs and spoken language (Harris, 2012; Knoors & Marschark, 2018). In the case of deaf children for whom spoken language is often the preferred modality, the CI has been considered a helpful device when providing a favourable communication environment.

1.2.2.3. Neuroplasticity as a complementary perspective in spoken language development of deaf children with CI

An explanation of the efficacy of the CI in facilitating spoken language development in deaf children can also be expounded within the framework of neuroplasticity. This perspective, might complement the socio-cognitive perspective of language development, offering insights into the critical period of brain development and its early connections. Considering connectionist accounts as brain working models, neuroplasticity describes the relationship between neural networks and brain regions, responding to stimuli and designing responses (Hagoort, 2015). This cognitive ability could also explain language development in typically developing hearing children and deaf children. Concerning this last group, early stimulation has been a crucial premise based on other factors for language development, which is described as a cerebral specialisation that emerges as learning from the environment at specific times (Sheehan & Mills, 2008). This cerebral specialisation in deaf children without hearing stimulation occurs through cross-modal plasticity, a neuronal adaptation to the deafness (Bavelier & Neville, 2002) where the brain changes its structure and function according to the visual input. Deaf children might show partial auditory responses due to visual colonisation in cortex areas, which typically process sound, speech and spoken language, promoting visual communication (Codina et al., 2011).

In hearing stimulation, the utilisation of CI in deaf children at an early stage has been identified as a complementary support, integrating hearing input with visual stimulation before neuronal adaptation. This process in children with CI might depend on critical periods based on neuroplasticity. However, not everything relies solely on assumptions drawn from neuroplasticity or Socio-Cognitive approaches to CI use in deaf children. The complexity of the device, as well as the development of language itself, necessitates a comprehensive analysis of both the device's functionality and its role in supporting spoken language development in deaf children.

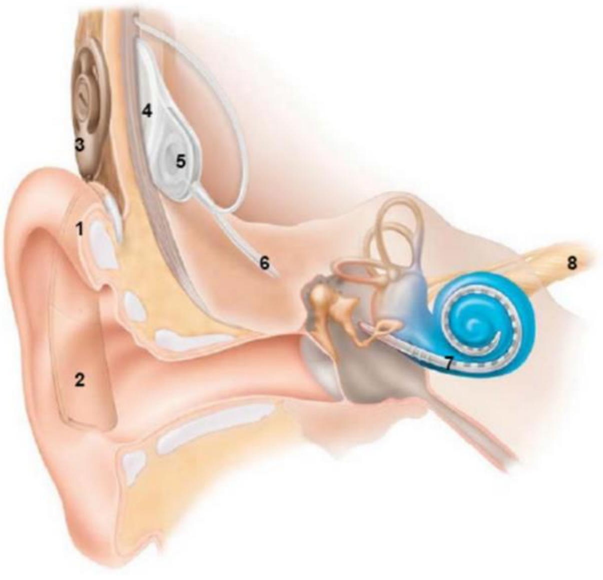
1.2.3. Cochlear Implants for spoken language development in deaf children

1.2.3.1. Functioning of a cochlear implant

The CI is an electronic device that transforms acoustic information into electric stimulation using an implanted device (Peterson et al., 2010). The device's stimulation increases hearing levels, allowing detection thresholds closer to the standard (Dinino & Arenberg, 2018).

Figure 1 shows a diagram of a cochlear implant. The device utilises an external microphone positioned either behind the ear or on the side of the head. It captures sounds and converts them into a digital signal. This signal is processed and transmitted wirelessly across the skull using radio frequencies. Inside the skull, an implanted internal coil receives radio frequency signals. The internal stimulator decodes the signal and converts it into electrical pulses. These pulses travel through wires and reach electrodes threaded through the cochlea. The electrodes are spread throughout the cochlea to ensure that the electrical pulses are filtered into different frequency ranges, specifically target neural groups (Zeng et al., 2008) . Although the brain interprets these pulses as organised sounds, they differ from natural hearing stimulation in their inability to accurately distinguish between different sound frequencies and effectively transmit rapid changes in sound amplitude. Under the current technology, cochlear implant systems employ merely 12 to 22 electrodes for stimulating the remaining auditory nerve fibres, whereas natural hearing encompasses 30,000 auditory nerve fibres to convey intricate details of incoming sounds and music (Hochmair et al., 2015; Kuczapski, 2019).

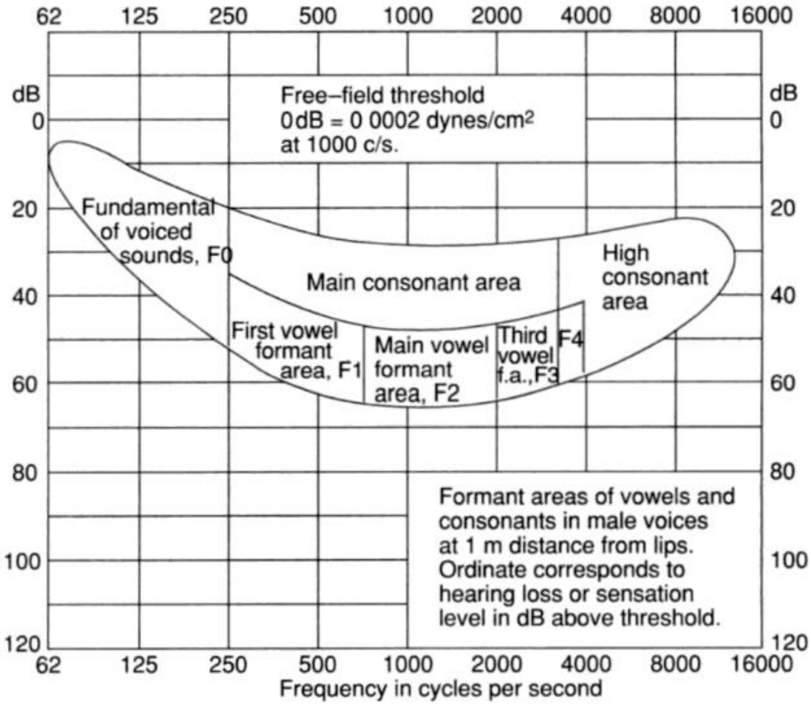
Figure 1. Diagram of a cochlear implant in a deaf user



Note: Numbers on the diagram 1) the behind-the-ear external processor, 2) the battery case, 3) the External magnet and coil, 4) the Internal receiver with magnet and coil, 5) the simulator, 6) wires threaded into the cochlea, 7) the electrode array, and 8) the auditory nerve. Image from Zeng et al. (2008).

Still, auditory information from the CI can facilitate speech perception by providing access to essential speech sounds that are often not lip-readable (Davidson et al., 2019). For example, /s/ is an essential non-lip-readable sound in English and Spanish because it is a morphological marker. The 'speech banana' illustrates how speech sounds are typically distributed according to their formants regarding frequency and intensity (Reyes-Quintos & Chiong, 2012). Figure 1 shows the speech banana with different formant areas in an audiogram with frequencies on the horizontal axis and intensity in decibels (dB) on the vertical axis.

Figure 2. Speech Perception Banana



Note: Schematised representation on the average speech spectrum within an audiogram in main formant areas. Intensity level (increasing downward) are relative to the standardised threshold. Image extracted from Fant (2004).

With access to this auditory input, children with CI will be able to hear voices and might acquire better speech discrimination and word recognition (Davidson et al., 2019). Although the device does not replace the natural hearing function, one of its principal aims in children is to contribute to the speech perception abilities and thus to spoken language development (Boons et al., 2012; Nicholas & Geers, 2013; Niparko et al., 2010; Thomas & Zwolan, 2019). However, this contribution may vary according to the deaf child's communicative context, as explained in section 1.2.3.2 below.

1.2.3.2. Cochlear Implant and Spoken Language outcomes in deaf children.

Spoken language, social inclusion and general well-being are among the most commonly measured outcomes in children with CI.

1.2.3.2.1. Speech Perception and Spoken Language Outcomes

Spoken language development in children with CI has been studied for the last 30 years, mostly in high-income countries, identifying multiple factors crucial for successful language development. Initially, research primarily concentrated on speech perception as a simple outcome, such as the ability to distinguish phonemes and words and the intelligibility of speech (Ganek et al., 2012).

As part of spoken language development, these abilities have continued to be used as practical monitoring skills, utilising scales filled out by clinicians and parents/caregivers. For example, a systematic review that evaluated the benefits of speech perception after cochlear implantation revealed that children who received implants significantly improved early speech perception. After one to three years, children with CI were expected to identify tones and recognise words in noise (Chen & Wong, 2017). Similarly, the Longitudinal Outcomes of Children with Hearing Impairment study (LOCHI) (Ching et al., 2018), which followed 468 Australian children with hearing loss up to the age of 12, found that early implantation had clear advantages in terms of speech recognition. The study showed that implantation between 6 months to 1 year resulted in a decrease of 0.3 standard deviations in the potential benefits of the CI in speech perception. Children implanted before the age of 12 months demonstrated significantly better auditory performance and improved speech perception outcomes compared to those implanted after 12 months of age.

In recent years, more comprehensive aspects of language development have been studied, including comprehension and production scales, discourse, pragmatic abilities, and vocabulary. In evaluations conducted in the last decade, children with CI might under-achieve in standardised assessments of speech and spoken language skills (Ching & Dillon, 2013; Ching et al. 2018; Hall et al., 2019; Hasnain et al., 2023; Välimaa et al., 2022). For instance, in the LOCHI study recently mentioned (Ching et al. 2018), when the effects of additional disabilities were accounted for in the 451 children with cochlear implants, the mean global language score was 77.8. This was in contrast to the typical score of 100 observed in typically developing hearing children (ibid). The result demonstrated a gap of more than one standard deviation below the normative mean, highlighting the disparity between children with hearing loss and their typically hearing counterparts at three years of age. Moreover, the National Deaf Children's Society and the Royal College of Speech and Language Therapists in the UK- a high-income country with good access to health and services (Dhrifi, 2018)- reported that 36% of CI users achieve typical parameters on spoken language development compared to 81% of typically development hearing children at the same age (RCSLT & NDCS, 2017).

Niparko et al. (2010) completed a prospective longitudinal study in 188 deaf children implanted before five years of age in the US, showing the performance on measures of spoken language comprehension and expression using the Reynell Developmental Language Scales (Reynell & Gruber, 1990). The results indicated that children who received cochlear implants improved spoken language performance more than their pre-implantation baseline scores. The average yearly improvement was 10.4 points per year in comprehension and 8.4 points per year in expression. However, the mean scores did not reach age-appropriate levels even after three years.

Similarly, Yoshinaga et al. (2018) researched 125 children with CI, ranging from 13 to 39 months old, using the Child Development Inventory and MacArthur-Bates Communicative Development Inventories (Fenson, 2007). Similar to the findings of Niparko et al. (2010), the average language abilities of the children in this study were significantly lower compared to the hearing children used as the normative sample for the language tests. The LOCHI study also established nine criteria for generating a global language score (Ching & Dillon, 2013) with global results below one standard deviation of the normative mean.

In discursive and pragmatic abilities, Crowe & Dammeyer (2021) reviewed 25 relevant studies and extracted data on participant characteristics of children with CI exhibiting a range of pragmatic skills. Findings indicate that pragmatic language difficulties are commonly observed in children with CI. Moreover, syntactic development seems to be also slower for children with CI, using Mean Length of Utterance in English, German or Dutch speakers compared with typically developed hearing children (Blamey et al., 2012).

According to Duchesne & Marschark (2019), children’s vocabulary levels are the most commonly reported outcomes for describing spoken language progression in children with CI during their first years of age. In a meta-analysis, Lund (2016) analysed twelve studies to assess whether children with cochlear implants demonstrate lower spoken language vocabulary knowledge than peers with normal hearing. The weighted effect size averages for expressive vocabulary measures ($g = -11.99$; $p < .001$) and receptive vocabulary measures ($g = -20.33$; $p < .001$) indicated that children with CI have significantly lower vocabulary knowledge compared to children with normal hearing. However, the studies were only made in English using different instruments, such as the British Picture Vocabulary Scale (Dunn et al., 1997), Expressive One-Word Picture Vocabulary Test (Brownell, 2000), Expressive

Vocabulary Test (Williams, 2007), Lexical Phonological Test (Vicari et al., 2007); and Peabody Picture Vocabulary Test (Dunn & Dunn, 2007). Moreover, the analysis did not consider the sociological determinant affecting vocabulary development in children.

While results concerning spoken language development in children with cochlear implants may vary significantly among studies and participants, a consistent trend observed in many studies suggests a continuous increase in vocabulary levels over time using the CI. For example, Fagan et al. (2015) demonstrated a substantial increase in the vocabulary performance for a small sample of 9 US children with CI, showing a mean rise from 0.67 [1.12] words at 4 months post-implantation to 102.33 [94.48] words at 12 months of age. Similarly, Koşaner et al. (2013) reported a 100-word increase in comprehension and production for Turkish children with CIs between 6 and 9 months after implantation. Therefore, evidence also suggests a diverse range of vocabulary growth in children with CI, often lower than observed in typically developing children (Dettman et al., 2016; Jung et al., 2020; Rinaldi et al., 2013). Jung et al. (2020) compared the receptive vocabulary of 126 children with CI to typically developing hearing children, both with an average hearing age of 8 months. Children with CI had a mean receptive vocabulary score of 19.5, while their typically developing peers scored 38. Despite this, considering the complexities of evaluation by parents/caregivers, vocabulary measures appear to be a reliable measure of early stage spoken language progression.

In a critical analysis of this evidence, the limitations inherent in small participant cohorts can influence the findings related to the performance of children with CI. For example, in the Crowe and Dammeyer (2021) review, out of the 25 studies included, 14 had fewer than 20 participants, with 8 of them having only one or two participants. This issue of studies with small numbers of participants is also evident for other skills, such as auditory training outcomes in children with CI. For instance, in a systematic review of studies, all 9 of the included studies had fewer than 13 participants, with some having only 1 or 2 participants (Rayes et al., 2019). This represents a weakness in much of the evidence, extending the findings and implications to every child with CI, which, at some point, can be not extensible to other contexts. Therefore, it is crucial to conduct studies with an adequate number of participants to facilitate rigorous data analysis and provide a higher quality of evidence.

Similarly, the availability of comprehensive evidence, such as longitudinal studies from low and middle-income countries, is scarce. For instance, when examining the body of evidence from Latin America in these types of studies, it becomes evident that they predominantly consist of smaller-scale research. For example, in Brazil, a limited cohort of ten children was followed to evaluate their receptive language skills using the Reynell Development Language

Scale, obtaining potential very positive results (Queiroz et al., 2010). Consequently, the majority of longitudinal studies cited in this review originates from high income countries. Thus, although these studies can offer valuable insights into diverse social and economic backgrounds, they may not fully capture the realities of countries lacking a robust national health system, facing challenges related to intervention in remote areas, or grappling with substantial disparities in the quality of services provided. Therefore, it becomes imperative to conduct additional longitudinal studies in low and middle income countries that accurately assess the circumstances faced by the approximately 80% of deaf children residing worldwide.

Moreover, although the positive benefits of the CI might be undeniable, considering the incidence of deafness and language complexity, the generalisation of highly positive findings around the cochlear implant can be challenged. In this context, considering the contribution of the device in language development, many studies have reported limited set of data describing children could develop communication skills as typically developing hearing children. For example, studies have reported findings in speech perception and language development using spoken, sign or mixed modality language during the administration (Crosson & Geers, 2001; Svirsky et al., 2000; Iwasaki et al., 2012; Lyness et al., 2013). Similarly, evidence has reported improvements in spoken language development only including speech perception and speech production broad scales, providing unspecific results about the real contribution of the device to spoken language development (Davidson et al., 2019; Lu & Qin, 2018; Peixoto et al., 2013). These limitations underscore the need for more detailed research that not only aligns with international evidence, but also serves as a valuable resource to fill the evidence gap in interventions and policy recommendations related to spoken language development for children with CI and their families

In summary, despite vast evidence of CI contributions to spoken language development, there are differences with less growth observed in spoken language skills among children with CI compared to typically developing hearing children. Spoken language as a cognitive ability with different skills might need favourable environments and rich social-communicative contexts to form it (Knoors, 2019). Furthermore, the research in this field requires a thorough analysis of existing evidence, taking into account the significant limitations that hinder the generalisability of findings from studies. In many cases, these studies exhibit biases that undermine their suitability as robust sources of research or as the basis for evidence-based recommendations.

1.2.3.2.2. Social inclusion and parental satisfaction with the CI

Various studies have reported social inclusion and general well-being outcomes of CI in deaf children, which are considered secondary aims of CI usage. Social inclusion aims to address and overcome imbalances that result from the lack of access to fundamental human, social, economic, and cultural rights within a state or society (Koehler et al., 2020). In the social dimension, a systematic review by Long et al. (2021) revealed disparities in findings regarding social-emotional development from 38 studies in preschool children with CI. Among the 15 studies that evaluated social inclusion and social interaction with peers, thirteen displayed positive results in social-emotional skills in children with CI compared to hearing peers. Six of the thirteen studies were completed through surveys to parents/caregivers, finding that children with CI aged on average three years, were able to show similar social interaction skills compared to their peers. However, the studies exhibited heterogeneity in terms of sample characterisation, utilisation of small sample sizes, and unequal evaluation methods, thereby limiting the conclusions that can be drawn regarding social inclusion outcomes.

A study conducted in India, a country with high social inequalities, with 200 parents/caregivers of children with CI using a questionnaire showed that 76% of children experienced improved social skills and participation (Sharma et al., 2017). The study also showed that 90% of parents considered that other children in the classroom socially accepted their children, which also may be high for children with CI at an early time. Regarding parental satisfaction, in the study by Sharma et al. (2017), at least half of the parents reported high satisfaction with the results of the device in their children. Nevertheless, the inclusion criteria for the study might provoke a significant bias, as it did not consider children with associated conditions and only included Auditory Verbal Therapy (AVT website) attendants, who are commonly selected as more potential spoken language speakers with the CI. In addition, participants of AVT usually need to pay for this type of treatment, thereby incurring a socioeconomic bias that predominantly shows results from wealthy children and families.

Finally, the outcomes expected with the CI and findings available have highlighted the nuanced challenges that the evidence has to evaluate the real impact of CI on a deaf child's life. Therefore, it is essential to acknowledge the need for more rigorous and standardised approaches to assess these outcomes, especially in regions without extensive evidence. In the next section, the evaluation of these mentioned outcomes in the context of cochlear implantation in deaf children in Chile and Latin America will be explored.

1.2.4. Instruments for outcome evaluation in Chilean children with CI

As mentioned in the previous section, a comprehensive evaluation of outcomes in deaf children can include, among other skills, speech perception, spoken language, social inclusion, and well-being/satisfaction by the child and parents/caregivers. Firstly, speech perception through auditory tasks such as sound, word and sentence recognition are commonly evaluated as outcomes. In the case of Chilean children with CI, the international instrument “Early Speech Perception Test” (Moog & Geers, 1990) adapted by Pallares de García (1993) is widely used (henceforth referred to as GeersM) in Latin America. Eight scale options in GeersM are assigned to each deaf child with HA or CI after completing three sets of assessments. Firstly, the Ling Test (Chilean Version) for the first category. Secondly, the “Prueba de Identificacion de Patrones (PIP)” as a multiple-choice word task for the second to the fifth category. And lastly, the assessment “Oraciones en Formato Abierto Para Niños” (OFA-N) of sentence repetition (Cochlear Americas, 2012) for the sixth and a formal assessment of language comprehension for the seventh category. More information about each category is available in Chapter 4 of Methods of Study 1. Moreover, assessments used in this project are available in Supplementary Material.

For spoken language, children with CI can be evaluated using receptive and expressive scales during their early years. The measurements can include developmental milestones observed by parents and therapists. In the literature, various options for observational reports can be found, which can be administered by different individuals, including therapists, parents, and teachers. The MacArthur-Bates Communicative Development Inventories (Fenson, 2007) have been extensively utilised in studies involving deaf children with CI, particularly in English-speaking countries (Yoshinaga-Itano, 2018; Fagan et al., 2015; Kosaner et al., 2013; Fenson et al., 2007). Although the instrument was originally designed for typically developing hearing children, it has proven to be highly useful in measuring spoken language development in children with CIs (Yoshinaga-Itano, 2018). Furthermore, the instrument has been translated into various languages, with country-specific versions adjusted to accommodate national dialects, thereby enhancing the reliability of evaluations within specific populations. For instance, distinct Spanish versions have been developed in Mexico and Chile (Jackson-Maldonado, 2013; Farkas Klein, 2010) to provide appropriate instruments for each respective population. Farkas Klein (2010) developed the Chilean Communicative Development Inventory "Words and Gestures" version (henceforth referred to as CDI). This version of the instrument represents a condensed proposal derived from the original instruments validated in Spanish by Jackson-Maldonado (2013), and it is intended for children aged 11-15 months.

Additionally, the Categories of Auditory Performance Index (CAP) (Archbold et al., 1995) and the Speech Intelligibility Rating Scale (SIR) (Allen et al., 2001) have been widely used as helpful instruments for evaluating auditory skills and everyday spoken language production. These instruments were adapted into Chilean Spanish as part of the current research project (Bustos-Rubilar et al., 2022). Further details are available in Chapter 3 (section 3.4.3).

Measuring social inclusion can be challenging, but one option is using surveys with Likert scales to offer response alternatives (Long et al., 2021). Parents/caregivers can complete questions based on their experiences of social inclusion with their children who have received CI. Similarly, assessments of general well-being and satisfaction can also be conducted through surveys completed by parents/caregivers, who serve as the most appropriate sources of information. Hence, surveys designed for parents/caregivers are valuable tools for gathering pertinent information regarding children with CI. These questionnaires can be administered in-person or remotely, the latter being the only viable approach during the Covid-19 pandemic starting in 2020.

Online and telephone surveys have emerged as valid alternatives for gathering data on outcome measures in children with CI (Contrera et al., 2014; Galvin, 2015; Jiménez-Romero, 2015; Punch & Hyde, 2011). For example, Contrera et al. (2014) successfully followed up on data regarding CI use in 402 patients, which accounted for 85% of the potential participants using email and telephone. Similarly, the study completed by Galvi et al. (2015) involved phone interviews with 71 parents of children who had their CI for up to 24 months, evaluating functional outcomes. The study found that 80% of parents reported their children being "happy to wear two implants together" after two months of CI use. Therefore, based on this information, the researchers and two committees created different surveys to collect information from children and adults with CI in Chile. These questionnaires and the procedures to create them are fully described in Chapter 3.

1.2.5. Important factors for spoken language development in children with CI

Positive outcomes in spoken language development in children with CI might require a favourable environment given by potential factors, which can be grouped as follows:

1) Early identification and diagnosis are considered the most critical factors influencing positive spoken language outcomes in children with CI (Ching et al., 2018; Jung et al., 2020; Leigh et al., 2016; McKinney, 2017). Early hearing detection intervention is

defined as neonatal hearing screening within the first month of age, with comprehensive hearing evaluation by three months of age and early intervention in a formal program by six months of age (Yoshinaga-Itano et al., 2018). While this factor can be considered a clinical variable, it appears to have a stronger relation with limited access to healthcare resources, such as neonatal hearing screening programs. Thus, the significance of social and economic inequalities in both Chile and Latin America might significantly influence the relevance of this variable within each region

2) The provision of hearing aids after the diagnosis of deafness and then early referral for CI is crucial to having a favourable auditory environment for spoken language development for children with CI (Shani et al., & Leigh, 2007; Dornhoffer et al., 2020; Filipo et al., 2004). Similar to early diagnosis, the availability of technical assistance for deaf children can be influenced by national healthcare systems and policies that promote early intervention for deaf children. This underscores the need to assess not only the performance of children with CI but also the effectiveness of the policies and programs delivering these services.

3) Medical-Audiological history and comorbidity are important. Auditory and medical conditions without syndrome comorbidity or disabilities without cognitive or behavioural compromise generally result in better-spoken language outcomes for children with CI (Barker et al., 2009; Berrettini et al., 2008; Gérard et al., 2010; Ingvalson & Wong, 2013). However, CI is not contraindicated for deaf children with additional difficulties, as its use can be beneficial in improving their spoken language and communication abilities. With respect to cochlear implantation itself, proper electrode array insertion in the cochlea and intactness of neurological function for auditory stimulation (Birman, Gibson & Elliott, 2015) are considered positive for having better outcomes. Moreover, using bilateral CI implanted simultaneously or consecutively within months can have better results in children at early stages (Easwar et al. 2018; Sharma et al., 2020).

4) As is the case for typically developing hearing children, social determinants of health and background inequalities for deaf children are essential considerations for better communicative interactions. The influence of low socioeconomic level, poor access to health care, education and other social facilities might be detrimental (Lu & Qin, 2018; Matiz et al., 2021; Omar et al., 2022). Children with CI from a high socioeconomic background show better results in spoken language development (Gérard et al., 2010; Schuh & Bush, 2021). Parental education, specifically the mother's years of learning,

is also essential for accelerating children with CI's spoken language abilities (Noblitt et al., 2018; Yoshinaga-Itano et al., 2018). Parental engagement during the treatment process is also reported to be beneficial for better outcomes with the CI. This means parental/caregiver knowledge about deafness, amplification and language development, and maternal-caregiver responsiveness might influence outcomes in spoken language development (Niparko et al., 2010). These factors hold significant importance in this project, particularly given the social and economic disparities prevalent in Chile and across Latin America. Furthermore, they might align with the Socio-Cognitive perspective of language acquisition in children, which underscores the necessity of a rich communication environment, often associated with better socio determinants of health.

5) EarlCI use in children and continuous professional support for the CI and for language development is critical for better outcomes. Following the Socio-Cognitive perspective of language acquisition, it is essential to have a constant and rich input in spoken language. In this context, as Wie et al. (2007) has shown, children with longer everyday CI use have better speech recognition skills than peers with less use. Similarly, Wiseman et al. (2021) suggests that deaf children who use the CI more than 8 hours per day have better outcomes in speech perception, speech recognition and spoken language skills. Regarding general rehabilitation with the device, evidence also suggests family engagement, actively participating in the intervention treatment, are essential factors for increasing spoken language outcomes at early stages (Bryce et al., 2018; Sarant et al., 2009).

6) Language choice and educational communication environment could impact spoken language outcomes in children with CI. Supporting the theory about the relevance of social input in language development, studies have suggested the benefits of rich spoken language contexts within the family and also in the educational environment (Archbold, 2014; Tait et al., 2007; Wiseman & Warner-Czyz, 2018). This does not conflict with the need to include early sign language and non-verbal communication at early stages of development in children with CI. Multimodal input remains essential even if the child is expected to communicate in the spoken language (Hall et al., 2019). It is crucial to recognise that in certain contexts, the choice of language may not even be an option due to the unavailability of hearing aids or cochlear implants for deaf children at early ages. In such cases, educational decisions are limited, and the sole possibility may be to access information through sign language in schools for deaf children.

Therefore, early identification and rehabilitation give children the best chance to follow a typical spoken language trajectory. The amplification given by the CI will contribute to the uptake of the spoken language input provided by adults, older siblings, and families. Favourable social determinants of health in family and educational contexts can facilitate the child having rich communication interactions (Hoff, 2006; Humphries et al., 2015; Lieven & Tomasello, 2020). Considering the potential relation between prevailing circumstances in Chile and the broader Latin American region, and adverse spoken language development in children with CI, the mentioned factors hold significance not only in monitoring individual treatment outcomes but also in shaping policy decisions, health regulations, and intervention guidelines for countries facing similar issues. At the time of writing, there is a lack of comprehensive characterisation of this population within Chile and there are no national reports on the outcomes of employing CIs in deaf children.

1.2.6. The value of evidence in shaping effective policies and interventions for deaf children

Research is crucial in shaping interventions and policies for children with disabilities. Adopting an evidence-based approach to developing effective strategies for children with CI ensures that resources are allocated to interventions that yield positive outcomes, maximising the impact of interventions and policies. Nicastri et al. (2021) evaluated the impact of parent training on the communication development of children with CI in a supportive family environment. The study involved 14 Italian families who received parental training and were compared to a matched group of families who did not receive any treatment. The results showed that the trained group experienced significantly more improvements in both the quality of interaction within the families and the language development of the children when compared to the control group. The program appeared beneficial for parents, focusing on empowering strategies and promoting communication skills in children with CI. Although the small sample size in the study has to be taken into account, it has important policy recommendations to improve parental engagement programmes rather than only focusing resources on the child with CI.

Therefore, by synthesising research findings, policymakers and stakeholders can gain insights into best practices, identify gaps in existing policies, and advocate for policy changes that promote interventions adapted to each context and group (Baron, 2018). For instance, the Individuals with Disabilities Education Act (IDEA) in the United States, which guarantees special education services to children with disabilities, was shaped by research on the benefits of inclusive education (Lipkin & Okamoto, 2015). Moreover, at the international level, the UN Disability Inclusion Strategy was shaped through a collaborative process that involved evidence and consultations with UNICEF staff from 80 countries, organisations representing individuals with disabilities, research evidence, civil society organizations, governments, and crucially, children and young individuals with disabilities themselves (Berman-Bielere et al., 2023).

In the context of public policy, governments and organizations develop their own plans and programs to make an impact on the public sphere. Many international conventions and local policies for children with disabilities, including children with CI, are evidence-based. That is the case of the United Nations Convention on the Rights of Persons with Disabilities (UNCRPD), which draws heavily on research to advocate for the rights and inclusion of children with disabilities worldwide. On a local level, the Chilean Ministry of Health launched a national plan for 2021-2030 for hearing health and ear care, focusing on creating new policies and programs for better and closer health/rehabilitation for hearing loss in children and adults (Minsal, 2022). Emphasising the role of the primary health sector aligns with the World Health Organization's recommendations to tackle the impact of socioeconomic status on people from countries worldwide (World Health Organization, 2021). The MINSAL policy includes these international evidence-based recommendations, evaluated by a separate Chilean Health Department of evidence-based health and health guarantees (Baron, 2018; MINSAL, 2018), which provide international and local evidence for health policies.

Nevertheless, there is a hierarchy of different types of evidence in support of policies (Dicenso & Williamson, 2009). For example, the characterisation of the national population in health can be considered low evidence. However, these reports provide very useful insights to some health conditions. On the other hand, systematic reviews from randomised control trials seem to be the higher level of evidence. However, many studies might not be applied the highest level of evidence to research in the context of psychology and language in children due to the complexity of following their requirements during the evaluation/intervention to children at an early age. Thus, in contexts where there is a lack of evidence, observational studies such as the characterisation of the population are necessary first steps in gathering evidence about a specific population. Thereafter, longitudinal research will provide further valuable and extensive evidence.

1.2.6.1. The value of characterisation evidence in Chilean children with CI.

Characterisations or profiles of children with CI have been conducted in several countries. These studies provide information on demographic, socioeconomic, epidemiological, audiological factors, and outcomes. Evidence from the UK, the US, India, China, Malaysia, Turkey, Japan, and other countries worldwide are available with differences given by country and policy context for children with CI (Byckova et al., 2020; Fortnum et al., 2002; Lu & Qin, 2018; Yusoff et al., 2017; Nassiri et al., 2022; Oliver, 2013; Shakrawal et al., 2020). For example, in the United States in 2015, only 12.5% of children who required a cochlear implant received one, and among those who did receive implants, 30% received bilateral implants (Nassiri et al., 2022). In addition, according to Teagle et al.(2019), the average age of implantation in the US is approximately 2.4 years. Evidence from this country might reveal that despite its early implementation, access to the CI is highly unequal across the country, highlighting the shortcomings of a system lacking national health insurance coverage.

In the case of the UK, Fortnum et al. (2002) shown that over 40% of the causes of congenital deafness were unknown, and 27.4% of children with CI and congenital deafness had additional disabilities. Furthermore, according to Bruijnzeel et al. (2017) and Hardman et al. (2020), the average age of cochlear implantation in the UK has been as early as 12 to 20 months. In Lithuania, Byckova et al. (2020) analysed the profile of children with CI, evaluating the data of 122 children. Their findings included that 53% of the users had non-syndromic deafness, showing the importance of policies of neonatal screening. In Malaysia, Yussof et al. (2017) presented a characterisation of 121 of the 205 children with CI implanted from the beginning of the policy in 2008. They showed that the average implantation age was 41.5 months and that there were specific recommendations for the Malaysian national programme for CI. In the Latin American context, one study in Brazil displayed demographic and audiological details (Magalhães Barbosa et al., 2014).

In the Chilean context, only one small study focused on a specific region was conducted by Guzmán, Fuentes-López, & Cardemil, (2020). This study characterised a sample of 10 CI candidates, including both children and adults, who were part of the public health service of Aconcagua, located in a valley area within the central region of Chile. In the group of children, the cohort study provided information on various aspects, such as age, location, audiological factors such as the site of implantation, median age at implantation, and the time elapsed between hearing aid implementation and CI implantation. Interestingly, the study revealed that 30% of the participants received their implants outside of the region, which is a positive indication supporting community-based interventions, ensuring that most children underwent implantation closer to their homes. On average, the time for implantation was 4 years and 4 months (or 52 months), with a gap of 48 months between the implementation of hearing aids and CI implantation. This gap may be attributed to the significant delay in implantation caused by the absence of a national hearing screening program. Nevertheless, it is essential to note that the study's extremely limited sample size do not allow the establishment of parameters for in-depth discussion or comparison within the national context.

Therefore, there needs to be more evidence about children with CI in Chile, about their sociodemographic data, expected language outcomes and the factors that affect outcomes. The current study is motivated by this need to map the characteristics of children with CI in Chile. This is particularly timely because of recent changes to the Chilean Public Health policies, which include guaranteed rights for deaf people, a new approach for high-cost health treatments as the CI, and structural reforms to the Health National System. The characterisation of children with CI presented in this project will add to the evidence base that is necessary for making better decisions about deaf children's treatment and, subsequently, policy adjustments.

1.2.6.2. The value of longitudinal studies of children with CI

Longitudinal studies examining the impact on children who receive CI at an early age are important for evaluating eventual outcomes. Firstly, a longitudinal study in children with CI can assess outcomes over time, and developmental trajectories can be postulated from that evidence. In this field of longitudinal language trajectory studies in children with CI, noteworthy contributions have been made by Niparko et al. (2010), Yoshinaga et al. (2018), and Ching et al. (2018) in the context of the LOCHI study.

Longitudinal studies are well-suited for investigating cause-and-effect relations. Observing changes over time can establish temporal sequences of events and identify potential causal relationships between variables. For example, a study developed by Persici et al. (2022) explored the communication characteristics of 18 Italian-speaking children with CI and their mothers during interactions at four time points, from before implantation (ages 10-33 months) up to one year after implantation. Results revealed delayed communicative development in children with CI compared to control group of typically developing hearing children, and the interlocutor's communicative behaviour was impacted for children and mothers. Although the sample size was very small, essential implications for language development support programs for families, and professionals working with children with CI were suggested.

An essential strength of longitudinal studies is the possibility of tracking individual variations and trajectories, helping to understand why specific outcomes differ among participants. For example, a follow-up study on language skills in the UK by Hand et al. (2023) mapped the receptive and expressive language development trajectory in a representative group of 44 children with CI. The study tracked these children for the first two years after implantation, categorising them based on age. The results indicated that children with CI generally acquire receptive and expressive language skills similarly to typically developed hearing children but with individual variations in specific skills. It was also revealed that a complex interplay of demographic variables influenced their language outcomes Although the study has limitations in terms of the small and heterogeneous sample, the findings highlight the diverse nature of this population and emphasise the importance of individual trajectory in spoken language development.

In the current study, it was deemed necessary to include a longitudinal study to contribute to a more comprehensive evaluation of variables affecting outcomes in children with CI in Chile. This would provide further insights to inform effective interventions and support appropriate policies considering the local context for deaf children in Chile and Latin America.

1.2.7. Research aims and research questions

This literature review discussed various factors influencing spoken language outcomes in children with CI and emphasised the need of research providing evidence-based interventions and policies, especially in Latin American countries. Moreover, the above review assessing access to health services for deaf children in the Chilean and Latin American contexts reveals the existence of shared barriers and challenges in CI interventions with a lack of extensive and local evidence.

Therefore, the current research aims to characterise a group of children with CI in Chile and explore the factors that can significantly affect the outcomes expected with the device. The potential findings from these research aims will contribute to enhancing interventions and policies and assess likely inequalities in the early intervention in health and education for children with CI in Chile and other similar contexts.

To complete the aims, three research questions will be addressed:

Research question 1 (RQ1): What are the characteristics of deaf children implanted from 2017 to 2019 within Chile's public health system?

Research question 2 (RQ2): Which factors are associated with good spoken language outcomes in deaf children implanted from 2017 to 2019 within Chile's public health system?

Research question 3 (RQ3): What factors predict progress made in deaf children’s spoken language skills over 12 months in Chile?

The next chapter will provide an overview of the project's aims and hypotheses.

Chapter 2: Studies Overview

2. Rationale and Overview of Study 1 and Study 2

The organisation of the project is described in the next four chapters. This chapter briefly introduces the original and the COVID-19 pandemic mitigation research plans, and in addition each research question and proposed hypotheses will also be presented. Three research questions and six hypotheses were assessed in two related studies – Study 1 and Study 2 –, which are documented in Chapters 3 to 6. Figure 1 displays the project flow chart, including Study 1 and Study 2, including actions, instruments, and other processes during the research. The project rationale, research questions, hypotheses, and methods for this project were pre-registered on the OSF platform (https://osf.io/jeyg6) in November 2021.

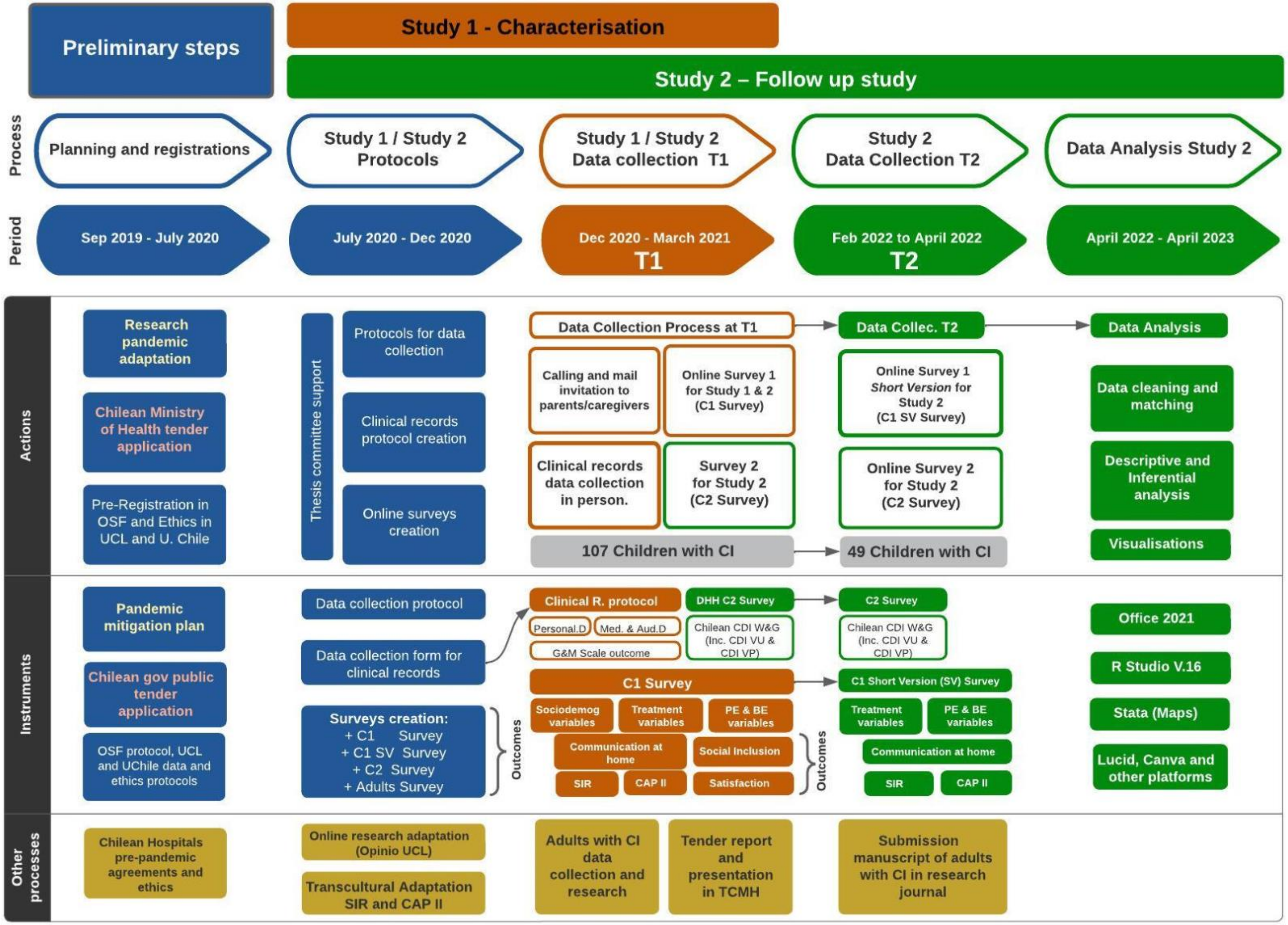
2.1 Introduction of research studies and COVID-19 pandemic mitigation plan (Chapter 3-6)

The original plan included two studies. The first study aimed to characterise children with CI who had received a CI in five Chilean public hospitals located in different regions of Chile. The second study aimed to conduct a longitudinal on-site evaluation in a sub-sample of 30 participants under five years who had received the CI under the age of three. The original plan was that participants were to be evaluated every six months using various spoken language assessments such as the Chilean version of The Bzoch-League Receptive-Expressive Emergent Language Scale (Sasvari, 1995), the general development scale “Test de Desarrollo Psicomotor” (Rivas et al., 2019), and the scales MUSS (Robbins & Osberger, 1990) and MAIS (Robbins & Osberger, 1998), commonly used in Spanish-speaking children with CI. The study also included on-site surveys for each parent/caregiver and each child's therapist to gather information on factors affecting language development.

However, the pandemic disrupted the original research plan, and the supervisors, thesis committee and the researcher at UCL formulated an immediate mitigation plan. The research design was adjusted for an online format. A new theoretical review of instruments and formats for online evaluation was conducted, and funds were acquired to create online instruments and for the data collection process. The research team applied for funding via a national research tender offered by Chile's government. This was successful and we were awarded funding for a national evaluation of policies and outcomes results in adults and children with cochlear implant from 2017 to 2020 under three different national policies. The tender "Caracterización de usuarios de implante coclear beneficiarios del GES, LRS y programa de Implantes Cocleares MINSAL del sistema público chileno" number 757-35-L120 was monitored by the Secretary Division of Public Health from the Chilean Ministry of Health (more information in section 3.2). The revised research procedures aligned with the aims of the original plan. New evaluation instruments were created, namely the transcultural adaptation of CAPII and SIR, to adapt speech perception instruments in an online format (more information available in section 3.4.3. Spoken language in children with CI was evaluated using the Chilean Mac Arthur Bates CDI evaluation (More information available in Chapter 5).

During the pandemic, a six-month reduction in doctoral work was required due to the COVID-related extenuating circumstances. However, the revised plan was successfully implemented, and online assessments and the funding application were completed. The researcher travelled to Chile during the pandemic, following strict measures set by the Chilean Ministry of Health, UCL and the UK, to collect data from clinical records in each hospital. The project was completed online, adhering to the pandemic regulations of each country and UCL. Thus, it was possible to maintain the hypotheses and research questions and hypotheses, which will be introduced in the next section.

Figure 3. Project flow chart, including Study 1 and Study 2.



Notes: Colours: **Blue** = General procedures, **Orange**= Study 1, **Green**= Study 2, **Brown:** other processes. Abbreviations: T1= Time 1, T2= Time 2, OSF= Open Science Framework, D.= data, Med.& Aud. D= Medical and audiological data, C1 Survey= Child with CI Survey 1, C1 SV Survey= Child with CI survey 1 short version, C2= Child with Survey 2, G&M= Geers & Moog Chilean Scale, CDI= Communicative Development Inventory Assessment, VU= Vocabulary Understand, VP= Vocabulary Production, CDI W&G= Words and gestures Chilean CDI, PE&BE= Parental Engagement variables, SIR= Chilean Speech Intelligibility index, CAP II= Chilean Categories of Auditory Perception II, Opinio= UCL survey platform

2.2 Research Questions and Hypotheses

Three research questions and six hypotheses were considered in this project.

2.3 Research Questions and Hypotheses

2.3.1 Research question 1 (RQ1): What are the characteristics of children implanted from 2017 to 2019 within Chile's public health system?

2.3.2 Research question 2 (RQ2): Which factors are associated with good spoken language outcomes in children implanted from 2017 to 2019 within Chile's public health system?

2.3.3 Research question 3 (RQ3): What factors predict progress made in children with CI spoken language skills over 12 months in Chile?

To assess the above questions, each following hypothesis was formulated considering the important factors affecting the spoken language outcomes and the predictions in the outcome results.

Hypothesis A:
Variables: Aetiology and Additional Difficulties.

According to the evidence (Barker et al., 2009; Berrettini et al., 2008; Gérard et al., 2010; Ingvalson & Wong, 2013), children with CI who have auditory and medical conditions without additional difficulties (that is, non-syndromic, without comorbidities or cognitive-behavioural disorders) make better progress in the development of spoken language compared to children with CI who present the aforementioned conditions. We predict that children with CI in Chile who do not have additional difficulties will have better spoken language outcomes than children with additional difficulties.

Hypothesis B:
Variables: Age at CI surgery/switch-on.

Early identification and diagnosis have been considered the most critical factors regarding CI outcomes (Dettman et al., 2016; Leigh et al., 2013; McKinney, 2017). As Ruben et al. (2018) described, the ideal period for implantation is between 10-12 and 24 months of age. We predict that Children with CI in Chile implanted before 24 months of age will show better results in spoken language outcomes than those implanted after 24 months.

Hypothesis C:
Variables: Socio-Economic Status (SHI), Borough Development Index (BDI), Family highest education (Family Ed).

It is possible that social determinants of health, such as SHI, access to health care, Family Ed and social facilities as BDI (Matiz et al., 2021), could affect spoken language outcomes expected for children with CI. In Latin America, these factors are compounded by inequalities and segregation, resulting in challenges to healthcare economics and access (Bright et al., 2019). The Chilean 'Borough Development Index' (BDI) (Hernández Bonivento et al., 2020) is an index variable showing a composite number related to well-being and access to service across Chile. It ranges from 0 (low) to 1 (high) in relation to each territory's socioeconomic outcomes, living deprivation, and urbanisation. High index might increase outcomes in children with CI in Chile. Thus, we predict that low SHI, low maternal/caregiver education and low BDI could result in worse spoken language outcomes in children with CI in Chile.

Hypothesis D:
Variables: Parental Engagement (PE): 1) CI Confidence and 2) CI Training.

Suskind et al. (2016), suggest that parental engagement considering confidence and training about language development and CI use can improve the expected outcomes in early CI use. Therefore, we expect these two sub variables of parental engagement can improve outcomes in early CI use by children with CI in Chile.

Hypothesis E:
Variables: CI use hours per day (CI use)

Consistent use of the CI during the day would benefit better spoken language outcomes. Wiseman et al. (2021) suggest that children with CI who used their CI for more than 8 hours per day had better auditory, speech recognition and spoken language skills than children who used their CI for less than 8 hours per day. We predict that children with CI in Chile who report continuous daily use of the device could have better results in spoken language outcomes than those who report less time using the CI.

Hypothesis F:
School Nursery Placement Attendance.

Studies have suggested that rich spoken language contexts at home and in classrooms could have a positive impact on the spoken language development of children with CI (Archbold, 2014; Tait, Nikolopoulos, & Lutman, 2007; Wiseman & Warner-Czyz, 2018). This could be complemented by learning sign language to provide children with additional language and with additional non-verbal cues. We predict that children with CI who have experienced rich contexts in spoken language in the education environment could have better outcomes in spoken language skills.

2.4 Design of the Studies

The research questions and hypothesis were assessed in two related studies. First, to assess RQ1, Study 1 was an observational study aiming to characterise children with CI in Chile implanted from 2017 to 2019 in the national public health system. The study considered data from two sources, which will be described in detail in Chapter 3. Second, to assess RQ2 and RQ3, Study 2 was a follow-up longitudinal study of 49 children with CI sampled from the 107 children characterised in Study 1. Further information about the design of each study is available in Chapter 3 for Study 1 methods, and Chapter 5 for Study 2 methods.

2.4.1 Ethics

Two Research Ethics Committees approved the studies: The Faculty of Medicine, University of Chile (167-2020) in December of 2020 and University College London (UCL) (LCD-2020-13) in November of 2020. The study was registered with UCL Data Protection, and all procedures for data management and transfer were followed. All the ethics documents can be provided on request. A risk assessment named UCL Standard Risk Assessment was completed and followed for the researcher travel to Chile, including data privacy protection, safety measures for visiting hospitals and working with people in Chile. Regarding data protection, anonymised digital data from the clinical records and from the online surveys were stored on an encrypted hard drive in the locked office of the University of Chile. The transcriptions and spreadsheets were also stored on this drive. Data was moved to the United Kingdom securely on a password-protected/encrypted database and memory stick. Finally, regarding Covid 19 pandemic measures, there was completed a specific risk assessment for moving research practices to an online level and avoiding hospital units at risk of COVID-19 transmission.

2.4.2 Chilean Ministry of Health (TCMH) research tender

The research team were awarded funding through the Chilean Ministry of Health (TCMH) research tender to evaluate three national policies providing CI to children and adults within Chile's public health system. The policies were “Garatías Explícita en salud 56 and 77” (GES) for children, High-cost policy “Ley Ricarte Soto” (LRS) for adults and “Programa MINSAL” for children and adults. This enabled the research team to characterise all the deaf population implanted under the national policies, from 2017 to 2019 for children and 2018 to 2020 for adults. The agreement with TCMH included producing a final report and presenting to TCMH, with the understanding that all information collected would be utilised in the researcher's doctoral thesis at UCL. Between December 2020 and July 2021, the researcher and three paid collaborators from the University of Chile collected the data, visiting seven hospitals in the country. Later, the researcher analysed the data and wrote the report, which was submitted in July 2021. The report provided a comprehensive evaluation of the three public policies from the separated analysis of children and adult data. The report included policy recommendations and is available only in Spanish, but an English extract is available in Supplementary Material. A presentation was delivered by the researcher in October 2021 to TCMH to disseminate findings and policy recommendations.

The data on children with CI was used for Study 1 and Study 2. The data and the analyses for deaf adults with CI were reported in a separate article published in the journal PLOS ONE (Bustos-Rubilar et al., 2023). The adult study aimed to evaluate the impact of the Chilean high-cost policy “Ley Ricarte Soto” on treatment success and labour market inclusion among adults with CI. The paper reports on examining and characterising outcomes based on self-reports about treatment success and occupation status at least one year after the CI implantation. This study makes an important contribution to understanding the current policies and deaf adults` intervention by the Chilean Ministry of Health.

Chapter 3: Methods Study 1

3. Characterisation of deaf children with CI in Chile, implanted in the public health system between 2017 to 2019

This chapter details the methods employed in Study 1, the aim of which was to characterise children with CI in Chile who underwent the implantation procedure within the national public services between 2017 and 2019. This section also outlines the research design, adaptation of the study during the pandemic, collaborative efforts with the Chilean Ministry of Health (TCMH), participant selection criteria, data collection procedures, and the employment of relevant assessment instruments.

3.1 Study 1 design

Study 1 addressed RQ1 – What are the characteristics of Children with CI in Chile implanted from 2017 to 2019 within Chile's public health system? This was an observational study conducted between September 2020 and March of 2021. The study included data from two sources. Firstly, information was included from clinical records of each child with CI reported by the public health system in all hospitals providing CI. The anonymised data collected in each hospital was audited following all ethical guidelines. Secondly, an online survey for each family-caregiver of audited children with CI was conducted, which was named Child with CI Survey 1 (C1 Survey).

3.2 COVID-19 Pandemic-related revisions for Study 1

As part the COVID-19 pandemic-related mitigation plan, online and telephone interviews were evaluated as valid options for collecting data about characterisation and outcomes in children with CI (Contrera et al., 2014b; Galvin, 2015; Jiménez-Romero, 2015; Punch & Hyde, 2011). It was concluded by the thesis committee and the researcher that the online format was needed in order to not only collect data about the children with CI during the pandemic, but also to enhance tele-practice and tele-rehabilitation procedures through the provision and implementation of new online assessments, which have become essential in the pandemic context (Claridge & Kroll, 2021). Thus, the online survey was designed using the OPINIO Platform (https://opinio.ucl.ac.uk/). All analysed data was stored in a unique spreadsheet in ".csv" format with a specific ID for each anonymised participant.

3.3 Study 1 Participants

All children with CI (and their parents/caregivers) who received their first CI between 2017 and December 2019 in all public hospitals providing CI in Chile aged between 1 and 15 years of age were invited to take part in the study. Table 1 describes the inclusion and exclusion criteria of Study 1. The Chilean Ministry of Health provided a list of 153 possible children, of which 148 met the inclusion criteria.

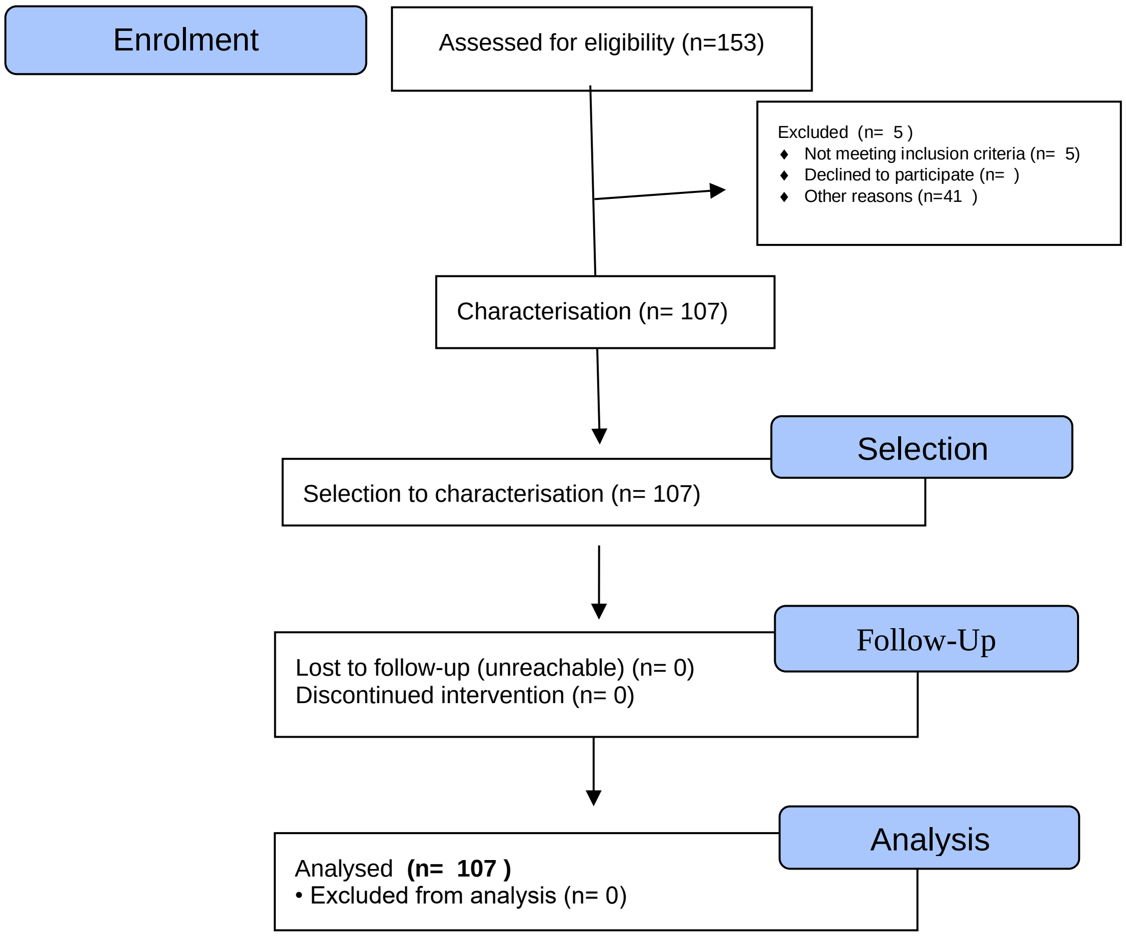
Table 1. Inclusion and exclusion criteria in Study 1

Inclusion Criteria	Exclusion Criteria
1. Children receiving the first CI during 2017 to 2019. 2. Children with at least 12 months of experience with CI. 3. Children from Chilean public health system. 4. Parents/caregivers deemed able to complete the C1 Survey.	1. Children implanted before 2017 and after 2019 2. Children implanted in private hospitals. 3. Children with incomplete personal and audiological data from clinical records. 4. Parents/caregiver deemed not able to complete the C1 Survey.

After the information from each clinical record was audited, all parents/caregivers were invited to take part in the research. 107 parents/caregivers agreed to participate and completed the informed consent and the online survey. A Consolidated Standards of Reporting Trial, Consort Diagram (http://www.consort-statement.org/), about the current study is shown in Figure 4. Data collection was conducted between September 2020 and March 2021.

Figure 4. Consort diagram for Study 1

Study 1: Factors affecting outcomes in deaf children with Cochlear Implant in Chile considering the Latin American Context. (Study 1)



3.4 Study 1 Instruments

3.4.1 Protocols

Study 1 was an observational study with two information sources — clinical records and online survey. These were conducted following specific research protocols (Supplementary Material) which delineated the procedures, actions, and considerations involved in both on-site clinical record collection and online survey administration. Furthermore, explicit measures were taken to formalise the invitation process for parents/caregivers to participate in the study. The two information sources are detailed below:

3.4.2 Clinical Records

Each child's clinical record was a reliable source for accessing their sociodemographic, audiological and treatment information, within additional questions about variables affecting results in children with CI. Moreover, data from the speech perception scale "Escala Geers and Moog" (GeersM Categories) (Minsal, 2008) adapted from "The Early speech perception test" (Moog et al., 1990) was collected as an outcome result from each clinical record. The information was in an online and digital format in each Chilean hospital. Protocols for collecting data in each hospital are available in Supplementary Material.

3.4.3 Online Survey

An online survey was developed for the Study 1 characterisation. This was called the Child with CI Survey 1 (C1 survey). The online survey was designed to collect information about each deaf child with CI and their family and crucially included two parent-reported outcome assessments to obtain more information about speech perception and spoken language skills. These were the Chilean Categories of Auditory Performance Index II (CAP II) and the Chilean Speech Intelligibility Rating Scale (SIR). These two assessments were transculturally adapted to Chilean Spanish following specific procedures as described in detail in section 3.4.3.

The survey questions were accomplished as follows: An English Language Committee composed of four members was set up; two researchers with expertise in language and cognition, one audiology researcher and one researcher in speech-language therapy. They considered the wording of proposed questions to parents/caregivers regarding factors affecting their children's outcomes. The answers were either a set of Likert scale alternatives or multiple choice. Some questions concerning CI use and parental engagement were inspired by previous research delivered by Suskind et al. (2016). Once the English versions were finalised, they were translated into Chilean Spanish. A Spanish Language Committee consisting of two speech and language therapists, one linguist, and one audiologist was then set up. They reviewed the translations to consolidate a suitable instrument in the Chilean Spanish Language. There were some changes made to the preliminary Chilean Spanish version, which were with regard to the grammar and complexity of some sentences for the target participants.

This preliminary version in Chilean Spanish was then piloted with 5 parents/caregivers of children with CI aged between 2 and 15 years. The parents/caregivers were randomly selected from a pool of possible participants from the database for the original project. Participants were asked to complete the online survey and make comments about any difficulties with understanding questions. There were specific comments about some sentences, which were not clear. These sentences were then modified without any change to the content. The final version of the survey “C1 Survey” was then adapted for online delivery on Opinio. Originally, the survey was planned to be completed in 20 minutes. The English and Chilean Spanish version of the surveys are available in Supplementary Material.

3.4.4 Outcome results

Six outcome results were evaluated in the Study 1 of characterisation. Table 2 shows each outcome variable with a description and the source of the information (clinical records and C1 Surveys).

Table 2. Outcome variables in Study 1

Outcome results in Study 1

Outcome	***Description***	***Source***
1. Communication at home	Four options for the question: How do you communicate with your child?: 1) Sign Language, 2) Spoken Language, 3) Mixed, using Sign and Spoken Language, 4) Other.	C1 Survey
2. Geer and Moog Latin American Categories of Speech Perception. Abb: GeersM	Eight options: 0) Unable to perceive any speech sound (Ling test), 1) Speech detection but unable to perceive even time-intensity pattern info in words with speech amplified, 2) Time-intensity pattern perception in amplified speech (Chilean ESP Test: Above 70% in testing with Chilean ESP), 3) Word identification by basic spectral information (Chilean PIP test: words with same metric and time, but different consonants and vowels), 4) Word identification in a group by their vowels (Chilean PIP Test, 5) Recognition of words in a group by their consonants (Chilean PIP test), 6) Word recognition by repetition (Chilean word repetition test) , 7) Spoken Language Comprehension (Chilean information evaluation of spoken language comprehension).	Clinical Record
3. Categories of Auditory Performance CAP II (Chilean CAP) Abb: CAPII	Ten levels in the scale: 0. No awareness of environmental sounds 1. Awareness of environmental sounds 2. Response to speech sounds 3. Recognition of environmental sounds 4. Discrimination of at least two speech sounds 5. Understanding of common phrases without lip-reading 6. Understanding of conversation without lip-reading with a familiar talker 7. Use of a telephone with a familiar talker 8. Understanding/Following group conversations. 9. Use the telephone with an unknown speaker in an unpredictable context.	C1 Survey
4. Speech Intelligibility Rating Scale SIR (Chilean Version of SIR), Abb: SIR	Six levels in the scale: 1. Connected speech is unintelligible. Pre-recognizable words in spoken language, the child's primary mode of everyday communication may be manual. 2. Connected speech is unintelligible; intelligible speech is developing in single words when context and lip-reading cues are available 3. Connected speech is intelligible to a listener who concentrates and lip-reads within a known context. 4. Connected speech is intelligible to a listener who has little experience of a deaf person’s speech. 5. Connected speech is intelligible to all listeners. The child is understood easily in everyday contexts.	C1 Survey
5. CI Satisfaction,	Five level Likert item*: Has the use of the device satisfied your expectations as a parent/caregiver?*: 1 (Unsatisfied), 2, 3, 4, 5 (Very Satisfied).	C1 Survey
6. Social Inclusion	Five level Likert item*: Do you feel that your child is included in school and social life?* 1 No, not too much included, 2,3,4, 5 Yes, the child is quite included.	C1 Survey

Notes: Abb: C1 Survey= Child with CI Survey Online 1, GeersM= Geer and Moog Latin American Categories of Speech Perception.

Outcome variables were chosen considering the online application for parents/caregivers and those typically reported in the literature, as follows:

- *1) A specific question about communication at home* was included in the C1 Survey to investigate how parents/caregivers report the communication that they use with the children with CI at home. This question has been used in previous research on deaf children with CI (Suskind et al., 2016).

- *2) Geers and Moog Latin American Categories of Speech Perception (GeersM):*
  This is widely used in Latin American countries for the evaluation of speech perception and comprehension of spoken language in a scale of eight options: 0) Unable to perceive any speech sound (Ling test), 1) Speech detection but unable to perceive even time-intensity pattern info in words with speech amplified, 2) Time-intensity pattern perception in amplified speech (Chilean Early Speech Perception (ESP) Test: Above 70% in testing with Chilean ESP), 3) Word identification by basic spectral information given by the Chilean Prueba de Identificación de Patrones (PIP) test: words with same metric and time, but different consonants and vowels, 4) Word identification in a group by their vowels (Chilean PIP Test, 5) Recognition of words in a group by their consonants (Chilean PIP test), 6) Word recognition by repetition (Chilean word repetition test) , 7) Spoken Language Comprehension (Chilean information evaluation of spoken language comprehension).

  The scale is an adaptation of "The Early Speech Perception Test" (Moog et al., 1990), which has been expanded by the inclusion of additional word identification assignments in Spanish (Giraudo, 2019). The instrument has recognition in the field of audiology and speech-language pathology in Latin America, as it is included in the Chilean regulation for measuring the progress of children with CI (Minsal, 2008). Results on the GeersM were available in the clinical records of every child with CI in the study. In order to meet the inclusion criterion of at least 12 months of CI use, children's GeersM results that had been recorded 2 months before the data collection were entered.

- *3) Speech Intelligibility Rating Scale* (SIR) (Allen, Rawlings, & Remington, 1993) was adapted into Chilean Spanish by the researcher and collaborators in 2022 (Bustos-Rubilar et al., 2022). More Information about this process is presented in section 3.4.3.

- *4) The Categories of Auditory Performance Index II* (CAP II) (Archbold, Lutman, & Nikolopoulos, 1998) was also adapted into Chilean Spanish by the researcher and collaborators in 2022 (Bustos-Rubilar et al., 2022) . More Information about this process is available in section 3.4.3.

- *5) CI satisfaction:* Parents/caregivers were asked if their child's use of the device satisfied family expectations. The satisfaction of parents/caregivers can contribute to understanding the achievement of expected outcomes (Baron et al., 2002). Moreover, the evaluation of parent/caregiver's satisfaction is also significant from a policy perspective, as it can provide valuable insights into the effectiveness of policies aimed at providing CI to children (Fenton at al., 2012). Therefore, examining the satisfaction of parents/caregivers with the use of CI is essential for understanding the impact of the device on parents/caregivers' expectations.

- *6) Social Inclusion:* The social inclusion of children with CI is considered to be an indirect objective of CI use, as evidenced by research evaluating the outcomes of children with CI (Constantinescu-Sharpe et al., 2017). In this study, parents/caregivers were asked to respond to the question, "Do you feel that your child is included in school and social life?" using a Likert scale. This outcome measure may provide valuable insights in the social perspective of the communication, but also the effectiveness of policies aimed at providing CI to deaf children and the impact of device use after a certain period (Punch & Hyde, 2011).

3.4.5 Transcultural Adaptation Chilean CAPII (CAP II) and SIR scales (SIR)

The Categories of Auditory Performance Index II (Archbold et al., 1998) and the Speech Intelligibility Rating Scale (Allen et al., 1993) were transculturally adapted to Chilean Spanish following the methodology given by Beaton et al. (2000). To address this issue, the researchers collaborated with two expert committees: the English Language Committee at UCL in the UK and the Chilean Spanish Language Committee in Chile. The purpose of these collaborations was to create instruments not only with translations into Chilean Spanish but also with additional information that would be suitable for non-expert respondents.

Moreover, in order to facilitate self-administration of the Chilean CAPII and SIR scales by non-expert respondents such as parents/caregivers of children with CI, additional examples and information were provided beyond what was originally included in the instruments. This extra information was intended to reduce possible misunderstandings and to adapt the scales in an online self-administration format for parents/caregivers. A publication detailing the transcultural adaptation was published in the Scopus peer-review journal Revista Chilena de Fonoaudiologia (Bustos-Rubilar et al., 2022).

3.4.6 Independent Variables

The independent variables for Study 1 included sociodemographic, audiological, treatment information and parental engagement with the treatment. Table 3 shows the independent variables including the variable description and data collection source.

Table 3. Independent variables in Study 1

Independent variable	Description	Source
Age	In months	Clinical Records
Gender	1) Female, 2) Male	Clinical Records
CI age	Age in months at CI surgery. Chronological age when the Children with CI have the CI surgery/Switch-On. In this study age at CI surgery and at Switch-On are considered the same due to the Chilean regulation, which requires the CI Switch on within one month after the CI surgery.	Clinical Records
Aetiology	1) Congenital, 2) Late Hearing Loss^	Clinical Records
SHI	Socioeconomic health insurance: 1) Low income, 2) Low- middle income, 3) Middle income, 4) Middle, high income. This public health insurance covers 82-83% of the entire Chilean population (Crispi et al., 2020).	Clinical Records
BDI	Index from 0.0 (low) up to 1.0 (high) Index Variable, "Desarrollo Comunal" in Spanish.	Clinical Records
Family Ed	1) Unknown, 2) Primary School Uncompleted, 3) Primary School Completed, 4) Secondary Uncompleted, 5) Secondary Completed, 6) Training Uncompleted, 7) Training Completed (In Chile from 2 to 3 years of formal education), 8) University Uncompleted, 9) University Completed (In Chile from 4 to 7 years of formal education)	C1 Survey
Add diff	1) Not declared, 2) Declared.	Clinical Records
CI condition	1) Operative-Without issues, 2) Operative but with some issues, 3) Not Operative - Technical Issues, 4) Not in use from time ago.	C1 Survey
CI status	1) Unilateral CI w/o contra HA , 2) Unilateral CI with contra HA , 3) is this bilateral?	C1 Survey
Rehabilitation attendance	1) Attending , 2) Attending with difficulties, 3) No attending.	C1 Survey
Frequency rehabilitation	1) Weekly, 2) Each 2 weeks, 3) Monthly, 4) Less than once per month.	C1 Survey
Duration Treatment	*Three levels from the question; How much time do you spend in each session? 1*) 1 hour, 2) 30 min, 3) Less than 30 min, 4) 40-45 min, 5) More than 2 hrs.	C1 Survey
Commute time	1) Very short time, 2) Short Time, 3) Enough Time, 4) Long Time, 5) Very long Time, 6) Not attending	C1 Survey
Education attendance	1) Not attending any ed. 2) Special school for the deaf, 3) Mainstream ed. w/o SNA, 4) Mainstream ed. with SNA, 5) Special school for SLD, 6) Mainstream nursery.	C1 Survey
CI use (ord)	1) Never, 2) Sometimes, 3) Frequently, 4) Always	C1 Survey
CI hrs per day	Minutes per day.	C1 Survey
Behavioural problems	Two level : 1) No, 2) Yes	C1 Survey
Treatment Professionals	Multiple selection variable from the question; *If he/she receives support for special needs with CI, who delivers this support?* 1) Interpreter, 2) Speech and Language Therapist, 3) ENT/Doctor & Audiologist, 4) Special Educator, 5) AVT Therapist, 6) Psychologist, 7) Unknown, Not remember, 8) Other.	C1 Survey
CI Training	1) No, 2) Yes	C1 Survey

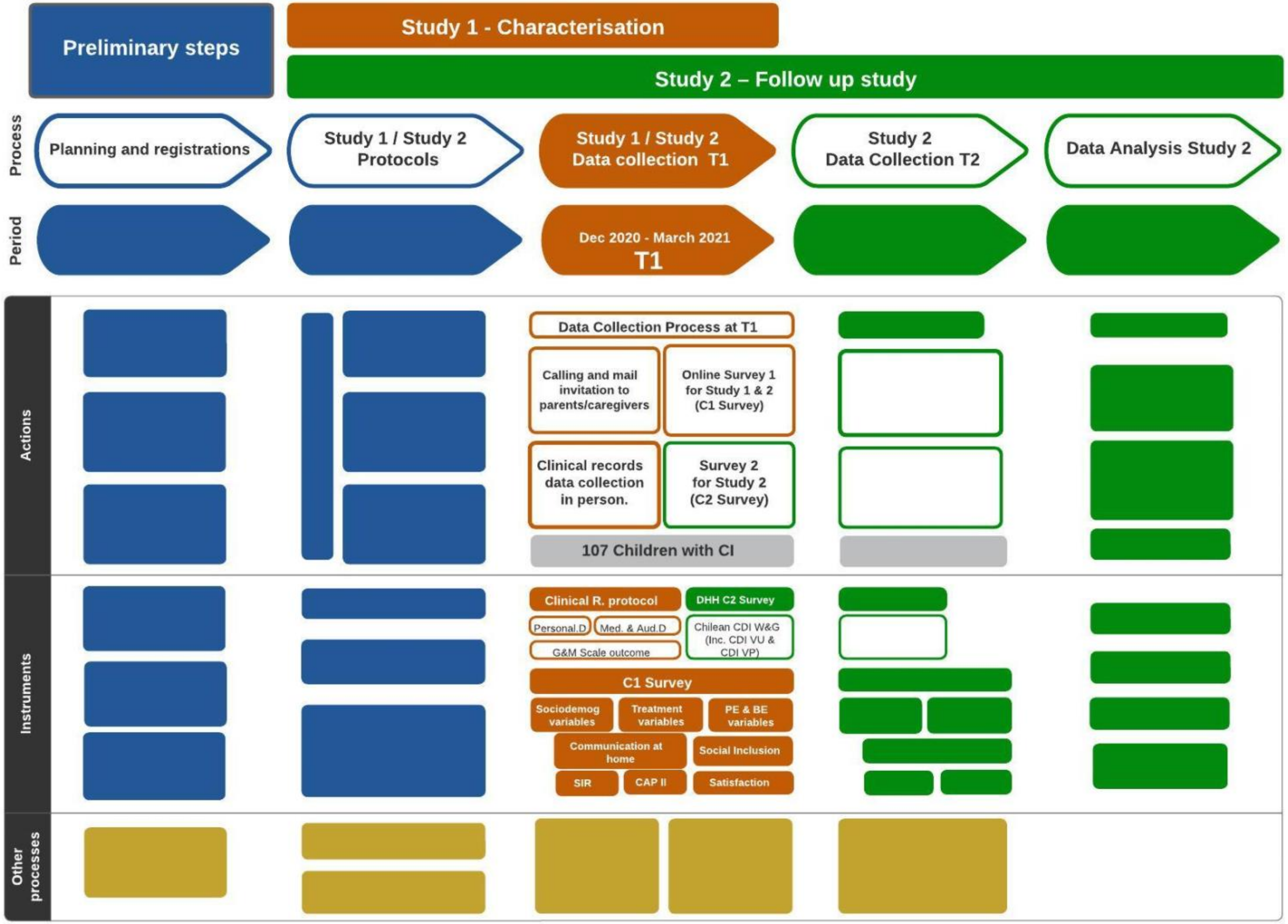
CI Confidence	: 1) No confidence, 2) Poor Confident, 3) Enough Confident, 4) Very Confident, 5) Very Poor Confident	C1 Survey

Notes: Abbreviations: NR= Not recorded, SHI= Socioeconomic Health Insurance level, BDI= Borough Development Index, Ed= Education, Add Diff= Additional Difficulties, ^= Hearing loss with onset after birth, CI= Cochlear Implant, C1 Survey= Child with CI Survey 1,Tech.= Technical, *CIuse= variable of CI use hours during the day, HA= Hearing aid/s, SNA= Special Needs Assistance, SLD= Speech and Language Disorders, Previous training variable, ENT= Ear, Nose and Throat, AVT= Auditory Verbal Therapy, CI Training: Parental Engagement variable about previous parental training with the CI, CI Confidence: Parental Engagement variable about confidence with the CI intervention.

3.5 Procedures

In September 2020, the researcher went to Chile to conduct and oversee the data collection process. Assistance with data collection was provided by two research collaborators from the University of Chile, and one paid trained collaborator (paid through The Ministry of Health grant). They collected data from designated hospitals and called parents/caregivers on the telephone, following the data collection protocols' requirements (Supplementary Material). As a result of the COVID-19 restrictions from March 2020, all measures were taken to follow the national guidance on research in health services. Finally, from January to March 2021, data collection was completed from the clinical records and the online survey. Figure 5 shows the Study 1 in the project flow chart.

Figure 5. Study 1 in the project flow chart



Notes: Colours: **Blue**= General procedures, **Orange**= Study 1, **Green**= Study 2, **Brown:** other processes. Abbreviations: T1= Time 1, T2= Time 2, OSF= Open Science Framework, D.= data, Med.& Aud. D= Medical and audiological data, G&M= Geers & Moog Chilean Scale, CDI= Communicative Development Inventory Assessment, VU= Vocabulary Understand, VP= Vocabulary Production, CDI W&G= Words and gestures Chilean CDI, PE&BE= Parental Engage and behavioural problems, SIR= Chilean Speech Intelligibility index, CAP II= Chilean Categories of Auditory Perception II, Opinio= UCL survey platform

3.5.1 Procedures for clinical records data collection

For the data collection in hospitals, an e-mail was sent to each Cochlear Implant team with the request to access clinical records in the hospital. When the online or physical clinical records were available, the researcher attended each hospital to collect the required data. The information was compiled in a spreadsheet, following a data collection protocol (Supplementary Material). Missing data were noted. As a result, two final documents, one spreadsheet with detailed information about each child with CI and one spreadsheet with pseudonymised data using an ID were created. Data was managed according to the data management plan that had been approved by ethics committees in the UK and Chile.

3.5.2 Procedures for online survey data collection

Once participant contact information was provided by the Chilean Ministry of Health and while the clinical record was being completed, the researcher and paid collaborator contacted each possible participant by telephone. The researcher started the call by explaining the project aims and the survey content. After the call, an email with the information sheet, consent form and also the personalised OPINIO link was sent. The link was also sent by WhatsApp to parents/caregivers who agreed to participate. The online platform enabled the participant to be tracked after they had completed the informed consent. Thereafter, guidance for participation in the survey was provided. This guidance was the same for all parents/caregivers. The person who was most familiar to the deaf child on a daily basis was asked to complete the survey. In case of difficulties with the online platform whilst completing the survey, telephone assistance from the researcher and the collaborator was available. In the case of accessibility for deaf people, a sign language interpreter and a video call for deaf parents/caregivers were offered. However, no participants required the sign language interpreter or other accessibility adjustment.

107 parents/caregivers completed the survey. There were some minor challenges; difficulties using the platform were reported by 21 participants, technical problems with the platform were reported by 8 parents/caregivers, and queries about sentences or questions were made by 16 participants. All these issues were dealt with through text message and/or video chat. As a criterion for considering the task fulfilled, each participant was required to complete all the surveys. In the case of incomplete surveys, a reminder from the collaborator was sent by e-mail and WhatsApp. Survey data were then added to the pseudonymised spreadsheet, which could then be transferred to the UK in accordance with the study data management plan as approved by UCL Data Protection.

3.6 Data Analysis

3.6.1 Descriptive Statistics for Study 1

The analysis plan for study 1 was pre-registered on the Open Science Framework (OSF) platform (https://osf.io/jeyg6). Descriptive statistics including means, quantiles, and standard deviations are used to characterise children with CI in Chile implanted from 2017 to 2019 within Chile's public health system. Additionally, we use visualisation tools using R (R Core Team, 2021) with ggplot(), and ggplot2(), in the package “tidydiverse” and “ggplot2”, respectively. For map visualisation design, we use STATA (Stata Corp., 2021) and Microsoft PowerPoint Office ®.

Descriptive results are presented in Chapter 4. Moreover, Chapter 4 provides an additional exploratory inferential analysis using the GeersM which will be fully explained in the chapter.

Chapter 4: Results Study 1

4. Characterisation of children with CI in Chile implanted between 2017 to 2019

4.1 Characterisation Results (Research Question 1)

4.1.1 Sociodemographic and Audiological information:

Our participants were implanted in seven Chilean public hospitals and were from 57 boroughs of the country. Table 4 displays descriptive statistics for children with CI in Study 1.

Table 4 Independent variables descriptive statistics in Children with CI in Study 1

Independent variable	Category /Level	Mean/Freq. [SD](%)
Age	Years and months of age. From min= 2y 4m, max= 15y 1m	7 years, 0 months [2.9]
Gender	Male	47 (44%)
CI age	Months of age at CI surgery	33.19 [10.2]
Aetiology	Congenital	89 (81%)
	Late Hearing Loss	18 (19%)
SHI	Low income	42 (39.3%)
	Low-middle income	28 (26.2%)
	Middle income	16 (15%)
	Middle - high Income	21 (19.6%)
BDI	Index from 0 up to 1	0.54 [0.1]
Family Ed	Primary incompleted	4 (3.7%)
	Primary complete	7 (6.5%)
	Secondary incompleted	46 (43%)
	Secondary completed	9 (8.4%)
	Training incompleted	12 (11.2%)
	Training completed	5 (4.7)
	University incompleted	16 (15%)
	University completed	8 (7.5%)
Add diff	Not recorded / Not declared	96 (89.7%)
CI status	Unilateral CI w/o contra HA	83 (77.6%)
	Unilateral CI with contra HA	10 (9.3%)
	Bilateral CI	6 (5.6%)
	Other type	8 (7.5%)
CI condition	Operative-Without issues	71 (66.4%)
	Operative but with some issues	29 (27.1%)
	Not Operative – Technical issues	3 (2.8%)
	Not in use from time ago	4 (3.7%)
Rehabilitation attendance	Attending	69 (64.5%)
	Attendance with difficulties	25 (23.3%)
	Not attending	13 (12.1%)
Easy rehabilitation attendance	Yes	76 (71%)
	No	31 (29%)
Frequency rehabilitation	Weekly	78 (72.8%)
	Each 2 weeks	10 (9.3%)
	Monthly	7(6.5%)
	Less than once per month	12 (11.2%)

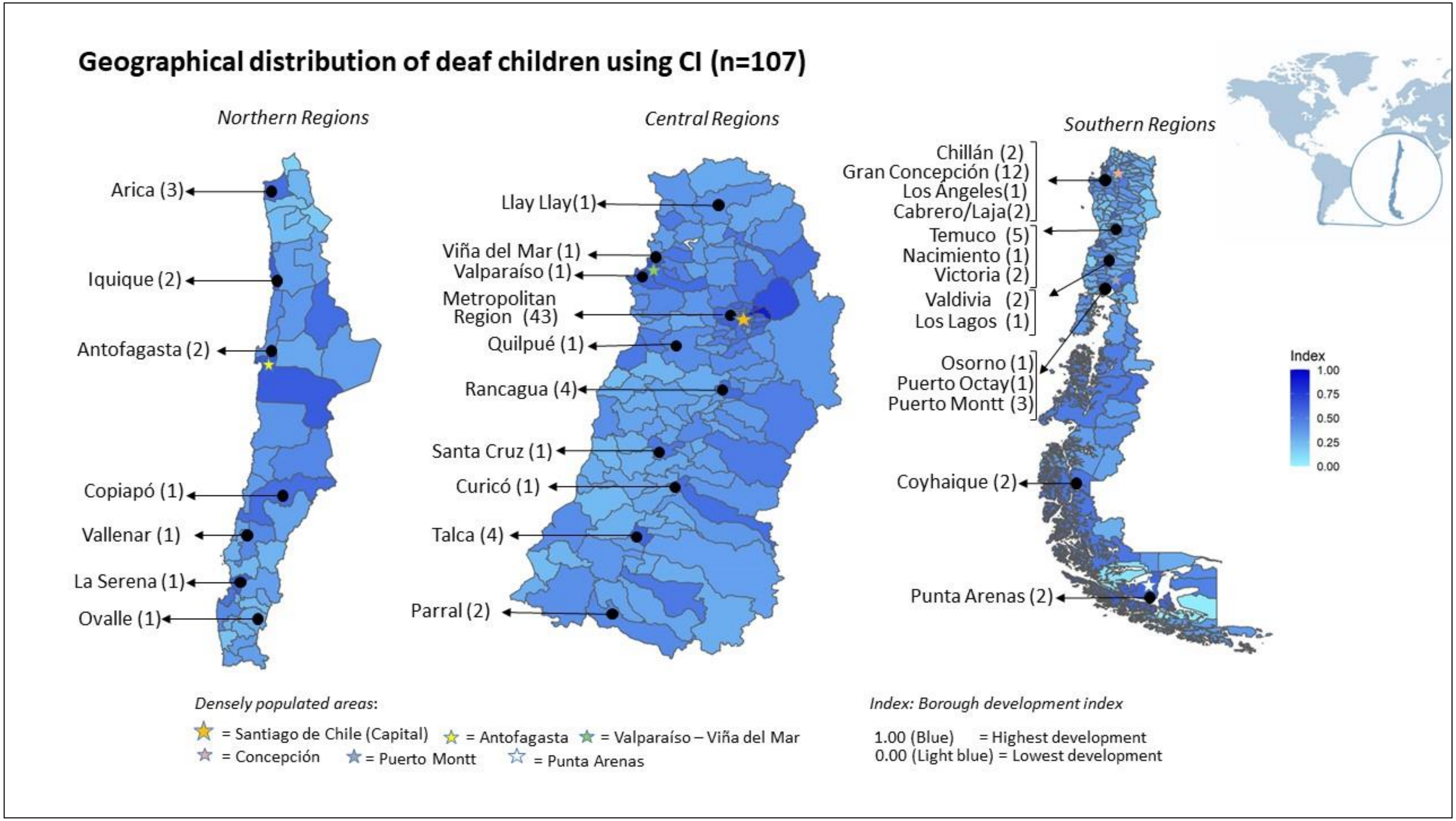
Duration treatment	More than 2 hours	2 (2.8%)
	1 hour	31 (29%)
	40-45 minutes	46 (43%)
	30 minutes	26 (24.3%)
	Less than 30 minutes	1 (0.9%)
Education attendance	Not attending any ed.	10 (%)
	Special school for the deaf	12 (12.2%)
	Mainstream ed. w/o SNA	6 (4.1%)
	Mainstream ed. with SNA	53 (59.2%)
	Special school for SLD	6 (10.2%)
	Mainstream nursery	13 (2.0%)
CI use (ordinal variable)	Never	2 (4.1%)
	Sometimes	1 (2.0%)
	Frequently	5 (10.2%)
	Always	41 (83.7%)
CI hrs per day	From min=0.0 max=19.0 hrs.	10.5 [3.6]
Behavioural challenges	No	86 (80.4%)
	Yes	21 (19.6%)
Treatment Professionals	Interpreter	9 (8.4)
	Speech & Language Therapist	89 (83.1)
	ENT/Doctor or Audiologist	50 (46.7)
	Special Educator	54 (50.5)
	AVT Therapist	28 (26.1)
	Psychologist	26 (24.2)
	Other	8 (7.5)
Parental Engagement: • CI Training	No	34 (31.8%)
	Yes	73 (68.2%)
Parental Engagement: • CI Confidence	No confidence	1 (0.9%)
	Very Poor Confident	4 (3.7%)
	Poor Confident	7 (6.5%)
	Somewhat Confident	41 (38.3%)
	Very Confident	54 (50.5%)

Notes: Abbreviations: SHI= Socioeconomic Health Insurance level, BDI= Borough Development Index, Ed= Education, Add Diff= Additional Difficulties, CI= Cochlear Implant, *CIuse= variable of CI use hours during the day, HA= Hearing aid/s, w/o= without, AVT= Auditory Verbal Therapy, SNA= Special Needs Assistance.

The age of the children with CI ranged from 2 years 4 months to 15 years 1 month, with a mean of 7 years [SD= 2.9]. There were 44% (47/107) males and 56% females (60/107).

The aetiology for 81% (89/107) of children with CI was “Congenital”, such as idiopathic, prematurity or genetic. Late Hearing Loss, such as infections, idiopathic and other conditions, represented around 19% of the cases. The vast majority of children with CI did not have any additional difficulties (89.7% 96/107) and only 10.3% (11/107) did.

Figure 6. Geographical distribution of Children with CI (N=107) and BDI in Study 1



Notes: BDI= Borough development index in Chile. The colour scale shows the Borough Develop Index (Bahamonde, 2020), which evaluates the country's living and environmental deprivation areas. It merges thirteen health, social well-being, economy, and education variables in indexes from 0 to 1. Less developed boroughs are coloured in light blue, while more developed boroughs are in blue.

The socioeconomic information by SHI ranged from low income with 42% (42/107) of the participants to middle-high income with 19.6% (21/107). According to the results, close to 65% of the participants in this study belong to the two lowest-income levels in the public health system. Figure 6 illustrates the geographical distribution of sampled children with CI by Chilean boroughs using the BDI scores (from 0.0 to 1.0). Most of the children with CI came from the central area (55/107, 51.4%), specifically Santiago (43/107, 40.1%), and southern regions (37/107, 35.5%). Santiago and Concepcion have the highest BDI scores (0.78 and 0.64, respectively), whereas the remaining areas ranged below 0.60. The average BDI value in our sample was somewhat higher than the country average (I.e.,0.54 and 0.37, respectively). In terms of the parental education levels, of the closest parent/caregiver, at least around 81% (87/107) of the families had someone who completed secondary education. 22% (24/107) of children with CI have a parent/caregiver with a “Training Completed” or “University Completed” level of education at home.

4.1.2 Audiological and treatment variables

The chronological age at CI surgery in children with CI varied considerably from one year of age to 12 years 4 months. The mean age at surgery was 4 years and 6 months [SD=2.8]. These figures cover the whole cohort, irrespective of whether deafness was present from birth or acquired later. However, if we only look at the 89 children with CI who had a congenital condition, the minimum and maximum age of CI surgery are the same. The mean age of CI surgery in this group of children with congenital deafness is 3 years 10 months [SD=26.0], decreasing the mean by 8 months when compared to the whole sample.

Concerning the device variables, 77.6% (83/107) of parents/caregivers declared their child was using unilateral CI without HA in the other ear. In terms of the “CI condition”, the majority (66.4%) of the parents reported their child’s CI “Operative-Without problems”. However, for 27.1% (29/107) children it was reported they have a CI “Operative but with some issues”.

With respect to the treatment variables, most parents/caregivers (94%) answered that their children were attending treatment with a speech language therapist or other therapists/clinicians before or during the pandemic. For treatment frequency, most of the answers were “Weekly” (78%) and only seven participants (6.5%) responded “monthly”. For treatment sessions, most of the children with CI (75%) have sessions from 40-45 minutes of duration. In terms of professionals during the CI treatment, 83.1% (89/107) of Children with CI were attending speech and language therapy, while the need for a Sign Language interpreter was reported only by 8.4% (9/107).

Considering the factor “School-Nursery attendance”, most of the children were attending a school or nursery (90.65% 97/107), while only 10 % were not attending any type of education. For CI use (using the device) parents reported as follows: “Always” (78.5%) and “Frequently” (12%). The mean of CI use of the CI per day was 10.53 hours [SD=3.6].

4.1.3 Behavioural challenges and parental engagement variables

80% (86/107) of parents reported no behavioural problems/challenges in the child with the CI. Two aspects of parental engagement were reported. First, in CI training, 94% (101/107) of participants reported that they had some specific CI training. Second, in CI Confidence from very low confidence (scale 1) to very high confidence (scale 5), most of the participants reported high or very high confidence with the device with 38% (41/107) and 51% (54/107) respectively.

4.2 Outcome variables in children with CI in Chile

4.2.1 Type of Communication at Home

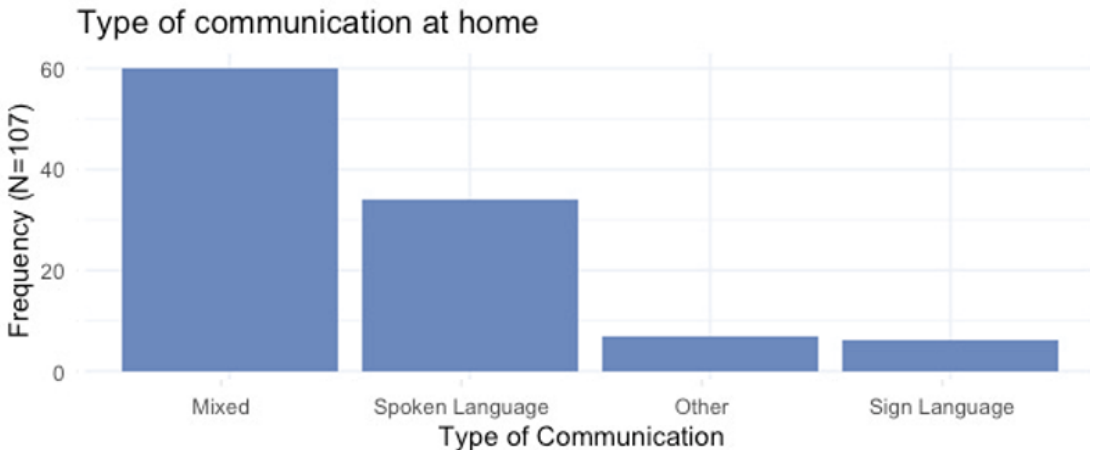
As can be seen in Table 5 and Figure 7, the most common communication type was “Mixed, using signs and spoken language” with 56% (60/107), with 32% (34/107) of participants describing spoken language as the communication used at home.

Table 5. Communication at home

Communication at home	N(107)	%
Mixed Language	60	56
Spoken Language	34	31.7
Other	7	6.5
Sign Language	6	5.6
Total	107	100

Notes: Mixed Language includes spoken and sign language. Other includes any other predominant communication at home.

Figure 7. Type of communication at home



Notes: Mixed Language includes spoken and sign language. Other includes any other predominant communication at home.

4.2.2 Social Inclusion

As shown in Table 6, parents/caregivers were positive in their answers to the question, “Do you feel that your child is included in school and social life?”. Interestingly, despite the diversity in speech perception/spoken language skills, most parents/caregivers gave high levels of social inclusion for their children, rating them at level 4 (22.4%) and level 5 (47.7%).

Table 6. Social Inclusion of children with CI by parents/caregivers

Social Inclusion	N (107)	%
1 No, not too much included	7	6.5
2 No, not included	4	3.7
3 Neutral	15	14
4 Yes, the child is included	22	20.6
5 Yes, the child is quite included	59	55.1
Total	107	100

Notes: Likert scale to the question “Do you feel that your child is included in school and social life?”

4.2.3 Cochlear Implant Satisfaction by parents/caregivers

Table 7 shows the responses chosen by parents/caregivers to the question “Has the use of the device satisfied your expectations as a parent/caregiver?”. Most parents/caregivers indicated “Satisfied” and “Very Satisfied” levels with 47.7% and 22.4%, respectively. On the other hand, 5.6% of participants chose the level “Very Unsatisfied”.

Table 7. CI Satisfaction by parents/caregivers

CI Satisfaction	N (107)	%
1.Very Unsatisfied	6	5.6
2. Unsatisfied	5	4.7
3. Neutral	21	19.6
4. Satisfied	24	22.4
5. Very Satisfied	51	47.7
Total	107	100

Notes: Likert scale to the question “Has the use of the device satisfied your expectations as a parent/caregiver?”

4.2.4 The Categories of Auditory Performance Index (CAP-II).

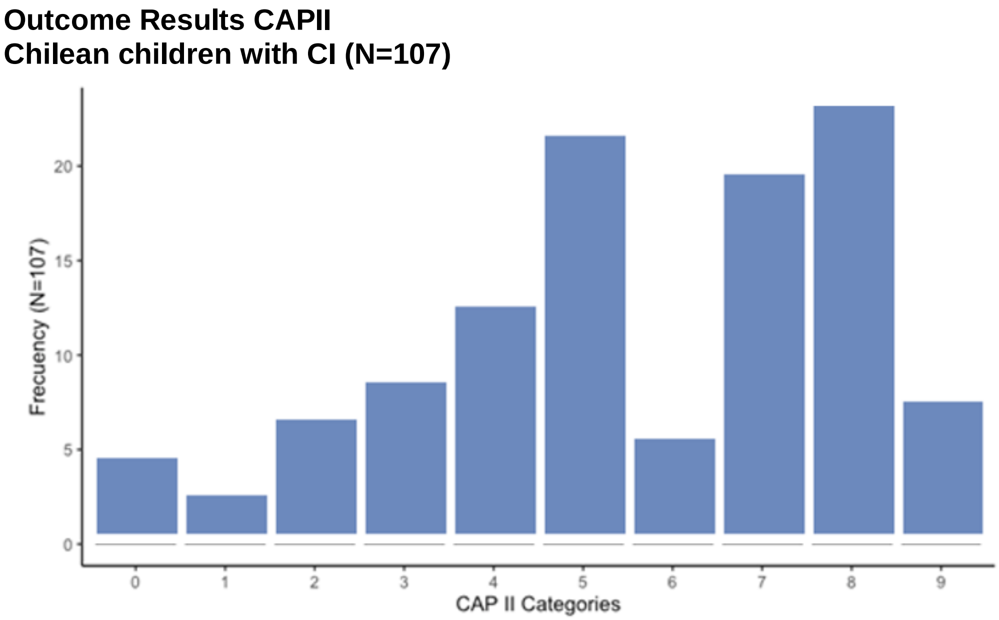
Table 8 and Figure 8 show the distribution of categories in the Chilean Spanish Categories of Auditory Performance Index (CAP-II) chosen by parents/caregivers for their children. As can be seen, categories five (21/107), seven (19/107) and eight (23/107), indicate more children in higher auditory performance categories. Most of the children with CI were rated above Category 5 of understanding of common phrases without lip-reading.

Table 8. Frequency table Chilean Spanish CAP II Categories

Chilean Spanish CAP-II Categories	N(107)	%
0. No awareness of environmental sounds	4	3.7
1. Awareness of environmental sounds	2	1.9
2. Response to speech sounds	6	5.6
3. Recognition of environmental sounds	8	7.5
4. Discrimination of at least two speech sounds	12	11.2
5. Understanding of common phrases without lipreading	21	19.6
6. Understanding of conversation without lipreading with a familiar talker	5	4.7
7. Use of a telephone with a familiar talker	19	17.8
8. Understanding/Following group conversations.	23	21.5
9. Use the telephone with an unknown speaker in an unpredictable context.	7	6.5

Notes: CAP II Categories are from the Chilean Spanish of CAP II

Figure 8. CAP II Results



Notes: CAP II Categories are from the Chilean Spanish of CAP II

4.2.5 The Speech Intelligibility Rating Scale (SIR)

The results of the Chilean version of the Speech Intelligibility Rating Scale (SIR) are presented in Table 9 and Figure 9. Almost half of parents/caregivers chose Children with CI's speech as 'intelligible' at category 4 (28%) or 'completely intelligible' (20.6%) at the top of the scale. Nevertheless, a reasonable proportion (38.3%) of participants described their child's speech, as "Connected speech is unintelligible. Pre-recognisable words in spoken language, the child's primary mode of everyday communication may be manual".

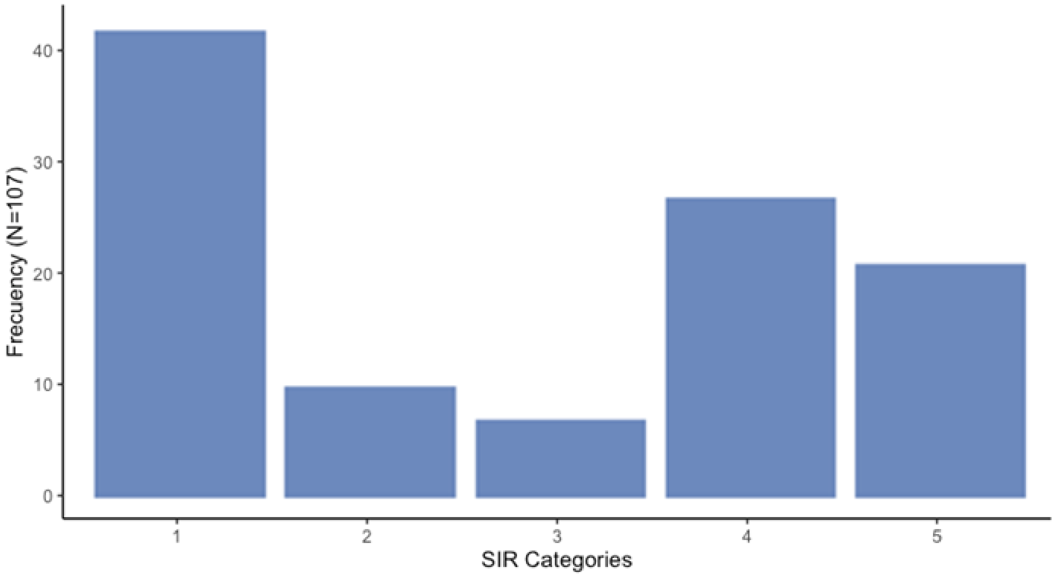
Table 9. Frequency table Chilean Spanish SIR Categories.

Chilean Spanish SIR	N (107)	%
1. Connected speech is unintelligible. Pre-recognizable words in spoken language, the child's primary mode of everyday communication may be manual.	41	38.3
2. Connected speech is unintelligible; intelligible speech is developing in single words when context and lip-reading cues are available	7	6.5
3. Connected speech is intelligible to a listener who concentrates and lip-reads within a known context.	7	6.5
4. Connected speech is intelligible to a listener who has little experience of a deaf person's speech.	30	28
5. Connected speech is intelligible to all listeners. The child is understood easily in everyday contexts.	22	20.6

Note: Categories from 1 to 5 in speech intelligibility of Children with CI with CI according to their parents/caregiver

Figure 9. SIR Results

Outcome Results SIR
Chilean children with CI (N=107).



Note: Categories from 1 to 5 in speech intelligibility of Children with CI with CI according to their parents/caregiver

4.2.6 The Latin American Geers and Moog Categories

Table 10 and Figure 10 show results for the Latin American Geers and Moog Categories (GeersM). More children with CI are located in categories “1. Speech detection but unable to perceive even time-intensity pattern info in words with speech amplified” (34/107) and “2. Time-intensity pattern perception in amplified speech” (25/107), which means poor speech perception with the device. Furthermore, in categories related to proficient speech perception there were seven participants located in category “6. Word recognition by repetition” and six in category “7. Spoken language comprehension word recognition by repetition”.

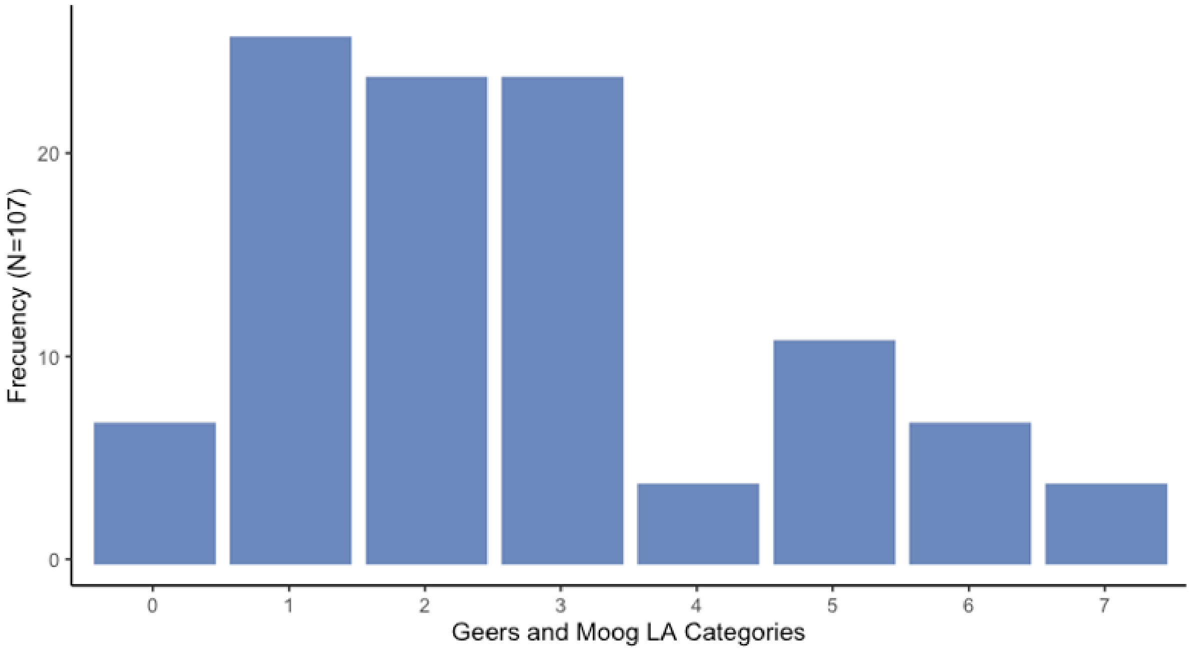
Table 10. Latin- American Geers and Moog Categories

GeersM Categories	N(107)	%
0. Unable to perceive any speech sound (ling test)	7	6.5
2. Speech detection but unable to perceive even time-intensity pattern info in words with speech amplified	34	31.8
3. Time-intensity pattern perception in amplified speech (Above 70% in testing)	25	23.4
4. Word identification by basic spectral information (Same metric and time, but different consonants and vowels)	10	9.3
5. Word identification in a group by their vowels	5	4.7
6. Recognition of word in a group by their consonants	13	12.1
7. Word recognition by repetition	7	6.5
8. Spoken language comprehension	6	5.6

Notes: GeersM : Geers and Moog Latin American Categories.

Figure 10. Latin- American Geers and Moog Categories

Latin- American Geers and Moog Categories
Chilean children with CI (N=107)



Notes: GeersM: Geers and Moog Latin American Categories.

4.3 Exploratory inferential analysis in Study 1

4.3.1 Procedures for the exploratory inferential analysis

RQ1 did not explicitly include a further examination of the association among variables, as these were to be evaluated in RQ2 and RQ3, in Study 2. Nevertheless, we performed an exploratory inferential analysis to investigate the associations between the independent variables and the GeersM outcome result. This is because the GeersM outcome result is the only outcome in Study 1 that was obtained from formal assessments documented in the deaf child's clinical records, and thus could enhance our comprehension of the factors that affect speech perception and spoken language outcomes.

Therefore, we evaluated the association between variables – Age, CI Age, SHI, BDI, family education, additional difficulties, education attendance, CI use, PE-T and PE-C– and the GeersM scale results. We used parametric and non-parametric tests, considering Pearson/Spearman correlations and t-tests. We used an alpha value of $p<.005$ for all zero-order correlations. To account for missing data, we employed multivariate normal distribution methods to minimise biases while obtaining appropriate estimates for uncertainty (Graham, 2009). The package used in R was "mice". This method was applied to two predictor factors - Borough and SES-, which had less than 3% of missing data, and GeersM outcome result, which had 13% of random missing data. Additionally, in order to avoid estimation biases, we examined factors distribution and tested for multicollinearity, using the Variance Inflator Factor (VIF).

To balance the control of Type I errors with maintaining reasonable statistical power, a Bonferroni correction was applied, resulting in a new significance level (alpha) of approximately $\alpha = 0.0083$ for each individual test. This is a rather stringent statistical control and therefore in the cases of alpha results between .05 and .0083, they were described as with potential significance.

4.3.2 Results for the exploratory inferential analysis

In the study, a potential significant correlation was observed between the age of children with CI and their GeersM scale results (cor = 0.277, p = 0.003*). This finding tends to indicate that older children had higher scores on the GeersM. Furthermore, a positive but small correlation was potentially observed between the age at which CI was implanted and the GeersM results (cor = 0.260, p = 0.006*). This finding implies that in cases where CI was implanted later, children with CI exhibited higher scores on the GeersM scale. The above is contrary to the evidence, but it could be expected considering the large variety within the group in terms of age, and the presence of children with CI with late hearing loss in the sample. This will be discussed further in the discussion section.

In the analysis of whether additional difficulties affect the outcome, a Kruskal-Wallis test revealed a significant difference in GeersM results between children with CI with and without additional difficulties (X^2 = 127.31, df = 1, p<.001). This finding indicates that children with additional difficulties tended to score lower on the GeersM scale compared to those without additional difficulties. This suggests that the presence of additional difficulties might have a negative impact on speech perception outcomes in children with CI in this study.

In contrast, no significant correlation was found between the Social Health Insurance (SHI) of children with CI and their GeersM scale results (cor = 0.021, p = 0.823). Similarly, there was no significant correlation between the Borough Development Index (BDI) and Family Education level of children with CI and their GeersM scale results (BDI: cor = 0.095, p = 0.350; Family Education: cor = 0.043, p = 0.655). These findings suggest that the mentioned social determinant of health did not significantly influence on speech perception outcomes as measured by the GeersM scale in this sample.

Furthermore, no significant correlation was observed between the daily hours of CI use by children with CIand their GeersM scale results (cor = 0.125, p = 0.200). This indicates that the duration of CI use per day did not have a notable impact on speech perception skills as assessed by the GeersM scale. The usage of CI can be influenced by the age of children, their sleep patterns, and other variables, which can be analysed in further studies by grouping children with CI into different age groups.

Finally, the study evaluated the influence of parental engagement factors on GeersM results. A significant difference was found between parents/caregivers who received training about CI and those who did not (X^2= 83.593, df = 1, p<.001). Parents/caregivers who received CI training were associated with higher rankings on the GeersM scale, indicating a potential positive impact of parental education on speech perception outcomes in deaf children with CI. However, no significant correlation was observed between parental confidence in the engagement sub-variable and GeersM scale results (cor = 0.05, p = 0.573).

In summary, the primary findings of study 1 offer valuable insights into factors that could potentially influence speech perception as a skill of spoken language abilities. The presence of additional difficulties in children with CI was found to be significantly associated with lower GeersM scores, indicating a potential adverse impact on speech perception outcomes. Additionally, parental engagement through CI training was significantly linked to higher GeersM scores, implying a potential positive influence on speech perception outcomes in deaf children with CI. The results also suggested a potential positive correlation between the age of children with CI and the age at which CI is implanted with GeersM scale results. These correlations might be attributed to the diversity in the ages and diagnoses of the children with CI in the sample. These findings Chapter 7 will further consider these preliminary findings from Study 1 along with the findings of Study 2.

Moving on to Chapter 5, Study 2 will be introduced, which aims to explore the influential factors affecting spoken language in children with CI in Chile through a longitudinal study.

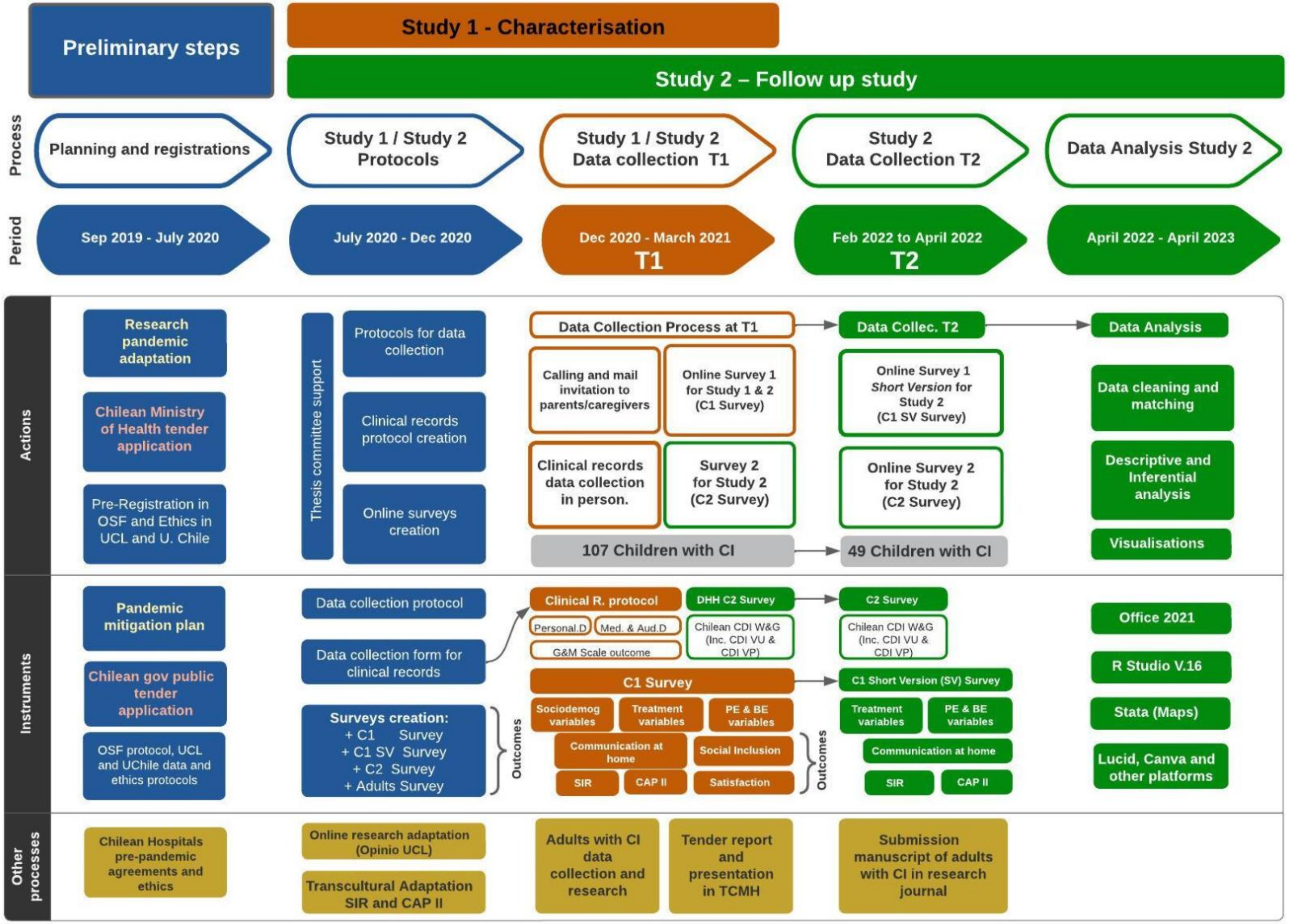
Chapter 5: Methods Study 2

5. Methods Study 2

Study 2 is a follow-up longitudinal study of 49 children with CI from the 107 children characterised in Study 1. Figure 1 shows the flow chart for Study 1 and Study 2, including the procedures and instruments.

Two Research Ethics Committees approved Study 2: The Faculty of Medicine, University of Chile (167-2020) and University College London (UCL) (LCD-2020-13). The study was registered with UCL Data Protection, and all approved data management and transfer procedures were followed. The methods for Study 2 were pre-registered on the OSF platform (https://osf.io/jeyg6), including research questions and hypotheses. The data collection was partially supported by a small grant from the Public Health System in Chile through the National Public Tender 757-89-l120. This grant covered research involving all children and adults who received and activated a CI between 2017 and 2019 for children and between 2018 and 2020 for adults. Participants were required to have used the device for at least one year at the start of the study. The data for both studies was collected from 2020 to 2021. The information about adults with CI was reported in a separate article submitted to the journal PLOS ONE in February 2023 (Bustos-Rubilar et al., 2023). The adult study aimed to evaluate the impact of the Chilean high-cost policy "Ley Ricarte Soto" on treatment success and labour market inclusion among adults with CI. The paper reports on examining and characterising outcomes based on self-reports about treatment success and occupation status at least one year after the CI implantation. This relevant contribution to the current policies and deaf adults` intervention by the Chilean Ministry of Health is included in Supplementary Material.

Figure 3. *Thesis project flow chart, including Study 1 and Study 2.*



Notes: Colours: **Blue** = General procedures, **Orange**= Study 1, **Green**= Study 2, **Brown:** other processes. Abbreviations: T1= Time 1, T2= Time 2, OSF= Open Science Framework, D.= data, Med.& Aud. D= Medical and audiological data, C1 Survey= Children Survey 1, C1 SV Survey= Children survey 1 short version, C2= Children Survey 2, G&M= Geers & Moog Chilean Scale, CDI= Communicative Development Inventory Assessment, VU= Vocabulary Understand, VP= Vocabulary Production, CDI W&G= Words and gestures Chilean CDI, PE&BE= Parental Engage and behavioural problems, SIR= Chilean Speech Intelligibility index, CAP II= Chilean Categories of Auditory Perception II, Opinio= UCL survey platform

5.1 Aims and Hypothesis for Study 2

The overall aim of this research was *to determine which factors affect spoken language outcomes in children with CI in Chile considering the Latin American context*. Study 2 sought to address this overall aim through two research questions following on from RQ1 in Study 1:

- Research question 2 (RQ2): Which factors are associated with good spoken language outcomes in children implanted from 2017 to 2019 within Chile's public health system?

- Research question 3 (RQ3): What factors predict progress made in children with CI spoken language skills over 12 months in Chile?

In order to evaluate the two research questions above, we developed individual hypotheses, taking into account factors influencing spoken language outcomes in children with CI (see section 1.2.5) and predicting the resulting outcomes:

Hypothesis A:
Variables: *Aetiology and Additional Difficulties.*

According to the evidence (Barker et al., 2009; Berrettini et al., 2008; Gérard et al., 2010; Ingvalson & Wong, 2013), children who have auditory and medical conditions without additional difficulties (that is, non-syndromic, without comorbidities or cognitive-behavioural disorders) make better progress in the development of spoken language compared to children with CI who present the aforementioned conditions. We predict that children with CI in Chile who do not have additional difficulties will have better spoken language outcomes than children with additional difficulties.

Hypothesis B:
Variables *Age of CI surgery/switch-on*

Early identification and diagnosis have been considered the most critical factors regarding CI outcomes (Dettman et al., 2016; Leigh et al., 2013; McKinney, 2017). As Ruben et al. (2018) described in their literature review, the ideal period for implantation is between 10-12 and 24 months of age. We predict that children implanted in Chile before 24 months of age will show better results in spoken language outcomes than those implanted after 24 months.

Hypothesis C:
Variables: Socioeconomic Health Insurance (SHI), Borough Development Index (BDI), Family highest education (Family Ed).

It is possible that social determinants of health, such as SHI, access to health care, Family Ed and social facilities as BDI (Matiz et al., 2021), could affect spoken language outcomes expected for children with CI. In Latin America, these factors are compounded by inequalities and segregation, resulting in challenges to healthcare economics and access (Bright et al., 2019). The Chilean 'Borough Development Index' (BDI) (Hernández Bonivento et al., 2020) is an index variable showing a composite number related to well-being and access to service across Chile. It ranges from 0 (low) to 1 (high) in relation to each territory's socioeconomic outcomes, living deprivation, and urbanisation. High index might increase outcomes in children with CI in Chile. Thus, we predict that low SHI, low maternal/caregiver education and low BDI could have worse spoken language outcomes in children with CI.

Hypothesis D:
Variables: Parental Engagement (PE): 1) CI Confidence and 2) CI Training.

Suskind et al. (2016), suggest that parental engagement considering confidence and training about language development and CI use can improve the expected outcomes in early CI use. Therefore, we expect these two sub variables of parental engagement can improve outcomes in early CI use by children with CI.

Hypothesis E:
Variables: *CI use hours per day (CI use)*

Consistent use of the CI during the day would benefit better spoken language outcomes. Wiseman et al. (2021) suggest that children with CI who used their CI for more than 8 hours per day had better auditory, speech recognition and spoken language skills than children who used their CI for less than 8 hours per day. We predict that children with CI who report continuous daily use of the device could have better results in spoken language outcomes than those who report less time using the CI.

Hypothesis F:
School Nursery Placement Attendance.

Studies have suggested that rich spoken language contexts at home and in classrooms could have a positive impact on the spoken language development of children with CI (Archbold, 2014; Tait, Nikolopoulos, & Lutman, 2007; Wiseman & Warner-Czyz, 2018). This could be complemented by learning sign language to provide children with additional language and with additional non-verbal cues. We predict that children with CI who have experienced rich contexts in spoken language in the education environment could have better outcomes in spoken language skills.

Research Question 3: What factors predict progress made in spoken language skills by children with CI over 12 months?

Evidence has shown improved spoken language outcomes in young children with CI after 12 or more months using the CI (Niparko et al., 2010; Uhler, Yoshinaga-Itano, Gabbard, Rothpletz, & Jenkins, 2011; Yoshinaga-Itano, Baca, & Sedey, 2010). We predict that children with audiological-medical conditions without additional difficulties, who received early cochlear implantation, exhibited advantageous health-related social determinants, heightened parental engagement, and an extended period of device utilisation would have better-spoken language progress evaluated by the Chilean Version of the CDI Language Assessment.

5.2 Participants

Forty-nine children with CI (and parents/caregivers) who had taken part in Study 1 were invited to participate in Study 2. Children were aged between 2 and 6 years and had received their first CI from a public hospital in Chile between January 2017 and December 2019, Table 11 details the inclusion and exclusion criteria of Study 2.

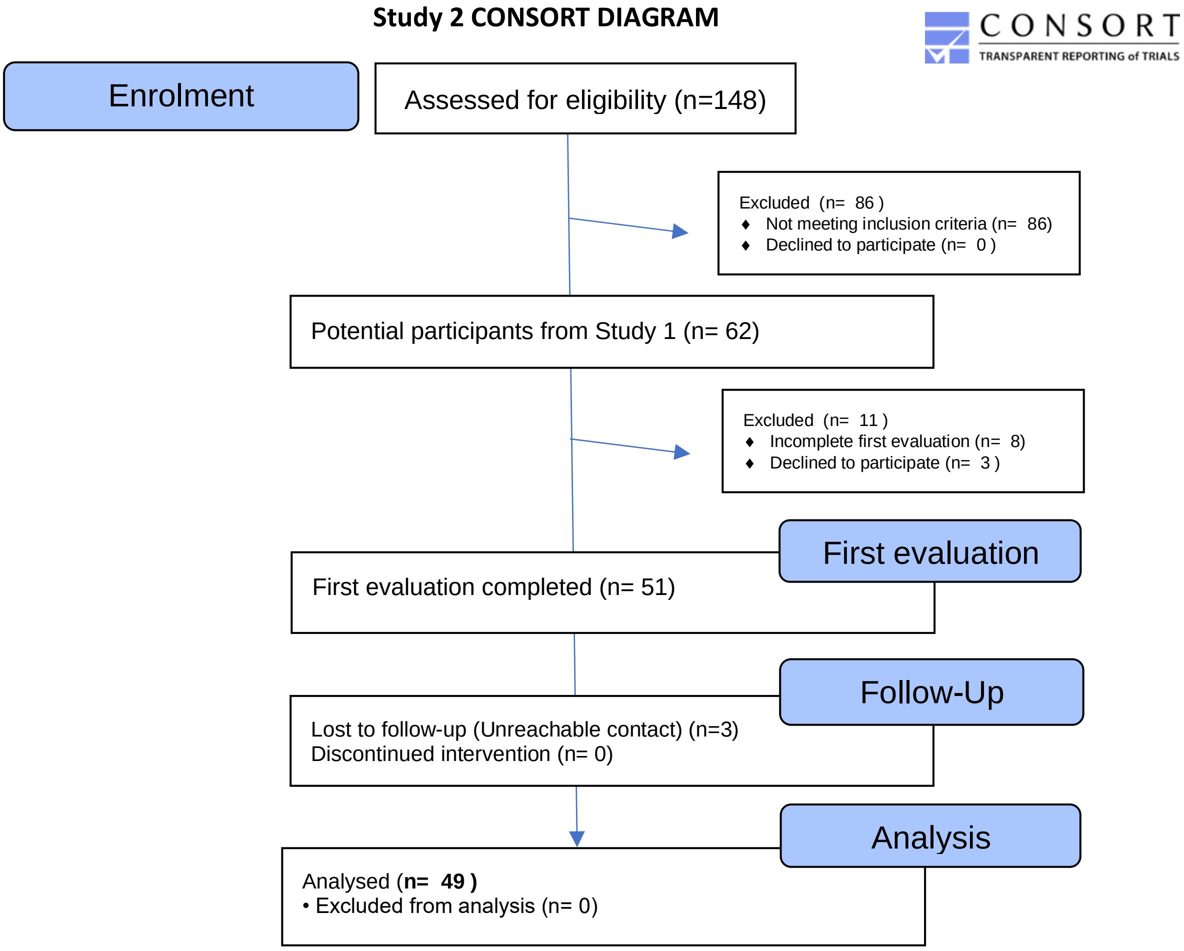
Table 11. Inclusion and exclusion criteria in Study 2

Inclusion Criteria	Exclusion Criteria
4. children receiving the first CI during 2017 to 2019 5. children from 2 to 6 years of age. 6. children from Chilean public hospitals. 7. children with at least one year from the implantation switch-on time. 6. parents/caregivers deemed able to complete the follow-up evaluation.	1. implanted before 2017 and after 2019 2. children older than 6 years of age 4. children implanted in private hospitals. 5. children with incomplete personal and audiological data from clinical records. 6. parents/caregiver deemed not able to complete the follow-up evaluation.

Note: Inclusion and exclusion criteria applied in Study 2.

During Study 1, The Chilean Ministry of Health provided a list of 153 possible children, of which 148 had met the inclusion criteria for Study 1. From these 148 initial participants, 62 children met the initial inclusion criteria and forty-nine were eventually included in Study 2. The primary inclusion criteria was the age of the participants. A Consolidated Standards of Reporting Trial, Consort Diagram (http://www.consort-statement.org/), about Study 2 is shown in Figure 11.

Figure 11. Consort diagram for Study 2



5.3 Instruments

Study 2 used data collected during Study 1 (henceforth Time 1) and further data collected 12 months later - henceforth Time 2. Study 2 was a follow-up longitudinal study in which the independent variables (*Age, CI status, CI condition, Education attendance, CI use, Frequency rehabilitation, CI Confidence and CI Training e in Parental Engagement sub variables)* and outcome variables (*Type of communication, SIR, CAP II, CDI words and gestures*) were collected twice. See Table 12 for more details.

Table 12. Outcome results

	Outcome Results	
Outcome	***Description***	***Source***
7. Communication at home	Four options for the question: How do you communicate with your child?: 1) Sign Language, 2) Spoken Language, 3) Mixed, using Sign and Spoken Language, 4) Other.	C1 Survey C1 SV Survey
8. Categories of Auditory Performance CAP II (Chilean CAP) Abb: CAPII	Ten levels. 0. No awareness of environmental sounds 1. Awareness of environmental sounds 2. Response to speech sounds 3. Recognition of environmental sounds 4. Discrimination of at least two speech sounds 5. Understanding of common phrases without lip-reading 6. Understanding of conversation without lip-reading with a familiar talker 7. Use of a telephone with a familiar talker 8. Understanding/Following group conversations. 9. Use the telephone with an unknown speaker in an unpredictable context.	C1 Survey C1 SV Survey
9. Speech Intelligibility Rating Scale SIR (Chilean Version of SIR), Abb: SIR	Six levels. 1. Connected speech is unintelligible. Pre-recognizable words in spoken language, the child's primary mode of everyday communication may be manual. 2. Connected speech is unintelligible; intelligible speech is developing in single words when context and lip-reading cues are available 3. Connected speech is intelligible to a listener who concentrates and lip-reads within a known context. 4. Connected speech is intelligible to a listener who has little experience of a deaf person's speech. 5. Connected speech is intelligible to all listeners. The child is understood easily in everyday contexts.	C1 Survey C1 SV Survey
4.1. CDI VU	160 words in Chilean Spanish. Do your child? (Tick in one option per word) ____ Doesn't understand in Spoken L, ____ Understand in Spoken L.	C2 Survey
4.2. CDI VP	160 words in Chilean Spanish. Do your child? (Tick or not in the option per word) ____ Produce in Spoken L.	C2 Survey

Notes: Abb: CDI VU = CDI Vocabulary Understand, CDI VP= CDI Vocabulary Production, C1 Survey= Child Survey Online 1, C1 SV Surv= Child Survey Online 1 Short Version, C2 Survey= Child Survey Online 2.

As with Study 1, information used in Study 2 was gathered through two sources. First, each child's clinical record provided socio-demographic and audiological data (see Table 3 in Study 1 Methods). Second, online surveys were used, which will be detailed below.

5.3.1 Online Surveys

There were three online surveys (See Figure 1):

- Child with CI Survey 1 (C1 Survey) for Time 1.
- Child with CI Short Version Survey (C1 SV Survey) for Time 2.
- Child with CI Survey 2 (C2 Survey) for Time 1 and Time 2.

These surveys were delivered in Chilean Spanish through the online platform Opinio ®. The original surveys in English, the surveys in Chilean Spanish, and the transcultural process for SIR and CAP scales are explained in detail in Study 1 methods. The protocols used for collecting data and online surveys are available in Supplementary Material. Each survey is detailed below:

Child with CI Survey 1 (C1 survey)

During T1, the C1 survey was administered. This included:

- Questions about independent variables, such as sociodemographic, audiological and treatment information. This data was used in Study 2.
- Five questions about outcomes: communication at home, parents/caregivers' satisfaction, children's social inclusion, the Chilean SIR and the CAP II scale. In Study 1 all these outcomes were considered, Study 2 used this Study 1 data to consider only communication at home, Chilean SIR and the CAP II scale outcomes.

Child with CI Short Version Survey 1 (C1 SV survey)

During T2, an additional short version survey with a few questions from C Survey 1 was included. The survey considered eight dependent variables – *Age, CI status, CI condition, Education attendance, CI use, Frequency rehabilitation, CI Confidence and CI Training as Parental Engagement sub variables* – and three outcomes of interest – Communication at home, Chilean SIR, Chilean CAP II – for assessing the RQ2 and RQ3.

Child with CI Survey 2 (C2 survey)

During T1 and T2, after the C1 and C1 SV surveys, the third survey containing the CDI measure was included. This survey was only available for Study 2 participants and could be completed by the closest parent/ caregiver of each participant. More details about the process for each survey are available in the following sections.

5.3.2 Outcome variables:

There were four instruments to assess speech perception and spoken language development at T1 and T2 in Study 2:

- 1) A specific question about communication at home was included in the C1 Survey and the C1 SV Survey to investigate how parents/caregivers report the communication that they use with the children at home. This question has been used in previous research on children with CI (Suskind et al., 2016). The parents' answers were described for T1 and T2, and the association between T1 and T2 investigated.

- 2) *Speech Intelligibility Rating Scale* (SIR) (T. E. Allen et al., 1993) was adapted into Chilean Spanish by the researcher and collaborators in 2022 (Bustos-Rubilar et al., 2022). The scale results were already used in the characterisation completed in Study 1.

- *3) The Categories of Auditory Performance Index II* (CAP II) (S. Archbold et al., 1998) was also adapted during 2022 (Bustos et al., 2022) As for the SIR scale, the scale results were used during Study 1.

4) Vocabulary Understand (CDI VU) and Vocabulary Production (CDI VP)

The CDI VU and CDI VP evaluations are from the Chilean short version of the original MacArthur–Bates Communicative Development Inventories (Fenson, 2007), adapted by Farkas Klein in the Words and Gestures version (2010). This instrument (hereafter referred to as CDI) offers a summarised version of the original short CDI instruments, which were validated in Spanish by Jackson-Maldonado (2013). During the validation process for Chilean Spanish, Farkas (2010) assessed the verbal and nonverbal language of typically developing hearing children aged 8 to 18 months, comprising 949 evaluation items. Farkas (2020) proposes a shortened version of the instrument, administered to caregivers and educators of 130 Chilean infants aged 11 to 15 months. Item analysis, reliability, validity assessments, and factorial analyses of sections were conducted.

The abbreviated version included 241 items distributed across two sections, which are described below. Evaluations of the psychometric properties of the scale yielded satisfactory results, demonstrating adequate internal reliability and validity. However, the instrument was not fully validated, as it lacked standardized overall scores or ages for the local population, nor did it have sub-scores for enabling comparisons between evaluated children or between groups from different regions. Additionally, the instrument lacks percentile or “months of age” results based on comparison with typically developing children in the country (Farkas Klein, 2010).

As mentioned in Section 2.1 of the Pandemic Mitigation Plan, the original plan considered the onsite use of the Chilean version of the Peabody vocabulary test (Sasvari, 1995), which present broader national validation and use for evaluating language development. However, given the necessity of online evaluation through parental/caregiver questionnaires during the pandemic, the vocabulary section of the proposed instrument for the Chilean population seemed to be a reliable tool for use during follow-up evaluations. This consideration primarily pertained to comparisons within participants after 12 months of CI use.

Regarding the target ages for the instruments and the participants' ages, the Chilean Spanish version proposed by Farkas (2010) was intended for typically developing hearing children aged 11-15 months. However, the average age of our participants was 5 years and 3 months at the time of the first evaluation.

Therefore, the rationale for using this instrument is that although the ages of the children in this study do not match the proposed ages for the CDI, their scales are widely used to represent spoken language development in children at the beginning of their hearing age (Rinaldi et al., 2013; Thal, Desjardin, & Eisenberg, 2007). Hearing age in children is calculated as their age in years after receiving their implant. In our sample, due to the delay in implantation, there was a significant difference between chronological age and hearing age calculated from the implantation time of each deaf child. Taking this factor into account, along with the hypothesised poor results in spoken language for some children who experienced delayed implantation, it was pertinent to consider this Chilean instrument.

In terms of the content considered from the CDI, the Chilean instrument proposed by Farkas (2010) had two sections. First, verbal language, comprising three checklists about gestures and sound understanding, vocabulary understanding, and vocabulary production. Second, a communicative skills and representations checklist without the use of verbal communication. In Study 2, only the vocabulary checklists from the verbal language section were used. This decision was made because vocabulary performance could better and more easily represent language development, considering both understanding and production scores.

The vocabulary extracted from the CDI included 22 semantic categories based on a list of nouns, verbs, adjectives, pronouns, prepositions, locatives, and quantifiers. During the evaluation, parents/caregivers were asked if their child does not understand, can understand, or can produce each word in a total of 160 possible words. After comprehensive discussions with the Thesis Committee and considering that there are studies using raw scores of vocabulary understood and/or production in children with CI (Lund, 2016), it was agreed to use the raw total numbers of words for a measure in vocabulary understood (CDI VU) and vocabulary produced (CDI VP). These were considered suitable measures following previous research using these scales.

5.3.3 Independent variables

Table 13 displays the independent variables used to describe the sample and evaluate research questions for Study 2. The table details each variable, time collected and source.

Table 13. Independent variables in Study 2

Independent variable	Description	Time collected	Source
Age	Years and Months	T1 & T2	Clinical Record
Gender	1) Female, 2) Male	T1	Clinical Record
CI age	Age in months at CI surgery. Chronological age when the children have the CI surgery/Switch On. In this study age at CI surgery and at SwitchOn are considered the same due to the Chilean regulation, which requires the CI Switch on within one month after the CI surgery.	T1	Clinical Record
Aetiology	All children recorded congenital hearing loss	T1	Clinical Record
SHI	Socioeconomic health insurance: 1) Low income, 2) Low- middle income, 3) Middle income, 4) Middle, high income.	T1	Clinical Record
BDI	Index from 0.0 (low) up to 1.0 (high) Index Variable, “Desarrollo Comunal” in Spanish.	T1	Clinical Record
Family Ed	1) Unknown, 2) Primary School Uncompleted, 3) Primary School Completed, 4) Secondary Uncompleted, 5) Secondary Completed, 6) Training Uncompleted, 7) Training Completed (In Chile from 2 to 3 years of formal education), 8) University Uncompleted, 9) University Completed (In Chile from 4 to 7 years of formal education)	T1	C1 Survey
Add diff	1) Not declared, 2) Declared.	T1	Clinical Record
CI condition	1) Operative-Without issues, 2) Operative but with some issues, 3) Not Operative - Technical Issues, 4) Not in use from time ago.	T1 & T2	C1 Survey
CI status	1) Unilateral CI w/o contra HA , 2) Unilateral CI with contra HA , 3) is this bilateral?	T1 & T2	C1 Survey
Rehabilitation attendance	1) Yes, Face to Face, 2) Yes, Hybrid, 3) Yes, Online, 4) No.	T1	C1 Survey
Easy rehab att.	1) Yes, 2) No.	T1	C1 Survey
Commute time	1) Very short time, 2) Short Time, 3) Enough Time, 4) Long Time, 5) Very long Time, 6) Not attending	T1	C1 Survey
Education attendance	1) Not attending any ed. 2) Special school for the deaf, 3) Mainstream ed. w/o SNA, 4) Mainstream ed. with SNA, 5) Special school for SLD, 6) Mainstream nursery.	T1 & T2	C1 Survey
SNPA	1) Rich spoken language communication environment, 2) Less rich spoken language communication environment.	T1 & T2	C1 Survey
CI use (ord)	1) Never, 2) Sometimes, 3) Frequently, 4) Always	T1 & T2	C1 Survey
CI hrs per day	Minutes per day. *Cluse= μ between T1 and T2	T1 and T2	C1 Survey
Behavioural problems	Two level : 1) No, 2) Yes	T1	C1 Survey
Frequency rehabilitation	1) Weekly, 2) Each 2 weeks, 3) Monthly, 4) Less than once per month.	T1 & T2	C1 Survey
CI Training	1) No, 2) Yes	T1 & T2	C1 Survey
CI Confidence	1) No confidence, 2) Poor Confident, 3) Somewhat Confident, 4) Very Confident, 5) Very Poor Confident	T1 & T2	C1 Survey

Notes: Abbreviations: NR= No recorded, SHI= Socioeconomic Health Insurance level, BDI= Borough Development Index, Ed= Education, Add Diff= Additional Difficulties, CI= Cochlear Implant, CR= Clinical Records, Tech.= Technical, S= Deaf students, *CIuse= variable of CI use hours during the day using the mean between reports from T1 and T2, HA= Hearing aid/s, SNA= Special Needs Assistance, SNPA= School Nursery Placement Attendance, SLD= Speech and Language Disorder, CI Training= Parental Engagement variable of previous with the CI, CI Confidence= Parental Engagement variable of confidence about the CI.

5.4 Procedures

Figure 3 shows a flow chart of the research, including periods, processes and actions completed in Study 2. This study entails two evaluation stages followed by a subsequent analysis period outlined below.

Data collection at T1:

In September 2020, the researcher went to Chile to conduct and oversee the data collection process for Study 1. Two research collaborators from the University of Chile and one paid trained collaborator (paid through The Ministry of Health grant) provided assistance with data collection. As a result of the COVID-19 restrictions from March 2020, the Chilean national guidance on research in health services was strictly followed (Minsal, 2020,Link). The collaborators collected data from designated hospitals and called parents/caregivers on the telephone to explain why calls were necessary (Covid, distance, travel costs etc). Other researchers have used telephone interviews and online platforms as valid options for collecting data from parents of CI users (Contrera et al., 2014; Galvin, 2015; Jiménez-Romero, 2015; Punch & Hyde, 2011).

Regarding clinical record data collection, an e-mail was sent to each CI team in each hospital requesting access to clinical records. When the online or physical clinical records were available, the researcher attended each hospital to collect the required data. The information was entered into a spreadsheet according to the data collection protocol (Supplementary Material). Missing data were noted. Two final documents were created: a spreadsheet with detailed information about each child and a spreadsheet with pseudonymised data using an ID.

To facilitate the completion of the online survey, the researcher called potential participants to explain the project's aims and content. After the call, an email with the information sheet, consent form and personalised Opinio ® link was sent to parents/caregivers who agreed to participate. The link was then also sent on WhatsApp. The online platform enabled the participant to be tracked after they had completed the informed consent. In case of difficulties with the online platform, telephone assistance from the researchers and the collaborator was available to the parent/caregiver whilst completing the survey. In the case of accessibility for deaf people, a sign language interpreter and a video call for deaf parents/caregivers were offered. No participants required the sign language interpreter or another accessibility measure at either T1 or T2.

Before the survey, parents/caregivers were fully informed about the survey (the type of questions, duration, recording, etc.). After giving verbal consent to participate during the call, parents were given a link to a website where they could provide formal informed consent at the beginning of the first survey C 1. Only those parents/caregivers whose children met the inclusion criteria for Study 2 were invited to participate in the follow-up study. At the end of the survey, parents were asked to indicate whether they would be willing to participate in the follow-up longitudinal study (Study 2), which attracted compensation of approximately $ USD 10 in Chilean pesos (CLP) for the completion time in a second survey (C2). They were informed that the research team would contact them again the following year to collect follow-up data. Thus, the data from clinical records and online surveys for T1 were completed between December 2020 and March 2021.

Survey data were added to the pseudonymised spreadsheet, which could then be transferred to the UK in accordance with the data management plan as approved by UCL Data Protection (Supplementary Material). At T1, there were some minor challenges; 21 participants reported difficulties using the platform, eight parents/caregivers reported technical problems with the platform, and 16 participants made queries about the wording of sentences or questions. All these issues were dealt with through text messages and/or video chat.

Data collection at T2:
Between February and April of 2022, the researcher and one paid trained collaborator (paid through The Ministry of Health grant) contacted each eligible parent/caregiver who agreed to participate in Study 2. They were invited to complete further surveys, which included C1 SV and the C2 surveys. The procedures were similar to those used for T1. Parents were contacted using the same contact details as one year before. There were no technical problems or difficulties at this time, and six parents/caregivers asked how to complete some survey questions. No special requests for accessibility, including assistance such as sign language interpretation or video calls, were requested by any of the parents/caregivers. Participants took less than 20 minutes on average to complete both surveys.

5.5 Data Analysis

Factors were divided into independent variables and outcome results. In Study 2, we use visualisation tools using R (R Core Team, 2021) with multiple package codes, detailed below. Study 2 includes two research questions and six hypotheses. To answer the research questions, the analysis was divided into three different sections:

5.5.1 Descriptive statistics for the independent variables

We conducted descriptive statistics for the independent variables, including sociodemographic, audiological, and treatment information of children with CI at T2. The descriptive statistics included means, quantiles, and standard deviations. Additionally, we used visualisation tools using R (R Core Team, 2021) with ggplot(), and ggplot2(), in the package “tidy-diverse” and “ggplot2”. For map visualisation design, we used STATA (Stata Corp., 2021) and Microsoft PowerPoint Office ®.

5.5.2 Outcomes variable report

We conducted descriptive statistics for each outcome evaluated in Study 2 including frequency, median, means, quantiles, and standard deviations. We used visualisations in each outcome result, such as bar graphs and paired box plots, to show the changes in the results over time. At the end of this section, a detailed description of some anomalous results that were not expected was included.

5.5.3 Analysis of factors associated with good spoken language outcomes and with the progress made between T1 and T2

This section analyses the two research questions contained in Study 2:

- Research question 2 (RQ2): Which factors are associated with good spoken language outcomes in Children implanted from 2017 to 2019 within Chile's public health system at T1 and T2?
- Research question 3 (RQ3): What factors predict progress made in spoken language skills over 12 months in children with CI in Chile?

Both questions consider spoken language as an outcome, assessed only using CDI Vocabulary Understand (CDI VU) and CDI Vocabulary Production (CDI VP). Thus, this section only includes the raw total score of the CDI VU and CDI VP results at T1 and T2. Research questions were discussed in each proposed hypothesis, which presents different types of analysis depending on the variables. Some continuous and ordinal variables were transformed into binary variables following each hypothesis. Results about transformed variables were described in detail in each hypothesis using descriptive statistics and table visualisations.

For the inferential analysis, Pearson/Spearman correlations, t-tests, one-way ANOVA, two-way ANOVA, MANCOVA and other parametric and non-parametric approaches were used to test associations between variables and between-group differences. Each used inferential test is described in each hypothesis. We used an alpha value of $p<.05$ for all parametric and non-parametric evaluations. Additionally, paired box plots were deemed suitable graphics to describe the differences in the outcome over time. Finally, a multivariate analysis (Tabachnick & Fidell, 2007) was conducted to examine relationships between independent variables and outcomes at T2.

To balance the control of Type I errors while maintaining reasonable statistical power, a Bonferroni correction was applied, resulting in a new significance level (alpha) of approximately $\alpha = 0.0028$ for each individual test. However, in case of alpha results between .05 and .0028, they were described as with potential significance.

Chapter 6: Results Study 2

6. Results Study 2

Results from Study 2 are from the follow-up longitudinal study of 49 children with CI, drawn from the original cohort of 107 children characterised in Study 1. These children underwent an initial evaluation one year after the implantation of the device, followed by a subsequent evaluation a year later. Descriptive statistics for independent variables and five distinct outcome results are presented below. An analysis of factors associated with positive spoken language outcomes and the progress made between Time 1 (T1) and Time 2 (T2) are also shown.

6.1 Descriptive statistics for the independent variables.

Table 14 describes results from sociodemographic, audiological and treatment variables for children with CI at T1 and T2.

Table 14. Descriptive statistics results for independent variables in children with CI at T1 and T2 (N=49)

Independent variable	Category /Level	Time 1	Time 2
		Mean/Freq [SD](%)	**Mean/Freq[SD](%)**
Age	Chronological age years/months (T1:Min 2y7m, Max 6y9m) (T2:Min 3y7m, Max 7y11m)	5 y 3 m [SD=13.5m] ME: 5y7m MO:3y 9m	6 y 3 m [SD=12.5] ME: 6y8m MO:6y 9m
Gender	Male	27 (55.1%)	NR
CI age	Months of age at CI surgery (Min 12m, Max 4y 6m)	33.19 [10.2] (2y 8m) ME:2y10m MO:2y4m	NR
SHI	Low income	17 (34.7%)	NR
	Low-middle income	12 (24.5%)	NR
	Middle income	7 (14.3%)	NR
	Middle - high Income	13 (26.5%)	NR
BDI	Index from 0 to 1	0.512 (0.0946)	NR
Family Ed	Primary incompleted	3 (6.1%)	NR
	Primary complete	0	NR
	Secondary incompleted	4 (8.2%)	NR
	Secondary completed	22 (44.9%)	NR
	Training incompleted	1 (2.0%)	NR
	Training completed	6 (12.2%)	NR
	University incompleted	3 (6.1%)	NR
	University completed	10 (20.4%)	NR
Add diff	Not recorded / Not declared	37 (75.5%)	NR
CI status	Unilateral CI w/o contra HA	35 (71.4%)	29 (59.2%)
	Unilateral CI with contra HA	10 (20.4%)	10 (20.4%)
	Bilateral CI	4 (8.2%)	10 (20.4%)
CI condition	Functioning-Without issues	37 (75.5%)	35 (71.4%)
	Func. but with some issues	9 (18.4%)	11 (22.4%)

	Not Func. – Tech. issues	1 (2.0%)	1 (2.0%)
	Not in use	2 (4.1%)	2 (4.1%)
Rehabilitation attendance	Yes, Face to Face	33 (67.3%)	NR
	Yes, Hybrid	8 (16.3%)	NR
	Yes, Online	6 (12.2%)	NR
	No	2 (4.1%)	NR
Easy rehabilitation attendance	Yes	36 (73.5%)	NR
	No	13 (26.5%)	NR
Commute time	Very short time	1 (2.0%)	NR
	Short Time	11 (22.4%)	NR
	Enough Time	13 (26.5%)	NR
	Long Time	8 (16.3%)	NR
	Very long Time	7 (14.3%)	NR
	Not attending	9 (18.4%)	NR
Education attendance	Not attending any ed.	6 (12.2%)	5 (10.2%)
	Special school for DC	6 (12.2%)	7 (14.3%)
	Mainstream ed. w/o SNA	2 (4.1%)	3 (6.1%)
	Mainstream ed. with SNA	29 (59.2%)	24 (49.0%)
	Special school for SLD	5 (10.2%)	0 (0%%)
	Mainstream nursery	1 (2.0%)	10 (20.4%)
SNPA	Rich spoken language env.	37 (75.5%)	37 (75.5%)
CI use (ord)	Never	2 (4.1%)	2 (4.1%)
	Sometimes	1 (2.0%)	3 (6.1%)
	Frequently	5 (10.2%)	4 (8.2%)
	Always	41 (83.7%)	40 (81.6%)
CI hrs per day	From min=0.0 max=19.0 hrs. *CIuse= μ T1,T2= 10.6 [3.3]	10.2 [3.6]	11.2 [3.7]
Behavioural problems	No	36 (73.5%)	NR
	Yes	13 (26.5%)	NR
Frequency rehabilitation	Weekly	37 (75.5%)	33 (67.3%)
	Each 2 weeks	7 (14.3%)	8 (16.3%)
	Monthly	3 (6.1%)	6 (12.2%)
	Less than once per month	2 (4.1%)	2 (4.1%)
Parental engagement	No	2 (4.1%)	14 (28.6%)
• CI Training	Yes	47 (95.9%)	35 (71.4%)
Parental engagement	No confidence	1 (2.0%)	2 (4.1%)
• CI Confidence	Very Poor Confident	1 (2.0%)	2 (4.1%)
	Poor Confident	3 (6.1%)	5 (10.2%)
	Somewhat Confident	22 (44.9%)	18 (36.7%)
	Very Confident	22 (44.9%)	22 (44.9%)

Notes: In the variable Aetiology= all participants (N=49) were recorded as having Congenital Hearing Loss. Abbreviations: Frec= Frequency, Func= Functioning, ME=Median, MO=Mode NR= No recorded, SHI= Socioeconomic Health Insurance level, BDI= Borough Development Index, Ed= Education, Add Diff= Additional Difficulties, CI= Cochlear Implant, Tech.= Technical, DC= Deaf children, *CIuse= variable of CI use hours during the day, HA= Hearing aid/s, ord= ordinal variable, w/o= without, SNPA= School and nursery placement attendance, env= communication environment.

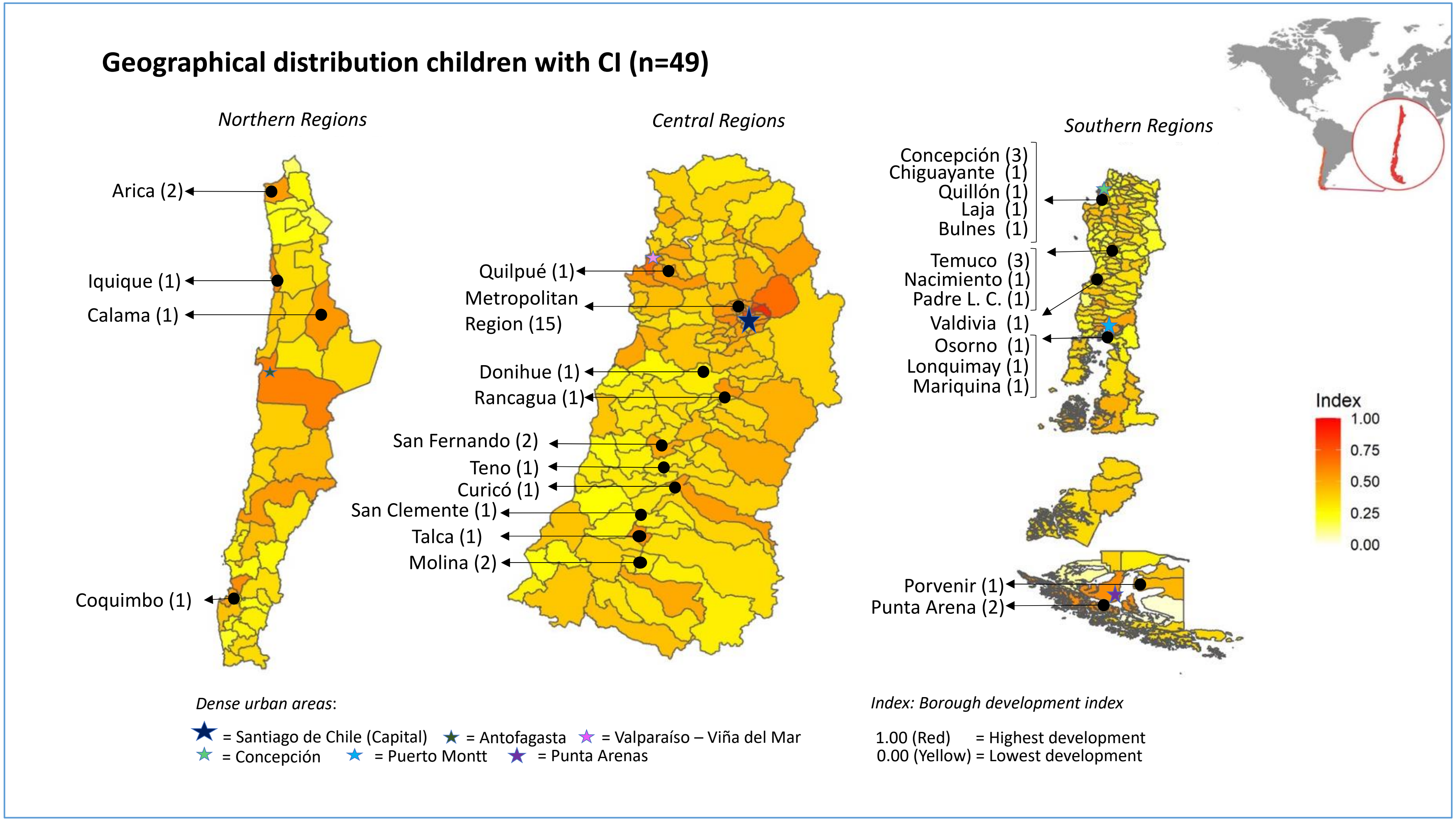
6.1.1 Sociodemographic variables

On average, participants were aged five years and four months of age (months= 63.7 [SD=13.5]) at T1 and six years and five months of age (months=76.4 [SD=12.5]) at T2. At Time 1, the minimum age was 2 years and 7 months, and the maximum age was 6 years and 9 months. At Time 1, the median was 5 years and 7 months, and the mode was 3 years and 9 months. At Time 2, the median was 6 yeas and 8 months, and the mode was 6 years and 9 months. Twenty-seven (55%) were male, and twenty-two were female (45%). All children had congenital deafness. Out of the 49 children, 75% (37) had no additional difficulties. The age of CI implantation, on average, was 2 years and 8 months (33.19 months [SD=10.2]). The minimum age of implantation was 12 months, and the maximum age of implantation was 4 years and 6 months. The median age of implantation was 2 years and 10 months, and the mode age was 2 years and 4 months.

In terms of Socioeconomic Health Insurance (SHI) levels, 34.7% of the children belonged to the low-income level, 14.3% to low-middle income, 14.3% to middle income and 26.5% to middle-high income. Most parents/caregivers had secondary education (44.9%), and a fifth had completed a university degree (20.4%).

Figure 12 illustrates the graphical distribution of children by Chilean boroughs using the BDI scores (from 0.0 to 1.0). Most of the children came from the central area (53%), specifically Santiago (31%), and southern regions (33%). Santiago and Concepcion have the highest BDI scores (0.78 and 0.64, respectively), whereas the remaining areas ranged below 0.60. The average BDI value of our sample was 0.56 compared to the average BDI of the country as a whole which is 0.37 . It means children with CI in this study came from slightly more developed boroughs than the average in the country.

Figure 12. Geographical distribution of children with CI in Chile (N=49) and BDI.



Notes: BDI= Borough development index in Chile. The colour scale shows the Borough Develop Index (Bahamonde, 2020), which evaluates the country's living and environmental deprivation areas. It merges thirteen health, social well-being, economy, and education variables in indexes from 0 to 1. Less developed boroughs are coloured in light yellow, while more developed boroughs are in red.

6.1.2 Audiological and treatment variables

Most of the participants had a unilateral CI without a contralateral HA at T1 (71.4%) and T2 (59.2%). Ten children (20.4%) had unilateral CI with contralateral HA at T1 and T2. There were 4 (8.2%) at T1 and 10 (20.4%) at T2 who had bilateral CIs. Most of the children had a functioning CI at T1 (75.5%) and T2 (71.4%). Moreover, most children with CI attended face-to-face rehabilitation at T1 (33/49, 67%). Thirty-six (73.5%) parents/caregivers described rehabilitation attendance as easy. In terms of education placement, most children were going to mainstream schools with special needs teams at T1 (59.2%) and T2 (49.0%). Thirty-seven (75.5%) children with CI attended schools where spoken language was the dominant communication mode. Most of the children with CI always used their device at T1 (83.7%) and T2 (81.6%). The average hours of CI use for T1 and T2 was 10.6 [SD=3.3] hours.

6.1.3 Behavioural issues and parental engagement variables

Among children with CI experiencing behavioural issues related to device usage, 36 (73.5%) did not report any problem. Most participants attended weekly rehabilitation sessions at T1 (75.5%) and T2 (67.3%). Considering parental engagement, two sub-variables of parental engagement were reported. First, for CI Training, most of the parents/caregivers had received training at T1 (95.9%) and T2 (71.4%). Second, for CI Confidence, the majority of parents/caregivers reported having either somewhat confidence (44.9 %) or being very confident (44.9 %) at T1, while in T2, most of the answers were for having somewhat confidence (36.7%) and being very confident (44.9 %).

6.2 Descriptive statistics for outcomes results

This longitudinal follow-up study collected four outcomes regarding speech perception, communication and language development in 49 children using CI. Parents or caregivers completed self-reported surveys twice over a period of one year. Descriptive statistics for each outcome at T1 and T2 are presented below.

6.2.1 Outcome 1. Type of Communication at home

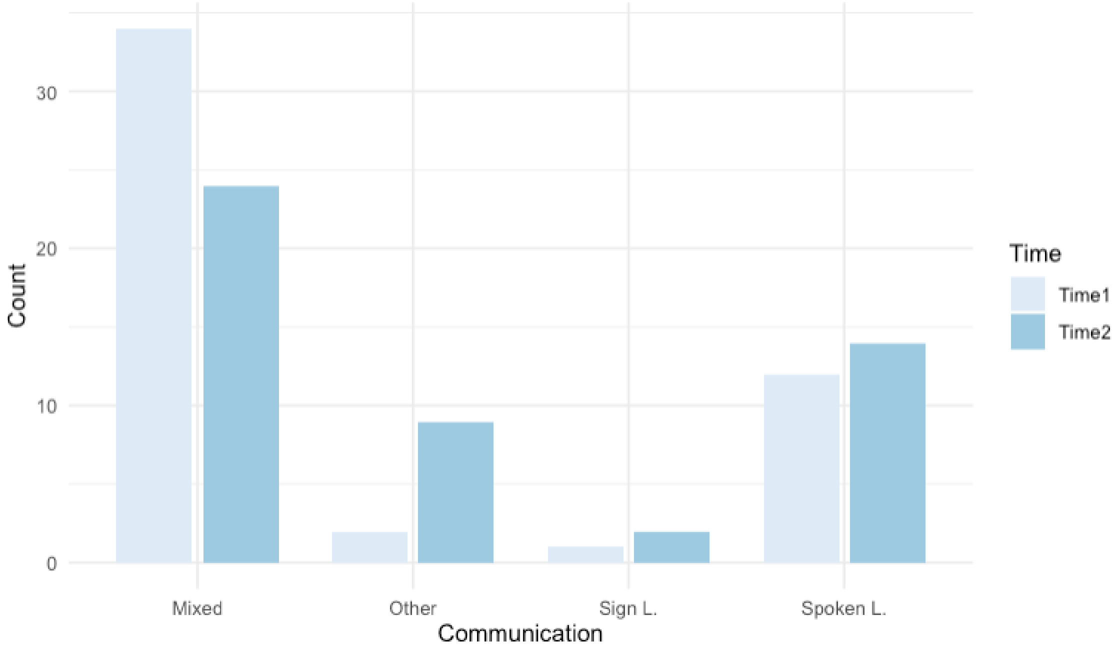
Table 15 shows the different types of communication reported by parents/caregivers at T1 and T2. Mixed communication (spoken and sign language) was the most frequently reported communication used at T1 and T2, 69% and 49%, respectively. This was followed by spoken language reported by 25% and 29% at T1 and T2, respectively. Figure 13 displays results for each type of communication and T1 and T2.

Table 15. Type of communication at home at T1 and T2.

Type of Communication.	T1		T2	
	Frequency	Percent	Frequency	Percent
Mixed	34	69.4	24	49
Spoken L.	12	24.5	14	28.6
Other	2	4.1	9	18.4
Sign L.	1	2	2	4.1

Notes: Abb: T1= Time 1, T2= Time 2, Sign L. = Sign Language, Mixed= Mixed Language, Spoken L.=Spoken Language.

Figure 13. Type of communication at T1 and T2



Notes: Count= Count of participants at Time 1 and Time 2. Sign L.= Sign Language. Spoken L= Spoken Language.

A Pearson's Chi-squared test was performed to evaluate the association between each type of communication over time. There was no statistically significant association between Children's type of communication reported by parents/caregivers at T1 and T2, $X^2(3, N = 49) = 6.67, p = .083$. Similarly, a small effect size of -0.31(CI95%= [-0.71–0.09]) was found using *Cohen's d* test. These findings provided insights about children with CI's preferred communication but will not be analysed further.

6.2.2 Outcome 2. The Categories of Auditory Performance Index (CAP-II)

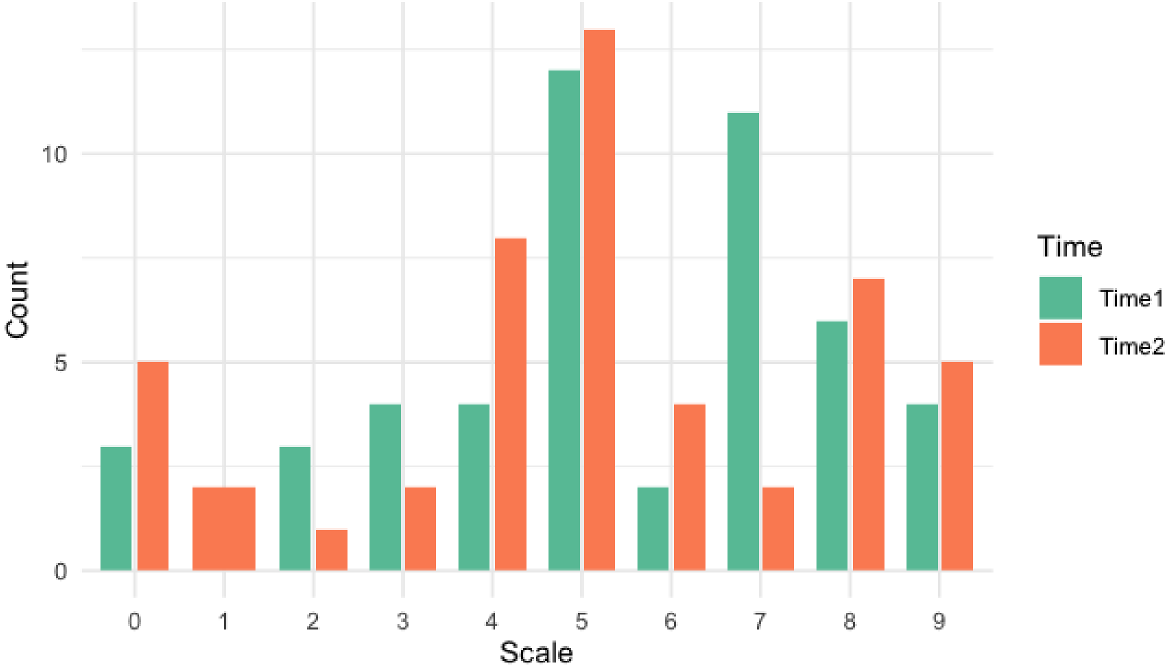
Table 16 and Figure 14 describe the distribution of categories in the Chilean Spanish Categories of Auditory Performance Index (CAP-II) reported by parents/caregivers about their child at T1 and T2. The median was 5 (min= 0, max=9, N=49) at T1 and at T2. The fifth category was the most frequently reported at T1 (12/49) and T2 (13/49). A paired sample Wilcoxon test for ranked non-parametric variables was performed, suggesting that there was no statistically significant improvement in the CAPII results between T1 and T2, T= 333.5, p = 0.0926.

Table 16. Chilean Spanish CAP-II categories.

Chilean Spanish CAP-II Categories	Time 1 (T1)		Time 2 (T2)	
	Freq.	%	Freq.	%t
0. No awareness of environmental sounds	3	6.1	5	10.2
1. Awareness of environmental sounds	0	0	2	4.1
2. Response to speech sounds	3	6.1	1	2
3. Recognition of environmental sounds	4	8.2	2	4.1
4. Discrimination of at least two speech sounds	4	8.2	8	16.3
5. Understanding of common phrases without lipreading	12	24.5	13	26.5
6. Understanding of conversation without lipreading with a familiar talker	2	4.1	4	8.2
7. Use of a telephone with a familiar talker	11	22.4	2	4.1
8. Understanding/Following group conversations.	6	12.2	7	14.3
9. Use the telephone with an unknown speaker in an unpredictable context.	4	8.2	5	10.2

Note: Categories from 0 to 9 in auditory performance of children with CI according to their parents/caregivers. Abb: Freq= Frequency.

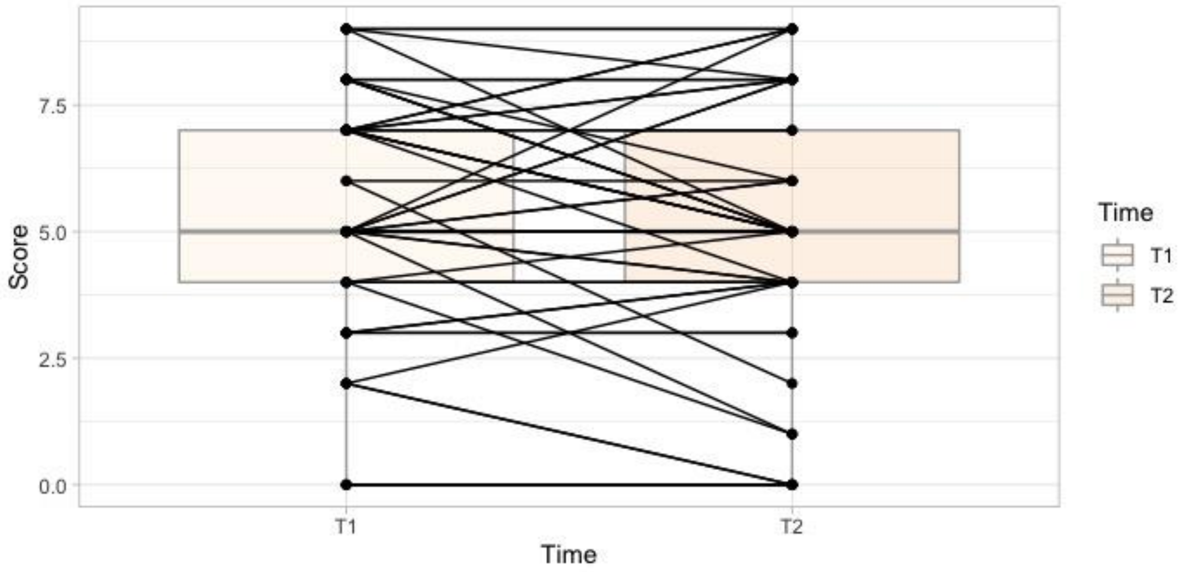
Figure 14. Chilean Spanish CAP II results at T1 and T2



Notes: Count= Count of participants at Time 1 or Time 2.

To describe the progress made by each child using CI over time, figure 15 shows a paired box plot with CAP-II results at T1 and T2. The visualisation illustrates each child's progress over time, including a boxplot figure for T1 and T2. Black lines represent the individual scores at each time point for children. The lines connecting T1 and T2 may represent one or more child's results because some children made the same progress.

Figure 15. Paired boxplot of scores for Chilean Spanish CAP-II Categories at T1 and T2



Notes: Abb: Scale= CAP II categories results at T1 and T2.

The lines show the progress made per child between T1 and T2. Seventeen children showed improvement in their CAP-II categories between T1 and T2. However, contrary to the expected progression, five Children decreased more than two categories of their CAP II performance over time. These non-expected results could be an anomaly, which will be described in section 6.3.

6.2.3 Outcome 3. The Chilean Spanish Speech Intelligibility Rating Scale (SIR)

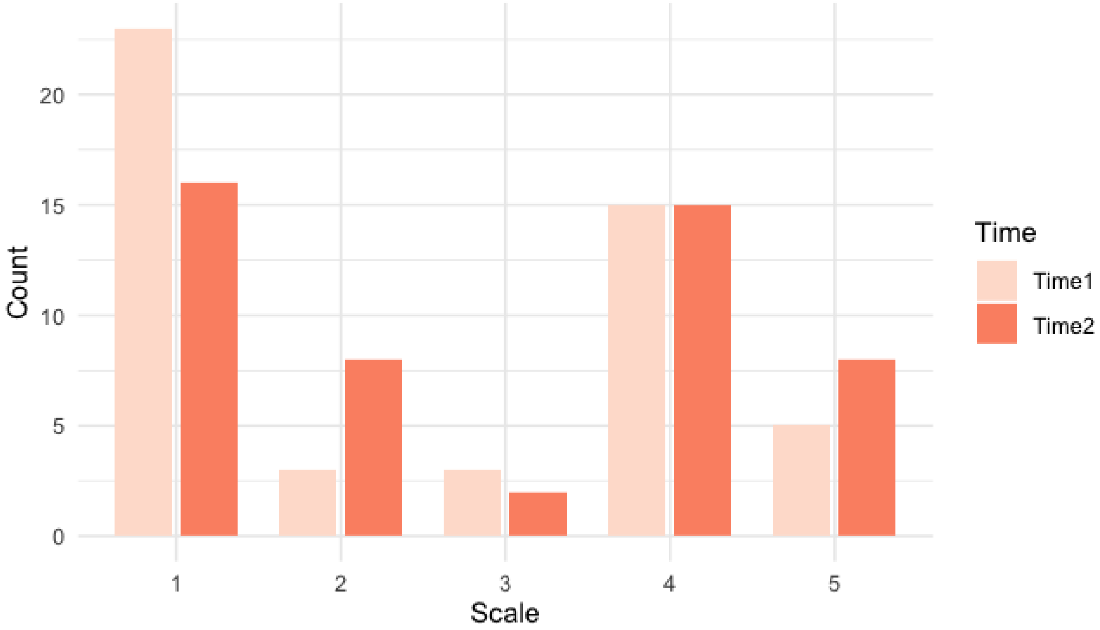
Table 17 and Figure 14 describe the SIR results at T1 and T2. The median was 2 and 3 (min=0, max= 5, N=49) at T1 and T2, respectively. Category 1 was the most frequently reported at T1, with 47% (23/49) and T2, with 33% (16/49). Category 4 was next, with 31% (15/49) at T1 and T2. A paired sample Wilcoxon test for ranked non-parametric variables was performed, suggesting that there was no statistically significant improvement in the SIR results at T1 and T2, T= 79.5, p = 0.212.

Table 17. Chilean Spanish SIR Categories results at T1 and T2.

Chilean Spanish SIR Categories	T1 (N=49)	%	T2 (n=49)	%
1. Connected speech is unintelligible. Pre-recognisable words in spoken language, the child's primary mode of everyday communication may be manual.	23	46.9	16	32.7
2. Connected speech is unintelligible; intelligible speech is developing in single words when context and lipreading cues are available	3	6.1	8	16.3
3. Connected speech is intelligible to a listener who concentrates and lip-reads within a known context.	3	6.1	2	4.1
4. Connected speech is intelligible to a listener who has little experience of a deaf person's speech.	15	30.6	15	30.6
5. Connected speech is intelligible to all listeners. The child is understood easily in everyday contexts.	5	10.2	8	16.3

Note: Categories from 1 to 5 in speech intelligibility of children with CI according to their parents/caregiver

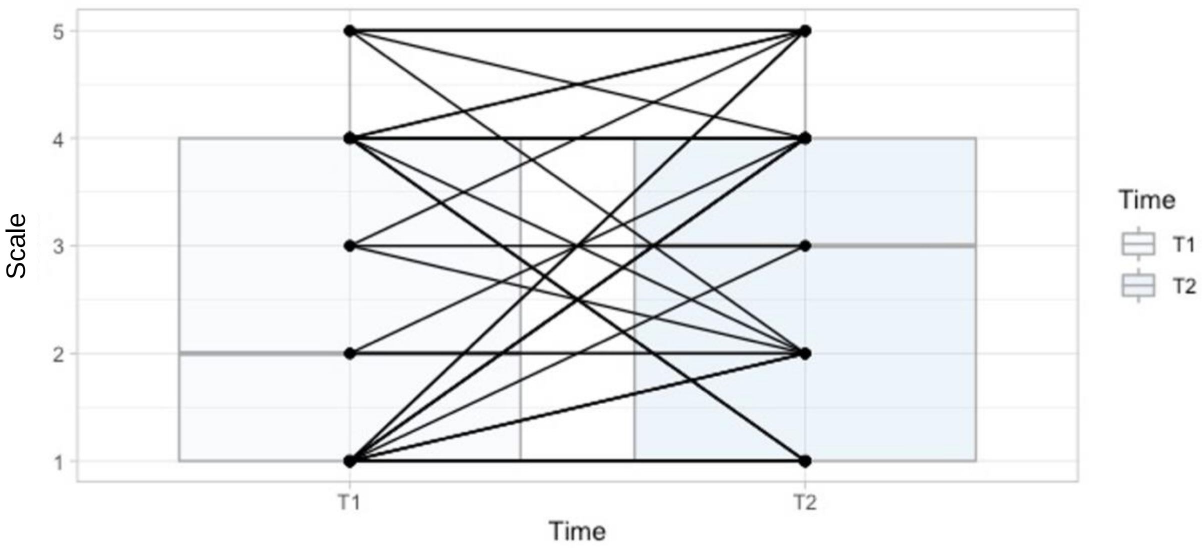
Figure 16. Chilean Spanish SIR results at T1 and T2



Notes: Count= Count of participants at Time 1 and Time 2. Scale= 1. Connected speech is unintelligible. Pre-recognisable words in spoken language, the child's primary mode of everyday communication may be manual. 2. Connected speech is unintelligible; intelligible speech develops in single words when context and lip-reading cues are available,3. Connected speech is intelligible to a listener who concentrates and lip-reads within a known context. 4. Connected speech is intelligible to a listener who has little experience with a deaf person's speech, 5. Connected speech is intelligible to all listeners. The child is understood easily in everyday contexts.

Figure 17 illustrates the progression in the SIR scale of each child using CI from T1 to T2. The visualisation illustrates each child's progression over time, including a boxplot figure for T1 and T2. Similar to the CAPII results, SIR results also revealed potentially anomalous findings whereby a decrease in more than two categories in the SIR scale over time was observed in three children with CI. A detailed discussion of these potentially anomalous findings will be presented towards the end of this section.

Figure 17. Paired boxplot of scores for Chilean Spanish SIR Categories at T1 and T2.



Notes: Abb: Scale= Chilean SIR categories results from 0 to 5.

6.2.4 Outcome 4. Chilean short version of Mc Arthur Bates Language Development evaluation (CDI)

Responses to six test sections from the Chilean short version of the CDI at T1 and T2 were collected, including imitation, gestures, and language development tasks. Three language development tasks were available: Vocabulary Production (CDI VP), Vocabulary Understand (CDI VU) and First sentences comprehension. Two of these tasks – CDI VP and CDI VU – were explicitly addressed in the research questions because evidence from the literature shows that vocabulary is crucial in spoken language evaluation for children with CI (Lederberg & Beal-Alvarez, 2012). Results for CDI VU and CDI VP are presented below.

6.2.5 Outcome 5. Results for CDI Vocabulary Understanding (CDI VU) and Production (CDI VP) scores

Both scores were completed for 49 participants at T1 and T2 by parents/caregivers. Respondents were asked to indicate if their children understood a word or not. A total of 160 words in Chilean Spanish are considered for both subsections. Specifically, for each word that a child correctly comprehends or produces, one point is added to their overall CDI score. Thus, each child's raw total score on the CDI is determined by the number of words they understood in the CDI VU score, or both understood and produced in the CDI VP score. Table 18 summarises raw scores using means, standard deviations (SD) and minimum and maximum scores. The means and standard deviation scores for the CDI VU were 102.77 [SD=56.04] at T1 and 103.10 [SD=63.49] at T2. For the CDI VP, the means were 37.14 [SD=48.41] at T1 and 53.53 [SD=56.41] at T2. A ceiling effect was found at T1 and T2 in sixteen children with CI (32%).

Table 18. Descriptive statistics CDI Vocabulary Understand scores at T1 and T2.

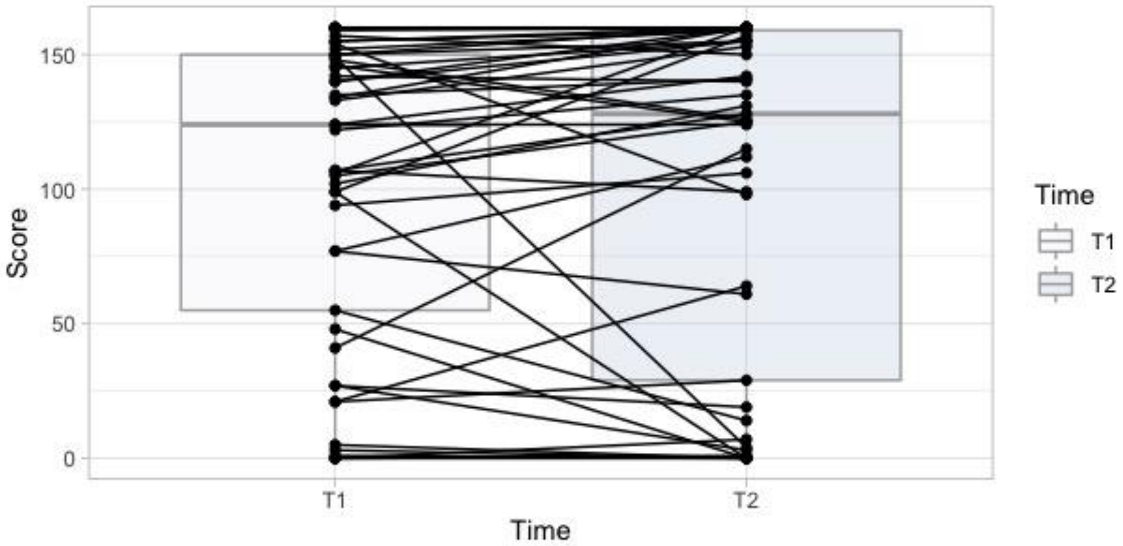
CDI scores	Time T1 Mean [SD]	 T2 Mean [SD]
CDI VU	102.77 [56.04] Min= 0, Max= 160	103.10 [63.49] Min= 0, Max= 160
CDI VP	37.14 [48.41] Min= 0, Max= 160	53.53 [56.41] Min= 0, Max= 160

Notes: Abb: CDI= Chilean Communicative Development Inventory, VU= Vocabulary Understand sub-score, VP= Vocabulary production sub-score, T1= Time 1, T2= Time 2. SD= Standard deviation, Min= Minimum value, Max= Maximum value.

A two-way ANOVA was run to evaluate the effects of subtest (CDI VU, and CDI VP) and time (T1 and T2) on the CDI vocabulary scores. There was a significant main effect of the subtest (F (1, 193) = 49.323, p = <.0001) but there was no main effect of Time (F (1, 193) = 0.853, p = .357), and no significant interaction between the subtest and time (F(1,193)= 0.780, p=.378).

Figure 18 shows paired boxplots of the raw scores for CDI VU, illustrating each child's progression from T1 to T2. In addition to boxplots for T1 and T2 results, black lines demonstrate different progression patterns in each child. In contrast to what was expected in vocabulary development, five participants showed a decrease of more than 20 points in their scores over the course of the evaluation. This could be a potentially anomalous result, which will be discussed in section 3 at the end of this section.

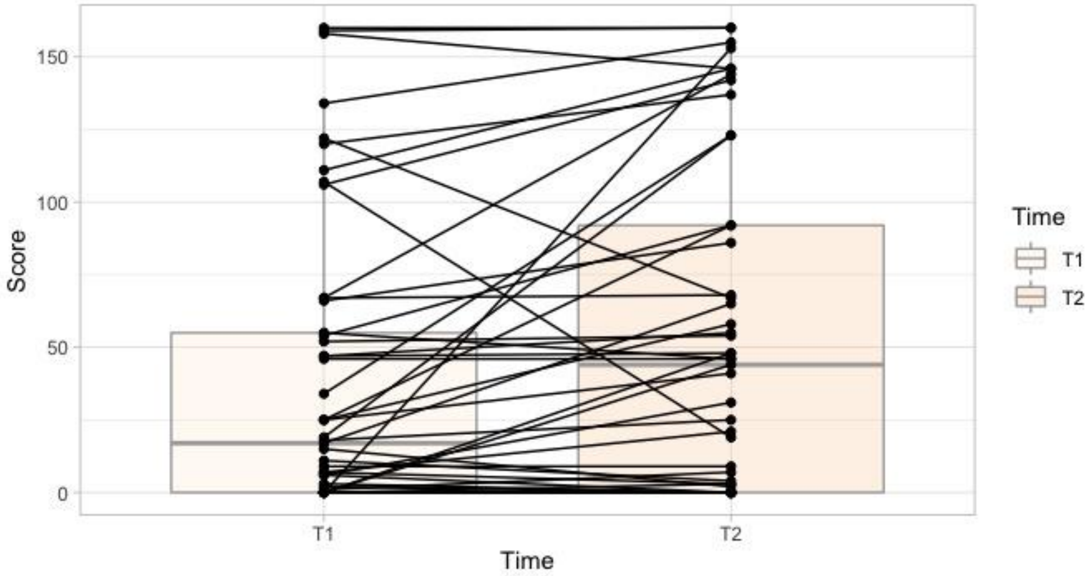
Figure 18. Paired boxplot of scores for Chilean Spanish CDI VU at T1 and T2.



Notes: Abb: Score= Sub score of CDI Vocabulary Understanding (VU) results from 0 to 160.

Figure 19 presents paired boxplots of raw scores results of CDI VP. Lines demonstrate different patterns of progression in each child using CI. Three participants decreased their scores by more than 20 points from T1 to T2. Similar to the results for CDI VU above, this anomaly will be discussed in detail at the end of this section.

Figure 19. Paired boxplot of scores for Chilean Spanish CDI VP at T1 and T2.



Notes: Abb: Score= Sub-score of CDI Vocabulary Production (VP) results from 0 to 160.

6.3 Description of potentially anomalous results

This section describes 14 children with CI who had a decrease in one or more outcomes. Although potentially anomalous results could be expected from self-report instruments (Bauhoff, 2014), and decreased performances can be found in children with additional difficulties such as autism, it is essential to examine these potentially anomalous results in detail.

Table 19 shows a description of the potentially anomalous results and specific independent variables for this subgroup. Among the outcome results, both CAP II and CDI VU results exhibited the highest cases of potentially anomalous results with five participants each. While CDI VP showed the fewest cases of anomalous results with only two participants. According to their parents/caregivers, most of the participants used mixed communication (8 participants), and other types of communication (5 participants) at T2. Only one child was reported to be using spoken language. This could explain why children in these children with potentially anomalous results achieved low scores on the current outcome measures. A variable explaining the potentially anomalous results might be the presence of additional difficulties, such as Autism, which has been reported in cases when some children with this condition appear to show typical language development initially but with a stagnation or apparent regression during their development (Hansen et al., 2008). Five children in our sample showed additional difficulties, and two had Autism reported in their clinical records. The education of the parents/caregivers could also be a critical factor: of the 14 children in the sub-group, only one participant's parent had completed a training course or university degree, and nine parents/caregivers had not completed secondary education. This could have influenced the completion of self-reports by parents/caregivers, which will be further discussed in the Discussion chapter. To investigate whether there was bias in the results, inferential analyses were conducted with and without this subgroup: both analyses showed similar descriptive results as can be seen in the analysis provided in the Supplementary Material. Thus, it was decided not to exclude these 14 cases from the analyses reported below.

Table 19. Description of 14 children with CI with potentially anomalous results.

Variable	N(14) / Percent
Outcome w/n AR *	
SIR	4
CAP	5
CDI VU	5
CDI VP	2
Type of comm at T2	
Other	5 (35.7%)
Sign L.	0
Mixed	8 (57.1 %)
Spoken L.	1 (7.1%)
Additional Difficulties	
Not recorded / Not Declared	9 (64.3%)
Other Conditions	5 (35.7%)
Family Ed	
Primary School Incompleted	3 (21.4%)
Primary School Completed	1 (7.1%)
Secondary Incompleted	5 (35.7%)
Secondary Completed	1 (7.1%)
Training Incompleted	3 (21.4%)
Training Completed	1 (7.1%)
University Incompleted	0 (0%)

Notes: Outcome w/n AR: Outcome with potentially anomalous results. Type of comm at T2= Type of communication at T2.

6.4 Inferential analysis

6.4.1 Analysis of factors associated with good spoken language outcomes and with progress made between T1 and T2

Study 2 proposed two research questions:

- Research question 2 (RQ2): Which factors are associated with good spoken language outcomes in deaf children implanted from 2017 to 2020 within Chile's public health system at T1 and T2?
- Research question 3 (RQ3): What factors predict progress made in spoken language skills over 12 months in children with CI in Chile?

Both questions consider spoken language as an outcome. Thus, CDI Vocabulary Understanding (CDI VU) and CDI Vocabulary Production (CDI VP) results were used in this study. These are commonly used proxies for spoken language outcomes. Both RQs are discussed in terms of the following six hypotheses, displaying subgroups descriptive statistics and inferential analyses to assess each RQ.

6.4.1.1 Hypothesis A — Aetiology and Additional Difficulties:

Hypothesis A is *that children with CI who do not have additional difficulties will have better-spoken language outcomes than children with additional difficulties.*

There were two independent variables to assess: additional difficulties and aetiology. However, aetiology was not considered in the analysis because there was no variability within our sample – all had congenital hearing loss. Table 20 shows descriptive statistics for the sample divided into two subgroups: no additional difficulties (30/49) and additional difficulties (19/49). The CDI scores are presented for each raw subtest score: The means and standard deviation scores for the CDI VU were 120 [50.1] at T1 and 119 [56.0] at T2 for children without additional difficulties. In children with additional difficulties, the means and standard deviation scores were 75.7 [55.5] and 77.4 [67.5] at T1 and T2. For CDI VP, the means and standard deviation for children without additional difficulties were 52.1 [51.9] at T1 and 68 [58.7] at T2. And in children with additional difficulties, means were 18.2 [37.3] at T1 and 30.7 [45.2] at T2.

Table 20. Hypothesis A. CDI scores considering additional difficulties in participants.

	Without AddDiff (N=30)	With AddDiff (N=19)	Overall (N=49)
CDI VU T1			
Mean (SD)	120 (50.1)	75.7 (55.5)	103 (56.0)
Median [Min, Max]	144 [0, 160]	94.0 [0, 160]	124 [0, 160]
CDI VU T2			
Mean (SD)	119 (56.0)	77.4 (67.5)	103 (63.5)
Median [Min, Max]	152 [0, 160]	106 [0, 160]	128 [0, 160]
CDI VP T1			
Mean (SD)	52.1 (51.9)	18.2 (37.7)	38.9 (49.4)
Median [Min, Max]	40.0 [0, 160]	6.00 [0, 158]	17.0 [0, 160]
CDI VP T2			
Mean (SD)	68.0 (58.7)	30.7 (45.2)	53.5 (56.4)
Median [Min, Max]	54.5 [0, 160]	4.00 [0, 146]	44.0 [0, 160]

Notes: CDI VU= CDI Vocabulary understand results, CDI VP= CDI Vocabulary production results, T1= Time 1, T2= Time 2, AddDiff= Additional difficulties, SD= Standard deviation, Min= Minimum value, Max= Maximum value.

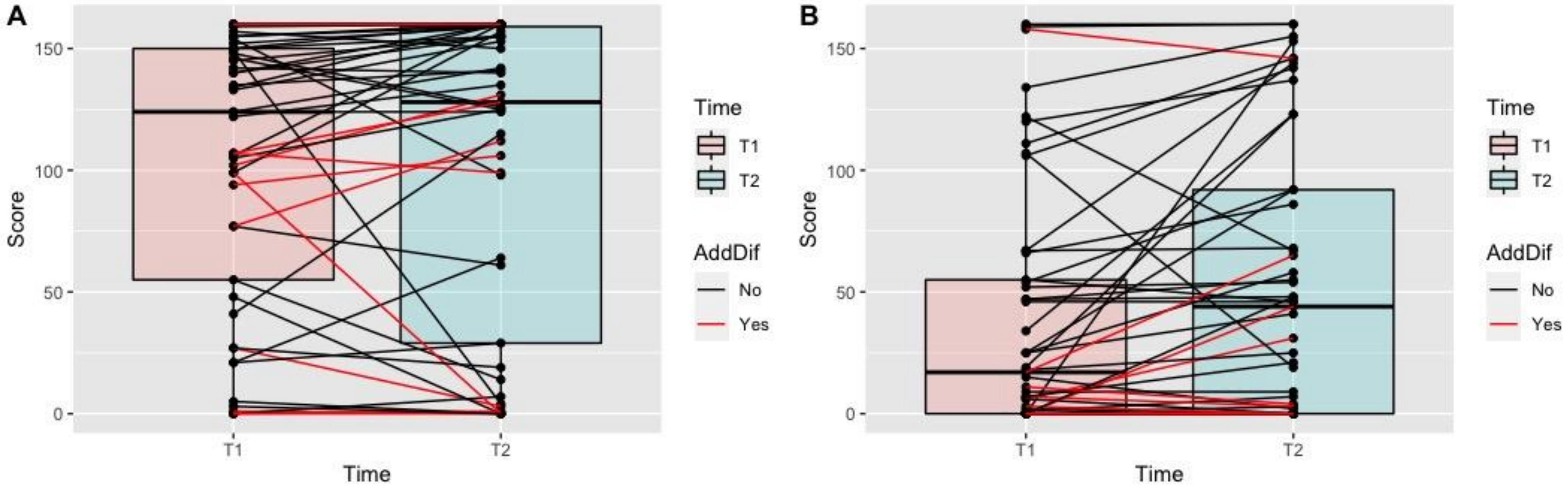
To evaluate RQ2 in this hypothesis, two two-way ANOVAs were run to investigate whether children without additional difficulties had better-spoken language outcomes on the CDI VU and CDI VP than children with additional difficulties. For the CDI VU, there was a significant main effect of additional difficulties (F (1, 95) = 16.642, p <.0001), but no main effect of Time (F (1, 95) = 0.012, p = .912), or interaction between additional difficulties and time (F(1,95)= 0.0064, p=.800). Similarly for CDI VP, there was a main effect of additional difficulties (F(1, 95) = 13.778, p <.0001), and no main effect of Time (F(1, 95) = 0.389, p = .534). The two-way interaction between additional difficulties and time was also not significant (F(1,95)= 0.000, p=.984). Thus, children without additional difficulties had better-spoken language outcomes at both time points than children with additional difficulties.

Progression over time for RQ3

To evaluate RQ3 and hypothesis A, Figure 20 illustrates paired box plots to show progression between T1 and T2 for children with and without additional difficulties. Figures 20- A and 20-B show CDI VU and CDI VP results, respectively. In addition to boxplots for T1 and T2 results, red lines represent the individual scores at each time point for Children with additional difficulties and red lines for individuals without additional difficulties. As seen in Figure 9-A, there was more individual variation in vocabulary growth in Children with additional difficulties. In Figure 9-B, it can be seen that many deaf children with additional difficulties achieved low scores at T1 and T2 for vocabulary production.

Two further ANCOVA tests were run to determine if children without additional difficulties make more progress on the CDI VU and CDI VP results than children with additional difficulties. After controlling for T1 score results, the interaction between additional difficulties and outcome results at T2 showed no significant difference in CDI VU results (F (1,46) = 0.000407, p= 0.984) and CDI VP results (F(1,46) = 0.591, p= .446). Thus, although the spoken language scores of children without additional difficulties were significantly higher than for individuals with additional difficulties, the two groups did not differ in the progress they made over time.

Figure 20. CDI scores over time in children with and without additional difficulties (Fig. 20-A CDI VU results at T1 and T2, Fig. 20-B CDI VP results at T1 and T2).



Notes: Fig.= Figure, Figure 1- A: Results from CDI VU at T1 and T2 in children with CI with and without additional difficulties. Figure 1- B: Results from CDI VP at T1 and T2 in children with CI with and without additional difficulties. Abb: T1= Time 1, T2= Time 2, AddDif= Additional difficulties.

6.4.1.2 Hypothesis B — Age of CI surgery/switch-on:

Hypothesis B is *that children implanted before 24 months of age will show better results in spoken language outcomes than those implanted after 24 months.* Table 21 shows descriptive statistics of our sample divided into subgroups of children implanted before 24 months (9/49) and implanted after 24 months (40/49). Results are presented using raw scores for CDI VU and CDI VP at T1 and T2. The mean scores for CDI VU for children implanted before 24 months of age (<24 months) were 104 [61.2] at T1 and 118 [67.7] at T2. The mean results on the CDI VU in children implanted after 24 months (>24 months) were 103 [55.6] at T1 and 99.7[62.9] at T2. For the CDI VP, the means for children implanted before 24 months were 31.4 [38.7] at T1 and 70.0 [67.7] at T2. In the case of children implanted after 24 months, the means were 40.6 [51.7] at T1 and 49.8 [56.1] at T2.

Table 21. CDI scores considering CI Age groups at Time 1 and Time 2.

Dependent Variables	<24 months (N=9)	>24 months (N=40)	Overall (N=49)
CDI VU T1			
Mean (SD)	104 (61.2)	103 (55.6)	103 (56)
Median [Min, Max]	74.0 [1.00, 160]	67.5 [0, 147]	69.0 [0, 160]
CDI VU T2			
Mean (SD)	118 (67.7)	99.7 (62.9)	103 (63.5)
Median [Min, Max]	155 [0, 160]	125 [0, 160]	128 [0, 160]
CDI VP T1			
Mean (SD)	31.4 (38.7)	40.6 (51.7)	38.9 (49.4)
Median [Min, Max]	19.0 [0, 111]	16.0 [0, 160]	17.0 [0, 160]
CDI VP T2			
Mean (SD)	70.0 (58.0)	49.8 (56.1)	53.5 (56.4)
Median [Min, Max]	48.0 [0, 146]	33.0 [0, 160]	44.0 [0, 160]

Notes: <24 months= Children implanted below 24 months, >24 months= Children implanted above 24 months, CDI VU= CDI Vocabulary understand results, CDI VP= CDI Vocabulary production results, T1= Time 1, T2= Time 2, SD= Standard deviation, Min= Minimum value, Max= Maximum value.

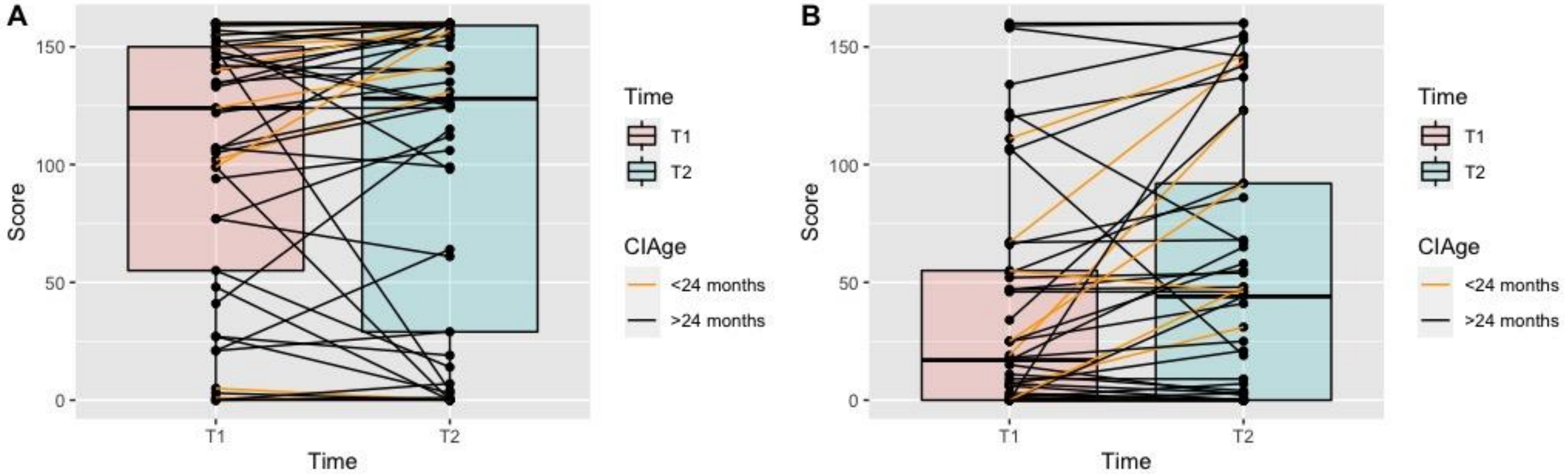
To evaluate RQ2 in this hypothesis, two two-way ANOVAs were run to evaluate if children implanted before 24 months of age had better-spoken language outcomes on CDI VU and CDI VP than children implanted after 24 months. For the CDI VU, there was no significant effect of age of CI surgery (F (1, 95) = 0.607, p = .438) and no main effect of time of evaluation (F (1, 95) = 0.010, p = .919), and no significant two-way interaction between the age of CI surgery and time of evaluation (F(1,95)= 0.545, p=.502). Similarly, for CDI VP, there was no main effect of age of CI surgery (F(1, 95) = 0.300, p = <.585), no main effect of time of evaluation (F(1, 95) = 0.340, p = .561) and no significant two-way interaction between additional difficulties and time (F(1,95)= 0.608, p=.437).

Progression over time for RQ3

To evaluate RQ3 in hypothesis B, Figure 21 illustrates paired box plots to show progression between T1 and T2 for children implanted before and after 24 months of age. Figures 21- A and 21- B show CDI VU and CDI VP results, respectively. In addition to boxplots for T1 and T2 results, black lines represent children implanted after 24 months of age, and yellow lines display the progress made by children implanted before 24 months. As seen in Figure 10-A, many children implanted before 24 months showed improvement in CDI VU scores. In Figure 10-B, it is possible to observe increased vocabulary production results from T1 to T2 in children implanted before 24 months.

ANCOVA tests were run to determine the effect of CI age of implantation (CI Age) on the CDI VU, and CDI VP results at T2 after controlling for T1. After adjusting for T1 score results, the interaction between Age of CI surgery/switch-on variable and outcome results at T2 showed no significant difference in CDI VU results (F (1,46) = 1.746, p= .193), but a significant difference in CDI VP results (F(1,46)= 4.521, p <.0001) was found. Therefore, children who were implanted before 24 months of age made more progress over time in CDI VP results.

Figure 21. CDI scores over time in Children implanted before and after 24 months of Age. (Fig. 21-A CDI VU results at T1 and T2, Fig. 21-B CDI VP results at T1 and T2).



Notes: Figure 2- A: Results from CDI VU scores at T1 and T2 in children implanted before and after 24 months of age. Figure 2- B: Results from CDI VP scores at T1 and T2 in Children implanted before and after 24 months of age.

6.4.1.3 Hypothesis C — Social determinants: Socioeconomic Health Insurance level (SHI), family highest education (FHE), *borough development index (BDI).*

Considering hypothesis C, *low SHI, low FHE, and low BDI as social determinants of health could negatively affect spoken language outcomes in children with CI.* Table 22 shows the outcome results for these variables– SHI, FHE and BDI – in binary groups, which were categorised according to the hypothesis C premises: low vs high. First, for the SHI level, participants were divided into low SHI (18/49) vs middle/middle-high SHI (31/49) groups. Second, FHE was divided into parents/caregivers with secondary (29/49) vs higher education completed (20/49). Third, participants' BDI was divided into those indexed lower than the sample mean of 0.54 (19/40) vs those indexed higher (30/49).

Table 22. CDI scores considering socioeconomic variables at T1 and T2.

	SHI binary		Family highest education (FHE) binary		BDI binary	
Dependent Variables	Low (N=18)	MHigh (N=31)	Secondary (N=29)	Higher Ed (N=20)	<0.5 (N=19)	>0.5 (N=30)
CDI VU T1						
Mean (SD)	111 (53.6)	98.1 (57.8)	105 (57.9)	100 (54.6)	122 (44.1)	90.5 (59.9)
Median [Min, Max]	129 [0, 160]	124 [0, 160]	133 [0, 160]	70.0 [0, 160]	140 [3, 160]	124 [0, 160]
CDI VU T2						
Mean (SD)	108 (58.6)	100 (66.9)	100 (66.6)	108 (60.1)	123 (56.2)	90.7 (65.6)
Median [Min, Max]	129 [0, 160]	128 [0, 160]	126 [0, 160]	134 [0, 160]	150 [0, 160]	114 [0, 160]
CDI VP T1						
Mean (SD)	40.8 (50.6)	37.8 (49.4)	40.9 (48.3)	36.1 (51.9)	48.1 (47.8)	33.1 (50.3)
Median [Min, Max]	17.0 [0, 158]	17.0 [0, 160]	25.0 [0, 159]	9.00 [0, 160]	34.0 [0, 159]	5.00 [0, 160]
CDI VP T2						
Mean (SD)	54.2 (50.4)	53.1 (60.4)	52.4 (51.7)	55.1 (64.0)	63.8 (56.3)	47.0 (56.5)
Median [Min, Max]	46.0 [0, 153]	25.0 [0, 160]	46.0 [0, 160]	23.0 [0, 160]	48.0 [0, 160]	20.0 [0, 160]

Notes: CDI VU= CDI Vocabulary understand results, CDI VP= CDI Vocabulary production results, T1= Time 1, T2= Time 2, SD= Standard deviation, Min= Minimum value, Max= Maximum value. HSES= Health Socioeconomic status, BDI= Borough Development Index.

To evaluate RQ2 in this hypothesis, two two-way ANOVAs were run to assess each of the mentioned social determinants and their levels' effect on the Children's spoken language results. There was no significant effect of two social determinants– Socioeconomic Health Insurance level (SHI) and family highest education (FHE) – on the spoken language performance in the sampled children with CI. Concerning SHI evaluation, there was no significant effect of SHI in CDI VU (F (1, 95) = 0.151, p = .698) and CDI VP scores (F (1, 95) = 0.597, p = .442). Similarly, the time of evaluation had no significant effect on CDI VU (F (1,

95) = 0.010, p = .919) and CDI VP scores (F (1, 95) = 0.339, p = .562). In the two-way interaction between SHI and time of evaluation, there was also no significant effect on CDI VU (F (1, 95) = 0.009, p = .924) and CDI VP scores (F (1, 95) = 0.001, p = .982). Concerning FHE evaluation, there was no effect of FHE in CDI VU (F (1, 95) = 0.010, p = .930) and CDI VP scores (F (1, 95) = 0.153, p = .696). The time of evaluation was also not significant on CDI VU (F (1, 95) = 0.010, p = .919) and CDI VP scores (F (1, 95) = 0.337, p = .563). There was also no significant effect in the two-way interaction between FHE and time of evaluation in CDI VU (F (1, 95) = 0.331, p = .566) and CDI VP scores (F (1, 95) = 0.041, p = .841).

However, after running two-way ANOVAs using the BDI variable and considering the Bonferroni correction, there might be a significant effect on the CDI VU (F (1, 95) = 6.646, p = .011) and CDI VP scores (F (1, 95) = 4.010, p = .048). The time of evaluation was not significant in CDI VU (F (1, 95) = 0.011, p = .916) and CDI VP (F (1, 95) = 0.351, p = .554) scores. The two-way interaction between BDI and T1 and T2 in CDI VU (F (1, 95) = 0.079, p = .779) and CDI VP scores (F (1, 95) = 0.141, p = .700) were non-significant. Thus, there is a potential positive effect of the BDI in CDI VU and CDI VP scores of children in our sample, which means that children with CI living in boroughs with higher BDI had higher scores in CDI VU and CDI VP. However, after applying a stringent Bonferroni correction, the group differences might not reach the required alpha level for significance.

To assess the association between the BDI variables and CDI VU and CDI VP scores, a Spearman correlation test for non-parametric outcomes results was conducted. Table 23 illustrates the correlation between each outcome result and the BDI. A positive very low correlation was found between BDI and CDI VP results at T1, r = 0.369, p= 0.009. Therefore, higher scores on the BDI index were significantly associated with higher score on the CDI VP score in our sample. However, after applying a Bonferroni correction, the correlations may not reach the required alpha level for significance.

Table 23. Correlation between CDI scores and Borough development index (BDI)

Correlation table		
Dependent variables	Correlation (BDI)	*p-value*
CDI VU T1	0.226	0.117
CDI VU T2	0.235	0.103
CDI VP T1	0.369	0.009 *
CDI VP T2	0.230	0.110

Notes: CDI VU= CDI Vocabulary understand results, CDI VP= CDI Vocabulary production results, T1= Time 1, T2= Time 2.

Progression over time for RQ3

To evaluate RQ3 in hypothesis C, Table 24 displays ANCOVA tests used to determine the effect of SHI, FHE and BDI on the CDI VU and VP scores at T2 after controlling by scores at T1. Table 4 illustrates six tests for each dependent and independent variable. After adjustment for T1 results, there were no significant SHI, FHE or BDI group differences in the CDI VU and CDI VP cores at T2. Thus, the social determinants – SHI, FHE and BDI – did not predict progress over time in our sample.

Table 24. ANCOVA results for CDI VU and CDI VP scores and SHI, FHE, and BDI.

ANCOVA test – CDI VU and SHI			
Variable	*DFn, DFd*	*F*	*p*
CDI VU T1	1,46	105.324	< 0.001
HSES (Bin)	1,46	0.141	.709
ANCOVA test – CDI VP and SHI			
Variable	*DFn, DFd*	*F*	*p*
CDI VP T1	1,46	61.726	< 0.001
HSES (Bin)	1,46	0.018	.849
ANCOVA test – CDI VU and FHS			
Variable	*DFn, DFd*	*F*	*p*
CDI VU T1	1,46	109.518	< 0.001
FHS	1,46	1.404	.242
ANCOVA test – CDI VP and FHS			
Variable	*DFn, DFd*	*F*	*p*
CDI VP T1	1,46	62.567	< 0.001*
FHS	1,46	0.399	.531
ANCOVA test – CDI VU and BDI			
Variable	*DFn, DFd*	*F*	*p*
CDI VU T1	1,46	96.236	< 0.001*
BDI	1,46	0.045	.832
ANCOVA test – CDI VP and BDI			
Variable	*DFn, DFd*	*F*	*p*
CDI VP T1	1,46	59.669	7< 0.001
BDI	1,46	0.122	.729

Notes: CDI VU= CDI Vocabulary understand results, CDI VP= CDI Vocabulary production results, T1= Time 1, T2= Time 2

6.4.1.4 Hypothesis D — Parental Engagement: 1) CI Confidence and 2) CI Training.

Hypothesis D is that the two sub variables of parental engagement – CI Confidence and CI Training– can improve outcomes in early CI use by children with CI. Considering the nature of each independent variable, we employed various tests to address each research question in the hypothesis. We assessed each research question separately using distinct tests as described below.

Evaluation of RQ2 by variable

CI confidence

This variable was composed of a Likert scale measuring confidence about CI intervention and its care from parents/caregivers. CI Confidence results had a median of 4 with minimum and maximum values of 1 and 5, respectively.

CI confidence results were, correlated with CDI VU, and CDI VP results at T1 and T2. Table 25 illustrates Spearman correlation tests for non-parametric results between CDI scores and CI Confidence. Only one potential positive correlation is described between CDI VU T2 and CI confidence variable (cor = 0.322, p= 0.023*). These results suggest a moderate positive correlation between higher scores achieved by each child in CDI VU at T2 and a better level of confidence reported by parents/caregivers on the PE-C Likert scale. However, after applying a stringent Bonferroni correction, this finding might not reach the required alpha level for significance.

Table 25. Correlation between CDI scores and CI Confidence.

	Correlation table	
Dependent variables	Correlation (CI Confidence)	*p-value*
CDI VU T1	0.144	0.320
CDI VU T2	0.322	0.023*
CDI VP T1	-0.064	0.659
CDI VP T2	0.075	0.604

Notes: CDI VU= CDI Vocabulary understand results, CDI VP= CDI Vocabulary production results, T1= Time 1, T2= Time 2.

CI Training

We asked parents/caregivers at both T1 and T2 if they had received training to use and care for the CI device. We will use the T2 results because it reflected the most current treatment experience that parents/caregivers had. Table 26 shows descriptive statistics of CDI VU and CDI VP results at T2 of the sample divided into two CI Training subgroups of “No Previous Training” (14/49) and “Previous Training” (35/49).

Table 26. CDI VU and CDI VP results considering the CI Training at T2.

	PE-CI Training	
Dependent Variables	No Prev. Training (N=14)	Previous Training (N=35)
CDI VU T1		
Mean (SD)	112 (49.3)	99.2 (58.8)
Median [Min, Max]	128 [21, 140]	124 [0, 160]
CDI VU T2		
Mean (SD)	111 (63.8)	100 (64.0)
Median [Min, Max]	150 [0, 160]	125 [0, 160]
CDI VP T1		
Mean (SD)	43.2 (53.5)	37.2 (48.3)
Median [Min, Max]	16.5 [0, 158]	17.0 [0, 160]
CDI VP T2		
Mean (SD)	71.3 (69.5)	46.4 (49.6)
Median [Min, Max]	58.5 [0, 155]	44.0 [0, 160]

Notes: Abb: PE= Parental Engage. CDI VU= CDI Vocabulary understand results, CDI VP= CDI Vocabulary production results, T2= Time 2.

To evaluate RQ2 with this variable, a two-way ANOVA was run. For the CDI VU scores, there was no significant effect of CI Training (F (1, 95) = 1.520, p = .22), no main effect of time of evaluation (F (1, 95) = 0.011, p = .917), as well as no significant interaction in the two-way interaction between CI Training and time of evaluation (F(1,95)= 0.05, p=.82). Similar results were found for the CDI VP scores. There was no significant main effect of training (1, 95) = 0.960, p = .33), and there was no main effect of time of evaluation (F (1, 95) = 0.346, p = .558). Also, there was no two-way interaction between CI Training and the time of evaluation (F(1,95)= 0.180, p=.670).

Progression over time for RQ3

An ANCOVA test was run to evaluate RQ3 in hypothesis D to determine the effect of CI Training on the CDI VU and CDI VP scores at Time 2 after controlling for results at T1. After controlling for T1 score results, the interaction between CI Training and outcome results at T2 showed no significant difference in CDI VU results (F (1,46) = 0.011, p= 0.918) and CDI VP results (F (1,46) = 2.912, p= .950). Thus, the two groups in the variable receiving or not CI training did not differ in the progress they made over time in either the CDI VU or CDI VP. It is important to note that training was measured as a binary variable, which can limit the potential interaction with the outcomes. More complex variables could be useful to improve the analysis.

6.4.1.5 Hypothesis E — CI use hours per day

Hypothesis E is *that Children who report continuous use of the device could have better results in spoken language outcomes than those who report less time using the CI.*

To evaluate RQ2, we considered daily hours as both a continuous and binary variable. As a continuous variable, the mean of CI usage in hours for the sample was 11.66 [3.33]. Hours of CI use per day (CI hrs) were correlated with each CDI result at T1 and T2. Table 27 contains the Spearman correlations between CDI scores and CI use in hours. Potential positive correlations are described between all CDI scores and CI use in hours. However, after applying a Bonferroni correction, the findings might not reach the required alpha level for significance.

Table 27. Correlation between CDI scores and CI Use in Hours (μ T1 and T2) per day.

	Correlation table	
Variables	Correlation (CI use)	*p-value*
CDI VU T1	0.445	.001 *
CDI VU T2	0.374	.007 *
CDI VP T1	0.412	.003 *
CDI VP T2	0.411	.003 *

Notes: CDI VU= CDI Vocabulary understand results, CDI VP= CDI Vocabulary production results, T1= Time 1, T2= Time 2, CI Use= CI use in hrs.

Previous evidence (Contrera et al., 2014; Wiseman & Warner-Czyz, 2018) supports that typical daily CI use is 8 hours or more, which might contribute to better outcomes in spoken language development. Thus, we divided our sample into two groups of Children using the CI less (< 8hrs) and more (> 8hrs) than 8 hours per day. Table 28 shows the descriptive statistics of the mentioned two groups, using the device for less than 8hrs (13/49) and more than 8 hrs (36/49) per day, on the CDI VU and CDI VP scores at T1 and T2. In CDI VU scores, participants with less than 8 hrs of CI use showed means of 56.2 [59.9] points at T1 and 57.7 [33.7] points at T2. On the other hand, participants with more than 8 hrs of CI use had a mean of 120 [44.5] points at T1 and 120 [54.4] at T2. In CDI VP scores, Children with less than 8 hrs of CI use showed a mean of 13.3 [29.8] points at T1 and 12.5 [33.7] points at T2. Children with more than 8 hrs of CI use showed a mean of 48.2 [52.0] points at T1 and 68.3[55.9] points at T2.

Table 28. CDI scores considering CI use an hour per day at T1 and T2.

	CI Use in Hours (µ T1 and T2)	
Dependent Variables	< 8 hrs (N=13)	> 8 hrs (N=36)
CDI VU T1		
Mean (SD)	56.2 (59.9)	120 (44.5)
Median [Min, Max]	27.0 [0, 155]	140 [0, 160]
CDI VU T2		
Mean (SD)	57.7 (66.7)	120 (54.4)
Median [Min, Max]	19.0 [0, 160]	141 [0, 160]
CDI VP T1		
Mean (SD)	13.3 (29.8)	48.2 (52.0)
Median [Min, Max]	0 [0, 107]	25.0 [0, 160]
CDI VP T2		
Mean (SD)	12.5 (33.7)	68.3 (55.9)
Median [Min, Max]	0 [0, 123]	54.5 [0, 160]

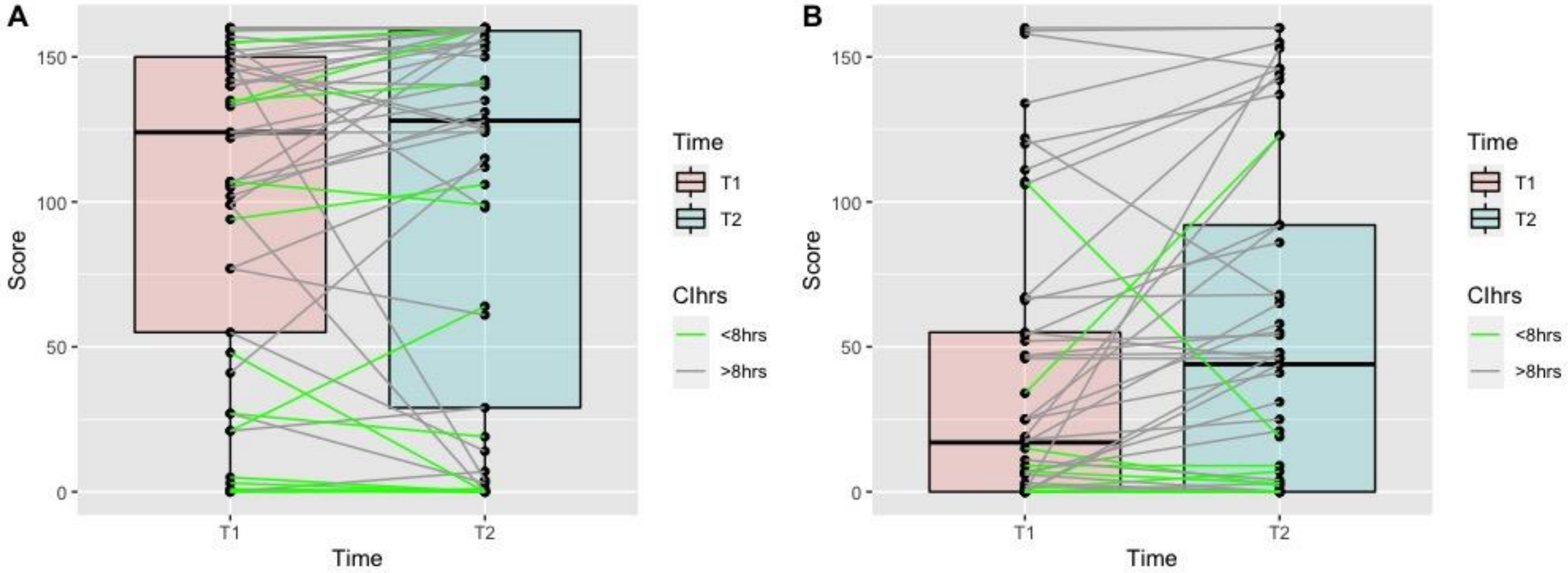
Notes: CDI VU= CDI Vocabulary understand results, CDI VP= CDI Vocabulary production results, T1= Time 1, T2= Time 2, SD= Standard deviation, Min= Minimum value, Max= Maximum value.

Two two-way ANOVAs were run to evaluate if children with more hours of CI use had better spoken language outcomes on CDI VU and CDI VP than children with less device use. For the CDI VU, there was a significant main effect of CI use (F (1, 95) = 29.052, p <.001) but no main effect of Time (F (1, 95) = 0.014, p = .907), or interaction between CI use and time (F (1,95) = 0.052, p=.821). Similarly, for CDI VP, there was a main effect of CI use (F (1, 95) = 23.003, p<.000), and no main effect of Time (F (1, 95) = 0.419, p = .519). The two-way interaction between CI use and time was also not significant (F(1,95)= 0.001, p=.973). Thus, for both receptive and productive vocabulary at each time point, children who used the CI for more than 8 hours a day had significantly better-spoken language outcomes than children wearing it for fewer hours per day.

Progression over time for RQ3

To evaluate RQ3 in hypothesis E, Figures 22-A and 22-B illustrate CDI VU and CDI VP results, respectively. In addition to boxplots for T1 and T2 results, green lines represent the individual scores at each time point for children using the CI for less than 8 hours per day. As seen in Figure 22-A, there was considerable individual variation in vocabulary growth in both groups of children using CI. In Figure 22-B, there was more variation in vocabulary growth in children using CI more than 8 hours per day, which are represented in grey lines.

Figure 22. Fig. 22-A CDI VU results at T1 and T2, Fig. 22-B CDI VP results at T1 and T2 in Children considering CI use.



Notes: Figures 11-A and 11-B illustrate CDI VU and CDI VP results. Green lines represent the individual scores at each time point for children using the CI for less than 8 hours per d

An ANCOVA test was run to determine the effect of CI hours of use on the CDI VU and CDI VP scores at T2 after controlling for T1. After adjustment for T1 results, there was no significant difference in CDI VU scores (F (1,46) 0.0033, p= 0.856). However, there was a potential significant difference in CDI VP scores at T2 (F(1,46)= 5.490, p= .004) after controlling for the scores at T1. After applying a Bonferroni correction, the findings might not reach the required alpha level for significance. Thus, there was a potential effect of the CI use predicting progress over time in CDI VP scores in our sample. Children who used the CI for more than eight hours per day made more progress in vocabulary production than children who used the CI for less than 8 hours per day.

6.4.1.6 Hypothesis F — School Nursery Placement Attendance

Hypothesis F is *that children with CI who have experienced rich contexts in spoken language at the education environment could have better outcomes in spoken language skills.* Thus, our sample was divided into two groups. First, children education environment places with less spoken language communication, such as deaf special schools and education at home, were allocated to education in less rich spoken language communication environments (Less rich spoken language). Participants attending education environments with rich spoken language communication, such as mainstream schools and nurseries, were allocated to rich spoken language in education environment (Rich spoken language).

Table 29 shows the descriptive statistics divided into the aforementioned two subgroups of participants. CDI VU mean scores for children in less rich spoken language communication environments were 72.8 [60.1] points at T1 and 57.4 [63.0] points at T2. The means for children in allocations in rich spoken language environments were 113 [51.8] points at T1 and 118 [56.9] points at T2. In CDI VP scores, results showed means of 10.0 [30.6] points at T1 and 10.1 [17.7] points at T2 for children in less rich spoken language communication environments. For those attending rich spoken language communication environments, the means were 48.3 [50.9] points at T1 and 67.6 [57.6] points at T2.

Table 29. CDI scores considering school nursery education attendance at T1 and T2.

Dependent Variables	Less rich spoken language (N=12)	Rich spoken language (N=37)	Overall (N=49)
CDI VU T1			
Mean (SD)	72.8 (60.1)	113 (51.8)	103.0 (56.0)
Median [Min, Max]	85.5 [0, 160]	134 [0, 160]	124. [0, 160]
CDI VU T2			
Mean (SD)	57.4 (63.0)	118 (56.9)	103 (63.5)
Median [Min, Max]	34.0 [0, 160]	142 [0, 160]	128 [0, 160]
CDI VP T1			
Mean (SD)	10.0 (30.6)	48.3 (50.9)	38.9 (49.4)
Median [Min, Max]	0 [0, 107]	25.0 [0, 160]	17.0 [0, 160]
CDI VP T2			
Mean (SD)	10.1 (17.7)	67.6 (57.6)	53.5 (56.4)
Median [Min, Max]	0 [0, 48.0]	55.0 [0, 160]	44.0 [0, 160]

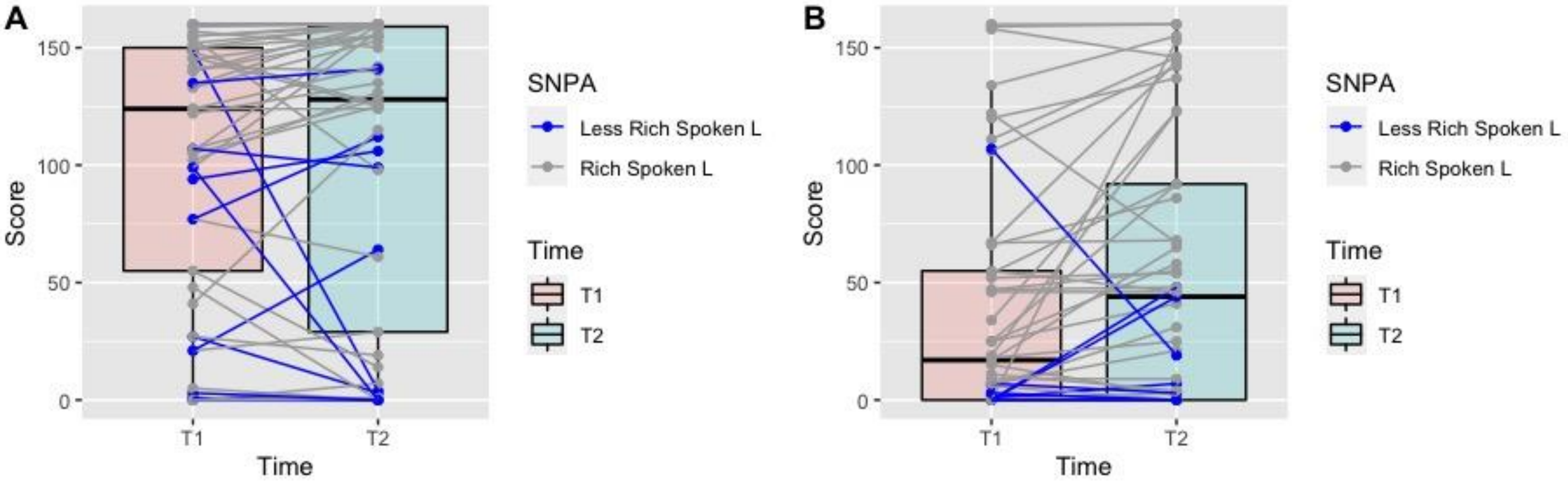
Notes: CDI VU= CDI Vocabulary understand results, CDI VP= CDI Vocabulary production results, T1= Time 1, T2= Time 2, SD= Standard deviation, Min= Minimum value, Max= Maximum value.

To evaluate RQ2 in this hypothesis, two two-way ANOVAs were run to evaluate if children attending rich spoken language communication environments had better-spoken language outcomes on CDI VU and CDI VP than children attending education with less rich spoken language communication environments. For the CDI VU scores, there was a significant positive main effect of rich spoken language communication environments (F (1, 95) = 26.255, p<.0001) and no main effect of time of evaluation (F (1, 95) = 0.012, p = .912). In the case of the two-way interaction between education with rich and less rich spoken language communication environments and time of evaluation, this was not significant (F (1,95) = 0.565, p=.453). For CDI VP scores, there was a main positive effect of attending education with rich spoken language communication environments (F (1, 95) = 26.251, p <.0001), and no main effect of time of evaluation (F (1, 95) = 0.431, p = .513). The two-way interaction between education with rich and less rich spoken language communication environments and time of evaluation was also not significant (F (1,95) = 0.086, p=.770). Therefore, children with CI who were exposed to rich spoken language communication environments in education showed better performance in CDI VU and CDI VP scores at both Time 1 and Time 2 compared to those in educational settings with less rich spoken language communication environments.

Progression over time for RQ3

To evaluate RQ3, figure 23 illustrates paired box plots to show the progression of participants in both subgroups from T1 to T2 in outcomes results. Figures 23- A and 23-B show results for CDI VU and CDI VP scores, respectively, detailing boxplots for T1 and T2 and each participant's over-time progression. Grey lines represent individual scores at each time point for children attending rich spoken language communication environments (Rich spoken language in the figure), and blue lines for children with CI in less rich spoken language communication environments (Less rich spoken language in the figure).

Figure 23. Fig. 23-A CDI VU results at T1 and T2, Fig. 23-B CDI VP results at T1 and T2 in Children considering school nursery attendance.



Notes: Figures 12- A and 12-B show results for CDI VU and CDI VP scores, respectively, detailing boxplots for T1 and T2 and each participant's over-time progression. Grey lines represent individual scores at each time point for children with CI attending rich spoken language communication environments and blue lines for children with CI in less rich spoken language communication environments in education. Abb: SNPA= School Nursery Placement Attendance, Spoken L= Spoken Language, T1= Time 1 , T2 = Time

An ANCOVA test was run to determine the effect of rich or less rich spoken communication environment in education on the CDI VU and CDI VP scores at Time 2 after controlling by results of these same assessments at T1. After adjustment for T1 results, there were significant differences in CDI VU (F (1,46)= 4.517, p<.0001) and CDI VP scores (F(1,46)= 4.726, p<.0001). Thus, sampled children attending education rich spoken language communication environments had more progress than those attending less rich spoken language communication environments in education.

6.4.2 Multivariate analysis of factors affecting spoken language results at time 2.

Better-spoken language outcomes have been found in young children with CI after 12 or more months of using the CI (Niparko et al., 2010; Uhler et al., 2011; Yoshinaga-Itano, Baca, & Sedey, 2010). Therefore, in order to evaluate RQ3, we considered factors associated with better spoken language results and the outcomes results at T2. In this manner, it was possible to cover the pre-registered prediction *that children with audiological-medical conditions without additional difficulties, who were implanted early, had better social determinants of health, high parental engagement about the CI treatment, and more time using the device, will be associated with better outcomes in the Version of the CDI Language Assessment at the last time of evaluation.*

To address this final prediction for RQ3, a multivariate analysis was run with CDI VU and CDI VP scores considering only the variables that were significantly associated in the previous sections with the outcome results: additional difficulties, CI Confidence, CI use per hour at day and education with rich or less rich spoken language environments of education. Table 30 displays two multivariate linear regression analysis models for the CDI VU and CDI VP. A high score in CDI VU results was positively associated with more hours of CI use per day (β=6.77; CIs= 1.58,11.97; *p*= .012) and higher parental CI confidence as parental engagement variable (β=19.95; CIs= 3.15, 36.74; *p*= .021). The model explains 38% of the variance for CDI VU scores. Therefore, CI use per day and CI Confidence were significant variables predicting better CDI VU score. Additionally, there were not significant variables predicting CDI VP scores.

Table 30. Multivariate regression analyses for CDI VU and CDI VP scores results and potential factors affecting spoken language outcomes at T2.

	CDI VU results at T2				CDI VP results at T2			
Predictors	*Estimates*	*β*	*CIs*	*p*	*Estimates*	*β*	*CI*	*p*
(Intercept)	-80.78	-185.91	-166.84 – 5.29	0.065	-48.51	-111.64	-131.58 – 34.57	0.246
Add diff	-8.91	-20.49	-49.30 – 31.49	0.659	-12.16	-27.998	-51.16 – 26.83	0.533
CI Confidence	20.79	47.85	6.03 – 35.55	**0.007**	7.86	18.08	-6.39 – 22.11	0.272
CI use	6.77	15.58	1.58 – 11.97	**0.012**	3.97	9.14	-1.04 – 8.99	0.117
Less rich SL Ed	36.69	84.45	-4.65 – 78.04	0.081	39.84	91.70	-0.07 – 79.76	0.050
Observations		49				49		
R^2 / R^2 adj		0.381 / 0.325				0.270 / 0.203		

Notes: Abb: CDI VU T1 = CDI Vocabulary understand at T1, CDI VU T2 = CDI Vocabulary understand at T2, Add Dif= Additional Difficulties (Binary variable yes/no), CI Confidence= Confidence with the CI in Likert scale as parental engagement variable. CI use = CI use in hrs using the average between T1 & T2 during the day, Less rich SL Ed= School Nursery Placement Attendance binary variable, which included rich and less rich spoken language communication environment in education.

6.5 Summarising of findings for Study 2

This chapter presented the results of Study 2, encompassing Research Question 2 and Research Question 3.

A notable finding was the detailed description of a subsample consisting of 49 children with CI from different regions in Chile. It reported an average of age of implantation of 2 years and 8 months in Chile. An extensive overview of sociodemographic factors, including social determinants of health of education, borough development and socioeconomic status in health was presented. The Borough Development Index highlighted the difference between the high sample average (0.56) and the country average (0.37). In treatment factors, a positive finding showing a high level of treatment attendance (73.5%) for children with CI, considering the pandemic situation in the country, was reported.

The chapter covered speech perception and spoken language using different outcomes. Only 24.5% of children at Time 1 and 28.6% at Time 2 had achieved spoken language as the type communication at home. In CAP II results, the median was reported as being 5 which was "*Understanding of common phrases without lipreading*" at Time 1 and also after one year of evaluation at Time 2. Similar results were found for the SIR with no progression between Time 1 and Time 2 reported and a median of category 4 of *"Connected speech is intelligible to a listener who has little experience of a deaf person's speech"*. In CDI VU results, the mean score was 102.77 at T1 and 103.10 at T2, with no significant progression made over time. Similarly for the CDI VP results, the mean scores were 37.14 at Time 1 and 53.53 at Time 2, and again no significant progression was made over time.

In addressing Research Question 2 and its corresponding hypotheses, the positive impact of the absence of additional difficulties on children with CI performance was confirmed in CDI VU and CDI VP results. Furthermore, daily CI use, high CI Confidence, a high Borough Development Index, and a rich spoken language communicative environment in educational settings were also found to have a positive impact on CDI VU and CDI VP as spoken language outcomes. These effects, non-effects, and interactions between variables will be discussed in the following chapter.

Lastly, Research Question 3, explored the influence of factors on the progression of vocabulary comprehension and production through CDI VU and CDI VP scores. The analysis revealed that additional difficulties, CI confidence, CI use per day, and educational environment significantly impacted the progression of spoken language outcomes results in our sample. These findings will be discussed in the following chapter.

Chapter 7: Discussion

The current project was designed to answer three overarching research questions:

1) What are the characteristics of deaf children implanted from 2017 to 2019 within Chile's public health system,
2) Which factors are associated with their spoken language outcomes and progression.
3) What factors predict progress made in deaf children's spoken language skills over 12 months in Chile?

Two main studies ─ Study 1 and Study 2 ─ were completed to address the research questions. In addition, an extra side study was embedded in this project which addressed the Chilean Ministry of Health's policy for deaf adults with CI. The adult study was written up and published (Bustos-Rubilar et al., 2023).

The present chapter will discuss the findings separately, organised by study. The findings presented in Chapter 3 for Study 1 (henceforth characterisation study) and in Chapter 6 for Study 2 (henceforth longitudinal study) provide novel information about deaf children in Chile and their progress in developing spoken language. In Section 7.1. the first comprehensive national characterisation study of children with CI in Chile is discussed. The section will also discuss the findings regarding factors affecting outcomes on the speech perception and spoken language abilities measured by the Geers and Moog Latin American Scale. Section 7.2. considers the main findings from the two side studies (the transcultural adaptation of the CAP II and SIR and the countrywide health policy in Chile for deaf adults with CI). Study 2 will be discussed in section 7.3, focussing on the findings about factors affecting outcomes in children with CI, considering local and international evidence. Moreover, implications from the findings relevant for intervention and policies will be proposed. The discussion will include suggestions for new approaches to intervention for children with CI at an early age. A policy dimension in this matter will also be addressed. Finally, sections 7.4. and 7.5., will set out the limitations of the studies and further steps and considerations, respectively.

7.1. The first national characterisation of children with cochlear implants in Chile

Study 1 provided the first comprehensive national characterisation of children with CI within Chile's public health system, representing 70% of children implanted in the country from 2017 to 2019. Thus, with this high percentage of children characterised, this sample is representative of the national reality of children receiving cochlear implants from the public health system, which covers around 82% of the national population (Crispi et al., 2020). Although published studies of characterisations of children with CI are available for regions of Mexico, Argentina, Brazil, Peru and Panama, the current study is the first description of a wide sample of children with CI in the Latin American and Caribbean Regions.

Our findings revealed the diversity of children receiving CI, the majority of whom belong to middle- and low-income families. Additionally, although the number of parents/caregivers with secondary education (82%) was higher than the average in Latin America (50%) (UNESCO, 2019), participants with training or university completed (26%) were lower than the average of high income countries (39%) (OECD, 2021). This may reduce the likelihood of children having access to a rich communicative environment and favourable conditions for receiving a CI, which, in turn, might impact their development of spoken language skills. The Borough Development Index is a living environment deprivation measure, which is increasingly used worldwide (Hernández Bonivento et al., 2020), enhancing the socio economic characterisation. The average BDI value varied when comparing the characterised and longitudinal samples to the national average. The average BDI in the characterisation study was .54 and in the longitudinal sample it was .56, which are both higher than the national average of .37. Thus, the children in the samples had more advantageous conditions than the average population in Chile.

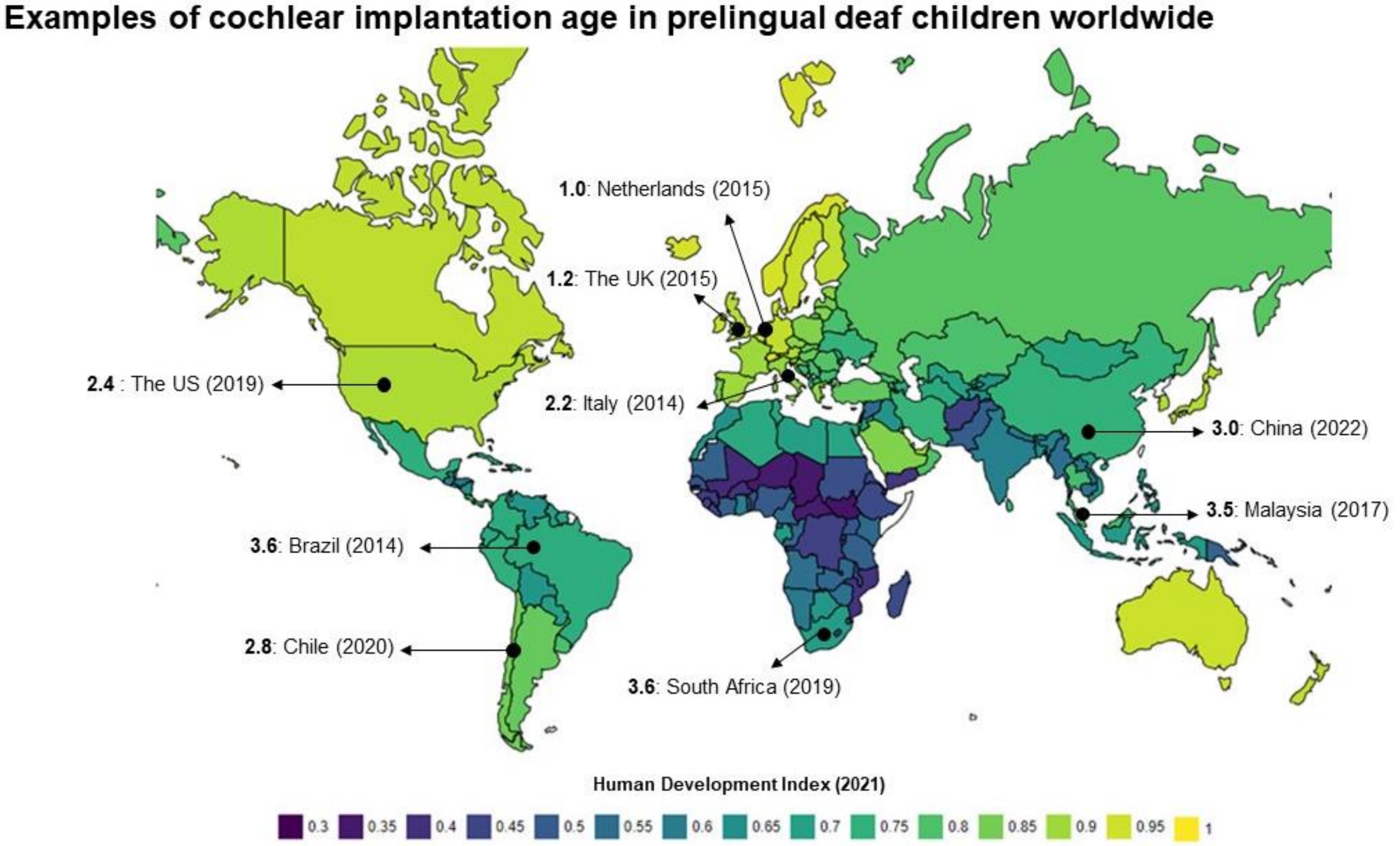
Consistent with Madriz (2000), findings from the characterisation and longitudinal studies suggested that children with CI, on average, originate from more developed boroughs compared to the national average. This inequality, which affects potential CI candidates from less developed boroughs, poses a challenge in ensuring equal access to CI, thereby underscoring the need for improved policies for early diagnosis and implantation. This aligns with findings from previous studies in Chile with adults using hearing aids, suggesting an association between higher education and socioeconomic variables and better social support and positive attitudes towards hearing loss or hearing aids (Fuentes-López et al., 2022). Therefore, social determinants of health, including healthcare access/quality, education access/quality, social and community context, economic stability, and neighbourhood environment, can directly influence the expected reach and results of the CI policy covering deaf children at an early age (Schuh & Bush, 2021).

In the audiological characterisation, the vast majority of children with CI were reported to have congenital rather than late onset hearing loss. Additionally, a low percentage (8%) of children were reported to have additional difficulties. This percentage is lower than the 30% of children reported with additional difficulties in previous studies (Corrales & Oghalai, 2013). Although the low representation in Chile may be due to the limited inclusion of children with additional difficulties in the CI policy, this can be partially explained by the under diagnosis of some additional developmental disabilities in deaf children (Daneshi & Hassanzadeh, 2007).

An important finding was the late CI surgery/switch-on time. This was on average 2 years and 8 months for the group with only congenital deafness. This could be explained by the delay in hearing loss diagnosis, which before implementation of the national screening program was around 3 years of age (Cardemil, 2012). This delay is important when we consider the extensive evidence suggesting CI surgery before 2 years of age leads to better outcomes (Iwasaki et al., 2012). Despite the lack of evidence in Latin America, delayed diagnosis is likely across the continent. For example, a study from one populous state of Brazil found that children were diagnosed on average at 3 years and 8 months (de Magalhães Barbosa et al., 2014). Furthermore, middle income countries such as South Africa and Malaysia have shown an average age at implantation around 3 and a half years (Bhamjee et al., 2019) and 3.5 years (Yusoff et al., 2017), respectively. In contrast, in high income countries, earlier ages of implantation are reported. For instance, according to Teagle et al.(2019), the average age of implantation in the US is approximately 2.4 years. Similarly, according to Bruijnzeel et al. (2017), the average age of implantation in the UK and Netherlands is 1.2 years and 1.0 years, respectively.

Figure 24 shows worldwide examples of the average time in years of cochlear implantation in prelingual children in a map displaying the human development index by country. The Human Development Index (2021) is a measure created by the United Nations Development Programme to assess a nation's average progress in three fundamental aspects of human development: life expectancy, education, and standard of living. In the map, the lowest scores from 0.0 are illustrated in dark blues and the highest scores up to 1.0 are displayed in green and yellow.

Figure 24. Worldwide examples of the average age in years for cochlear implantation in prelingual deaf children in a map displaying the human development index by country (World Population Review, 2023).



Notes: Examples were collected from different sources and could be measured differently. The examples do not necessarily represent the current national reality in each country, but they are useful references to compare implantation age and Human Development Index by country. The age is expressed in years, and each study's publication date is in parentheses. The original map is from World Population Review (2023)

It is important to acknowledge that the comparisons established have been made using the most recent literature available, which, in some cases, is not up to date. Furthermore, studies could employ different measures for the age of implantation, and there could also be variations in the inclusion criteria for participants. Therefore, these comparisons are intended solely for reference, given the diversity of evidence and the year of publication. Thus, although there are possible differences in how the countries' studies collected age of implantation data and the date of publication, the information might be useful to compare the Human Development Index (2021) by country and the age of implantation in the given cases. In the examples, countries with a higher human development index have a lower age of implantation in prelingually deaf children. The later age of implantation reported in countries with a lower human development index can be explained by the lack of resources for early diagnosis given by the minimal financially integrated programmes and policies supporting the early childhood development (Bhamjee et al., 2019).

In our findings, it is important to note the low percentage of children with CI using a contralateral hearing aid with unilateral CI (10%) or bilateral CI (6%). Although only unilateral CI has been evaluated as cost-effective in low and middle income countries in the Latin American region, it is likely that using contralateral hearing aids with a unilateral CI, or using bilateral CI might positively affect spoken language outcomes (Bento et al., 2018; Swami et al., 2021). In our study, an appreciable percentage (27.1%) of children with CI experienced technical issues with their CI, implying that without a contralateral hearing aid, they will have had periods of time with no amplification. This shows the relevance of having optimal and continuous access to functional devices which enable hearing stimulation and spoken language interaction. In addition, a lack of access to technical support has been reported in Chile which serves as a further barrier for children to achieve better outcomes regarding spoken language and social inclusion (Bustos-Rubilar et al., 2021). Thus, the importance of offering full access to sign language becomes necessary at all cases, but especially in cases of potential communication barriers caused by technical issues with CI and the associated support limitations.

High attendance (94%) from parents/caregivers was reported regarding treatment and education. This is particularly positive for the Chilean public health system because most children with CI received treatment despite difficulties attending the centres, especially during the COVID-19 pandemic. Although more than 85% of children with CI received treatment from speech and language therapists, less than 30% reported treatment from a psychologist, and less than 10% worked with a sign language interpreter or deaf educator. Recommendations before and after CI surgery advise receiving support from other professionals such as psychologists and contact with the deaf community (Jambor & Elliott, 2005). Although most education centres in Chile might not have experts in CI or in deaf children's spoken language development (Bustos-Rubilar et al., 2018), the high participation of children with CI in formal education-nursery (90%) could be beneficial for providing more opportunities for language interaction.

The last two factors in the characterisation were CI use and parental engagement variables. Surprisingly, a high percentage (78.5%) of the participants reported "always" using the CI. Evidence from high income countries such as Australia provides similar results in parent reports, describing around 80% of CI use as "always" (Marnane & Ching, 2015). However, Marnane and Ching (2015) and Contrera et al. (2014) suggest an overestimation of the device usage in parents' reports. This overestimation is likely the result of a deliberate or subconscious inclination to align with previous guidance that underscores the significance of consistent CI utilisation. Thus, although data logging records in the CI are not available on all devices, the logs could provide valuable data for monitoring children's CI use (Wiseman et al., 2021). The current study reported a mean CI use of 10.5 hours per day, indicating high CI use as reported by the parents. Prior evidence has suggested different average times in reports by parents. For example, while Contrera et al. (2014) in the US reported an average of 12 hours per day in 474 participants, Wiseman & Warner-Czyz (2018) showed an average of 7.6 hours per day in 71 children with CI. Nevertheless, eight hours of CI use daily might be ideal for better-spoken language outcomes (Contrera et al., 2014; Wiseman & Warner-Czyz, 2018).

Turning to our findings concerning parental engagement, most parents/caregivers of children with CI received some training about the device (94%), and they had high (38%) or very high confidence (51%) in their CI Confidence. This is a positive observation, particularly since rehabilitation practices typically prioritise the child's needs, often overlooking the educational support for parents and caregivers regarding CI and language development. Education and direct parent support depend more on what is provided by individual rehabilitation centres rather than guidelines within the current Chilean policies (Bustos-Rubilar et al., 2021). Thus, it is necessary to understand more about what and how parents/caregiver are receiving their education and CI training. Although the lack of consistency in their regulations, high income countries such as Australia and the UK offer information regarding providing advice and training about CI rehabilitation for parents/caregivers (Sorkin & Buchman, 2016). A model of parental school and tailored parents monitoring using new technologies could be options to support parents/caregiver in the country.

7.2. Outcomes for children with CI in Study 1 and Study 2

In both studies 1 and 2, nearly a third of parents/caregivers reported that their child used spoken language at home and with others. Moreover, when changes over time are observed, the increment from 24.5% to 28.6% of children with CI using spoken language at home was not significant. Therefore, less than a third of children with CI were using spoken language at home after at least two years of device use. Thus, it is important to consider this low percentage. Hall et al. (2020) have shown the disparities between the information given about CI performance in spoken language development and the real results with the device in deaf children. This is important in the Latin American context, where more evidence is needed to understand how children with CI progress in their spoken language over time.

The findings concerning satisfaction of parents/caregivers and social inclusion of the children with CI were only evaluated during the characterisation and were not included in the longitudinal analysis. The majority of parents were very satisfied with their child's CI, which is important considering the variation in the spoken language outcomes with the CI. A possible explanation for this is that rather than basing the satisfaction on spoken language outcomes, a high level of satisfaction by parents/caregivers could indicate a bias of the CI intervention whenever parents/caregivers associate satisfaction with free delivery of products and services by public health entities. This is a risk when the success of the CI is measured only in terms of satisfaction. For example, one study about CI success in 16 participants in Chile was quite confident about the results of the device only considering satisfaction with the CI. They used a standardised quality of life questionnaire, which comprised 24 questions equally distributed across six subscales: physical well-being, psychological well-being, self-esteem, family, friends, and educational performance. The study showed positive results in the mentioned subscales (Morales et al., 2018). Although it is important that parents/caregivers and children are satisfied with the health service and the CI, the focus should remain on the main objective of providing CI for deaf children, which is spoken language development.

On the other hand, high satisfaction could be linked with a higher social inclusion reported by parents/caregivers. The social inclusion results in the current study were high (75% reported the child was included or quite included), compared with previous evidence indicating the social inclusion challenges children with CI have in their adolescence (Dammeyer et al., 2018). On the other hand, the high satisfaction could also be influenced by a courtesy bias or a lack of criticism due to the fact that the services are mainly free of charge in the public system (Ministerio de Salud, 2016). Further research might be needed comparing the social inclusion in groups using spoken or other language modalities or children with CI attending mainstream nurseries/schools or institutions for deaf children.

The Chilean CAP II and SIR instruments, which were transculturally adapted by the research group, were found to be suitable tools for evaluating children’s auditory perception and spoken language intelligibility in both studies. The transcultural adaptation process from English to an online Chilean Spanish format created new instruments of evaluation that are important at the national level. This represents a significant contribution to the intervention of children with CI in clinic contexts in Chile, as it represents a simple yet useful online instrument for measuring and monitoring progress in speech perception and speech intelligibility at early stages. In addition, recognising the geographical challenges to accessing CI specialists in a vast territory, this tool can contribute to the remote evaluation and monitoring of children with CI. This aligns with evidence suggesting the strengths of online intervention and rehabilitation of deaf children, especially after the pandemic (Claridge & Kroll, 2021). Nevertheless, as mentioned in Bustos-Rubilar et al. (2022), further evaluation using the instruments in longitudinal studies is needed to complete the reliability evaluation.

The Chilean CAPII findings showed that in the characterisation study, over 50% of the children with CI could understand common phrases and conversations through spoken language. This finding was similar in the longitudinal study with a subsample of children with CI, where the median was the same level of understanding. Moreover, in the longitudinal evaluation of the CAP II in the subgroup of younger children with CI, children’s scores did not significantly improve between Time 1 to Time 2. There are possible explanations for these findings. Firstly, parents/caregivers could overestimate the real ability of each child at early times after cochlear implantation, especially if they do not have prior knowledge regarding CI or language development (Socher et al., 2019). Therefore, there might be a plateau of auditory performance estimation. This plateau might be observed for levels reflecting concrete abilities, which are more present in higher scales of the CAP II. For instance, in level 7 of “Use of a telephone with a familiar talker”, parents/caregivers can easily check whether their children with CI can use the telephone or not, offering a more reliable insight about the child’s abilities. According to Dockrell & Marshall (2015), there are many complications in measuring language development in deaf children due to the interpretation of language assessments, which depends on factors such as socioeconomic status, language proficiency, dialect, and level of deafness. Moreover, this difficulty to evaluate spoken language can also be related to the low percentage of parents/caregivers reporting spoken language use during communication at home.

On the intelligibility results from the SIR scale, around 50% of parents/caregivers reported that their children's speech was intelligible to a listener with experience with deaf people. Additionally, 38% of children with CI in the characterisation study used non-intelligible spoken production or manual communication. While in the longitudinal study, the percentage of children using non-intelligible speech decreased from 47 % in Time 1 to 33% in Time 2, although this was non-significant in the inferential analysis. Thus, there were disparities in the results of this evaluation between the two studies, enabling two discussion avenues in this context. First, international experience suggests that, in general, disparities of outcomes are part of the diversity of results in children with CI (Hall et al., 2019; Hall, 2017). Second, variations in longitudinal assessments, as well as discrepancies when contrasting SIR results with CAP II performance, can be attributed to the data source, which relied on parents independently filling online surveys. Although reports from parents and caregivers about outcome results in their children are widely used in psychology and language development in deaf children (Mayor & Mani, 2019), this can be a limitation of the research, which will be assessed in Section 7.5. below.

To counteract the issues concerning data collected by parental reports, the Geers and Moog Latino American scale result collected from each child's clinical record in the characterisation study was an appropriate speech perception outcome to consider. One interesting finding was that more than 50% of children with CI completed the lowest level for speech perception "Time-intensity pattern perception in amplified speech". Moreover, similar to the findings in communication at home outcome, only around 15% of children with CI could complete word recognition or spoken language comprehension, which is close to the highest level for speech perception. This percentage might be quite low compared with aforementioned studies. Thus, although the results show disparities across the SIR and CAPII outcome measures, it remains noteworthy that there was a high proportion of children with CI not achieving the expected results in speech perception and spoken language production abilities. In addition, it is important to note that results from all the studies in this project were taken after one year of CI use. This is contrary to the evidence suggesting very positive results after 12 months of CI use in children from high income countries (Saunders et al., 2016). Therefore, It is important to take into account data from low and middle income countries, where more than 80% of children with disability live (World Health Organization, 2021).

To take advantage of the Geers and Moog Latin American scale as the only outcome directly collected from the clinical records, we evaluated the relationship between the scale results and five factors that could potentially influence the results. We found significant relationships between performance on the Geers and Moog Scale and children's chronological age, age of cochlear implant (CI) surgery, additional difficulties in the child, daily CI usage, and CI training as part of the parental engagement variables:

1. Older children with CI appeared to achieve higher scores on the scale results, which was expected due to the wide age range of children from two to fifteen years old. Additionally, approximately 19% of children in the sample had late hearing loss with a maximum age of 15 years and one month of age, with likely spoken language development preceding the hearing loss.
2. Contrary to existing evidence (Shakrawal et al., 2020), our sample showed that a later age of CI implantation was associated with higher scores on the scale results. Similar to the previous findings regarding age, this result is understandable considering the varying ages of the children and the presence of late hearing loss in the sample. Thus, the longitudinal study evaluated a subsample with participants of similar age, the same aetiology, and the time of implantation to better understand these age-related variables.

3. Children with additional difficulties in the extensive sample of the characterisation study achieved lower rankings in the scale results compared to those without additional difficulties. This observation aligns with prior evidence indicating that additional difficulties might adversely affect spoken language development in children with CI (Barker et al., 2009; Gérard et al., 2010; Lyness et al., 2013). Thus, rather than denying these children access to the device due to potentially poor outcome results, the focus for these users should be on providing targeted support and monitoring. This support can be delivered during the CI intervention process and reinforced during early intervention to enhance language and psychosocial abilities (Cejas et al., 2015).

4. As a fourth finding, the daily CI usage hours for children with CI was not found to be significantly related to performance on the scale results. This finding is not consistent with previous studies investigating CI usage throughout the day (Wiseman et al., 2018). Nevertheless, CI use emerged as a critical factor for vocabulary understanding as part of the longitudinal study (section 7.3.5.)

5. Parents/caregivers who received training about CI were related with higher scores in the scale results than those who reported no training. This finding is in line with previous evidence, which evaluated this variable's relationship with spoken language outcomes (Ganek et al., 2012; Nicastri et al., 2021; Suskind et al., 2016) . The implications of this finding, coupled with the influence of CI usage throughout the day for each child with CI, could represent a significant opportunity for direct intervention with parents/caregivers and children with CI

during the rehabilitation process. While assessing social determinants of health and policies supporting CI interventions can be complex, these findings offer a straightforward yet impactful approach to improving outcome results for children with CI. These findings will be discussed further in section 7.3.4.

Finally, although the social determinants of health did not significantly influence the Geers and Moog scale results, this does not mean they are not relevant for better outcomes in children with CI, especially in the Chilean and Latin American contexts. Restricted essential services in healthcare, education, and rehabilitation without adequate infrastructure and proximity are still significant obstacles faced by children with CI in Chile and Latin America. A possible reason for the lack of significant associations in the current study could be that the social measurements were not extensive or robust. According to Dockrell & Marshall (2015), it is necessary for a comprehensive evaluation of multidimensional aspects of social and economic conditions in a family, which includes extensive income and expenditures measures.

7.2.1. Vocabulary from the MacArthur-Bates Communicative Development Inventory (CDI) as spoken language outcome result in children with CI

The Chilean version of the MacArthur-Bates Communicative Development Inventory (CDI) was employed in the longitudinal assessment of a subset of children with CI during Study 2. The instrument measured the number of words each child understood in CDI VU, and understood and produced in CDI VP, from a standardised vocabulary set commonly utilised in such assessments worldwide (Fenson et al., 2007). A total of 160 words in Chilean Spanish were considered for vocabulary understanding (VU) and vocabulary production (VP) subsections.

An important finding to highlight is that the mean scores for the CDI VU were virtually identical at T1 and T2, but the CDI VP scores made a non-significant progression over time. These findings are contrary to studies suggesting that young children with CI might show fast emergence of first words and a substantial amount of vocabulary acquisition at the end of the first year after cochlear implantation (Chilosi et al., 2013; Faes et al., 2017; Fagan, 2015; Jung et al., 2020; Koşaner et al., 2013). For example, Fagan et al. (2015) showed that in a very small sample of 9 children with CI in the US, the mean performance in the CDI increased from 0.67 [1.12] words at 4 months after implantation to 102.33 [94.48] words at the age of 12 months. Similarly, Koşaner et al. (2013) reported that Turkish children with CI increased their word understanding and production by 100 words between 6 and 9 months after implantation.

In the Latin American region, a recent article from México used the CDI to evaluate vocabulary knowledge in 14 children with CI (Ramírez-Barba et al., 2022). The study found that the mean number of words produced by children was 207.3 and the mean number of words understood was 156.7 words. These results suggest that children in this Mexican study were producing more words than they understood, which seems unlikely and might in fact represent errors in the research. Considering this lack of data from the region, it is vital to advocate for the necessity of reliable regional data. The potentially unsatisfactory results found in children with CI in Chile invite questioning the situation in regional countries with less support for children and families, approaching realities that might be a public health concern in Latin America.

Nevertheless, apart from the previously mentioned articles, there is evidence indicating a diverse range of vocabulary growth in children with cochlear implants, and in many cases the progression tends to be generally lower than that observed in typically developing children (Dettman et al., 2016; Jung et al., 2020; Rinaldi et al., 2013). For instance, Jung et al. (2020) conducted a comparison between the receptive vocabulary of 126 children with CI and typically developing hearing children, both having an average hearing age of 8 months. In this study, children with CI had a mean receptive vocabulary score of 19.5, whereas their typically developing peers scored 38. However, it might not be entirely robust to juxtapose these figures with the outcome results of the longitudinal study directly. The Jung et al. (2020) study only completed 160 words from the usual 300 found in the extended version of the CDI. On the other hand, considering the complexity of having the evaluation completed by parents/caregivers, the vocabulary production appears to offer a reliable measure of spoken language progression, as there was no ceiling effect at early time.

Another point of discussion is the ceiling effect, especially in the CDI VU results. Approximately seventeen children with CI (34%) achieved the maximum score of 160 at both T1 and T2, making it difficult to assess their progress over time. Conversely, the CDI VP results did not exhibit a ceiling effect among participants, thus enabling the acquisition of progress-related information without such limitations. However, both results appear to be disappointing concerning progress in both domains, warranting crucial further research, particularly for understanding the dynamics affecting children in the country and region.

In summary, it is important to highlight the low mean score that children with CI had in vocabulary understanding and production, suggesting a very low performance of this group in the country. It is important to analyse in detail the potential reasons for these results, which are assessed in the following sections on factors affecting outcomes. Moreover, although the findings contrast with previous studies suggesting rapid vocabulary growth in children with CI, it essential to note that vocabulary progression in this group varies widely, often lagging behind typically developing peers.

7.2.2. Potentially anomalous results in the outcome results.

Chapter 6 section 3 describes 14 children with CI who experienced a decrease in one or more outcome results evaluated during Study 2. These outcome results included CAP II, SIR, CDI VU, and CDI VP. Despite the analysis showing similar results in terms of factors affecting the outcome results in children with CI, regardless of whether this group was included or excluded from the data analysis, it remains crucial to discuss the possible reasons behind these potentially anomalous results. Firstly, it is important to note that previous research (Bauhoff, 2014) has highlighted the existence of anomalous or inconsistent results in longitudinal evaluations when using self-report instruments. Secondly, it is important to note the presence of children in the study who have additional difficulties which may not have been diagnosed. Some children might initially exhibit typical language development but later experience stagnation or apparent regression during their developmental progression, making this aspect important to consider in further studies (Hansen et al., 2008). Finally, the education of parent respondents could influence how complete and how consistent their answers were over time. Moreover, providing better and more active support to respondents during the survey process could serve as a sensible measure to ensure consistent results among parents/caregivers.

In summary, while the evaluation of outcomes reported by parents/caregivers is widely used, it is essential to consider and investigate potential anomalous results. Finding possible explanations for these results might enhance the research process, providing a comprehensive understanding of the results and valuable insights for the findings discussions.

7.3. Factors associated with good spoken language results in children with CI

7.3.1. Additional difficulties as an expected factor predicting progress in deaf children with CI

There was a negative influence of additional difficulties presence in the spoken language progression results of children with CI in the longitudinal study. As mentioned in section 7.2 of the Geers and Moog scale results analysis in the characterisation study, this finding aligns with previous evidence (Barker et al., 2009; Gérard et al., 2010; Lyness et al., 2013). The need for more sensitive intervention for children with CI and additional difficulties is imperative. An evidence review about outcomes and benefits of CI in children with additional disabilities completed by Cejas et al. (2015), analysed more than 50 studies on outcome results in language and wellbeing in children with CI and additional difficulties. Some of the conclusions suggest benefits of early implantation in this group, regardless of their additional difficulties. However, many studies were not evaluating spoken language development per se. Improved attention, behavioural regulation, sign language development, social functioning, school performance, and health-related quality of life are examples of measured outcome results (Cejas et al., 2015).Therefore, it is important to consider the potential influence of additional difficulties on the anticipated spoken language outcomes when in discussion with therapists and families of children with additional disabilities.

In addition, it is important to note that the main focus of this thesis was on the spoken language outcomes resulting from CI use. Therefore, information regarding communication using sign language among groups facing additional language difficulties was not considered. Deaf children with CI and additional difficulties benefit greatly from the early use of sign language (Knoors & Marschark, 2018). Further research needs to encompass a broader evaluation of communication among children with CI, as well as to consider the cognitive dimension of performance. Cognitive evaluation is necessary to understand the impact that additional difficulties may have (Cejas et al., 2015). Further research should consider cognitive performance when trying to understand the implications of cognitive factors on outcomes in children with CI and additional difficulties, as well as those without.

From a policy perspective, deaf children with additional difficulties might constitute a very vulnerable population due to the challenges of the comorbidity. In this context, deaf children with CI and additional difficulties and their families experience unique challenges. Policies providing early care and CI should take these challenges into account. The UNICEF Disability Inclusion Policy and Strategy 2022-2030 (Berman-Bieler et al., 2023) describes children with disabilities as having to face multiple and intersecting forms of discrimination and exclusion. Therefore, in these groups, rather than simply focusing solely on one outcome result in early development, there should be cross-sectional strategies and priorities, including access to assistive technologies such as CI, as well as providing comprehensive communication care and support services.

7.3.2. CI age as a detrimental factor in late implantation

The average CI age at implantation for children in Study 2 was 2 years and 8 months which was almost one year younger than the average age in the characterisation group in Study 1. The average age of CI in the longitudinal study might better represent the time of implantation in the public health system for children who are born deaf in Chile. For the above reason Section 7.1 and Figure 24 of this chapter is using 2 years and 8 months of average age.

The CI Age was a significant predictor of the progress made in vocabulary production. This aligns with evidence suggesting an effect of early implantation on lexical abilities in children with CI (Dettman et al., 2016; Leigh et al., 2013; McKinney, 2017). The review of 49 studies completed by Duchesne and Marschark (2019) assessed the relation between CI and spoken language outcome results. The study findings suggested considering the environmental characteristics of the child and the family as part of the factors affecting spoken language abilities.

Although offering an early CI can be a concrete action, accelerating complementary processes around diagnosis and implementation for early care is very complex, especially in Chile and other Latin American countries. In Chile, only since 2020 has a pilot program of neonatal universal hearing screening started (Minsal, 2022). This means that the recommendation of the “EHDI 1-3-6 guidelines” for neonatal screening by 1 month, confirmation of hearing loss by 3 months, and intervention by 6 months of age (Yoshinaga-Itano et al., 2018) could be evaluated in the next few years with further research. In the case of Latin America, considering 32 countries of the South American continent and the Caribbean region, only 6 countries provide over 90% coverage in national screening, including Cuba, Costa Rica, Chile, Uruguay, Argentina, and Paraguay (Giugliani et al., 2022)

Policies, including industry-sponsored diagnostic programs, play a significant role in facilitating access to early diagnosis. Nevertheless, to ensure the sustainability of neonatal screening and early diagnostic approaches nationally, an effective public healthcare service is crucial (Therrell et al., 2015). In Latin America, most countries face challenges due to insufficiently integrated healthcare services; navigating through fragmented healthcare systems presents a significant hurdle to achieving universal neonatal screening and early diagnosis (Giugliani et al., 2022).

7.3.3. Social determinants of health affecting the outcome results in children with CI

Social determinants of health factors, including Socioeconomic Health Insurance level (SHI), family highest education (FHE), and borough development index (BDI) variables, were important to this project. They represent one of the distinctive features of regional and country analysis and evidence, especially in Chile and Latin America. The participants in both studies reported better than average borough development index scores compared with the national average. This finding might suggest that deaf children might be not equally receiving CI interventions across the country. Deaf children from boroughs with low BDI could have less possibility for access to CI and treatment, impeding the universalisation of the policy access.

The causes of the inequality access to the CI might vary, major cochlear implantation in boroughs with high BDI index might have multiple contributing factors. When considering the healthcare system, low access to early specialised health services, lack of professionals and screenings, together with scant information from the health system can be more present in boroughs with lower BDI index. When considering parents/caregivers and deaf children context, the lack of family education to be able to request health assistance and lack of community awareness about deafness could be potential reasons of unequal access to CI. According to WHO (World Health Organization, 2021), challenges in early intervention for hearing loss stem from a lack of accurate information and the presence of stigmatising attitudes toward hearing loss. These factors hinder access to care. Even healthcare providers might lack knowledge about prevention, and early detection to offer suitable care. Moreover, in low and middle income regions Audiology and Rehabilitation services are often absent at the primary care level and inconsistently provided at secondary and tertiary levels (ibid).

After evaluating SHI, FHE, and BDI in relation to spoken language outcome results in the longitudinal study, only BDI showed a trend of relationship with improved vocabulary understanding and production during the two evaluation periods. It is important to notice that many of the analyses were completed using the variables as binary factors. Although this action can have the advantage of being a practical division between socioeconomic conditions, it can also represent disadvantages in the case of inferential evaluation and in the interpretation of results. The complexity of socioeconomic conditions in many cases cannot be understood by simple assignment of two groups. Further study may be necessary to define a more complex procedure for grouping socioeconomic variables. Regarding the BDI influence on vocabulary, this might underscore the importance of the territorial context and the public services access that families of children with CI have, which in turn might result in better outcomes for children with CI. Moreover, this potential finding aligns with evidence that indicates improved results for deaf children are influenced by access to healthcare, education, and other social facilities (Hernández Bonivento et al., 2020; Madriz, 2000).

However, rather than measures taken in the intervention context in children with CI, a concrete proposal in the political dimension can be formulated. A comprehensive social policy that includes health access as well as economic and social protection, with sensitivity to each deaf child and family, becomes a necessity. Therefore, section 7.4 provides a discussion of policy implications with recommendations for intervention and includes political dimensions.

On the other hand, while evidence recognises the influence of Socioeconomic Health Insurance level (SHI) as an SES variable and family highest education as a parent/caregiver education variable, these were not found to affect language outcomes in the current characterisation and longitudinal studies. In the case of SHI, it is possible that the lack of a significant relationship was due to a lack of variability in the sample. For example, approximately 60% of children with CI in the longitudinal study were from low to low-income backgrounds. Concerning the FHE variable, the survey asked about the highest level of education of the closest parent/caregiver, which in many cases, is not the head of the household or the primary contributor to the child's education and finances. For example, a similar limitation was identified in a study where information from the mother was collected in a self-report format in Mexican women and the evaluation of child receptive vocabulary (Gonzalez et al., 2017). Consequently, this limitation could exist within the current study, warranting further research to evaluate the real interaction of this variable with outcome results in children with CI.

7.3.4. Parental Engagement variables as important factors influencing spoken language outcome results in children with CI

Parental Engagement was assessed in this project using two variables – CI Confidence and CI Training – evaluated with the child’s spoken language outcome results in the longitudinal study. First, parental CI confidence was significantly associated with both vocabulary understanding and vocabulary production. However, after applying a Bonferroni correction, the association failed to reach statistical significance. Therefore, it is possible that with a bigger sample size, this might represent a potential finding about the importance of parental confidence during the intervention process. This would align with previous evidence supporting the positive influence of family participation and engagement in the process (Bryce et al., 2018; Sarant et al., 2009). CI confidence could result from actions driven by better social conditions and support, leading parents to be more present and engaged during their child's CI intervention. Moreover, the relationship between parental confidence regarding CI and language development in children with CI has received little attention, in comparison, for example, with the age of implantation. A study conducted by Suskind et al. (2016) developed a support program for parents of children with CI, considering parental confidence. After a parent-directed home-visiting intervention, findings showed that adult word stimulation, conversational turn counts, and child with CI vocalisation counts increased significantly during the intervention.

In the case of CI training as a measure of parental engagement, this variable was not associated with spoken language outcome results or their progression in the longitudinal analysis. This was surprising because we expected that parents receiving training about CI and spoken language development would have positive effects on their confidence and outcome results children with CI. The current lack of an association could be explained by the education and resources available for parents/caregivers during the early stages of a child with CI. At least in Chile, policies do not consider specific services for parents/caregivers, providing them with extensive information, communication, and interaction with the CI process (MINSAL, 2013). A good example of parental intervention is provided by the Australian Government. Queensland has a dedicated section in its technical policy guidance about ‘parenting schools’, outlining aims, timing, and strategies for parents/caregivers during the CI intervention for deaf children (Children’s Health Queensland, 2016). Nevertheless, attending the suggested parenting school becomes complicated if parents/caregivers need to work or care for others during their daily lives. Therefore, a specific measure in parents/caregivers needs to be complemented with comprehensive social measures to allow them to participate and receive training in CI and language development actively. More details about this implication and policy recommendations are available in section 7.4.

7.3.5. CI use as the most critical variable affecting outcome results

The length of daily CI use (in hours) in children with CI using the device for more than 8 hours per day was significantly related to better speech perception and spoken language outcome results in both studies. Additionally, CI use of more than 8 hours per day positively influenced the progression of vocabulary production based on the CDI VP results. Furthermore, in the final multiple regression model, CI use in hours per day and CI Confidence variables explained 38% of the variability in the CDI VU results at Time 2. It was estimated that each hour of use per day might lead to an increase of around 7 understood words from the CDI VU at Time 2 in the longitudinal study. This finding aligns with previous research that evaluated CI use (Wie, 2007; Wiseman, 2021). Positive outcomes in spoken language were found in children with CI below five years of age for using the device for more than 8 hours per day in Norway (Wie, 2007) and the US (Wiseman, 2021). Therefore, daily CI use in hours emerges as a critical variable due to its strong influence on expected outcome results and its easily measurable nature.

However, despite its apparent simplicity, increasing the number of hours the CI is used for can impact positively upon a complex outcome that requires collaborative efforts among various stakeholders involved in the early childhood overall development of each deaf child. Consistently using the device and having social interactions might require coordination among parents, grandparents, siblings, caregivers, CI teams, nursery teams, education workers, and others (Chen et al., 2020). Additionally, behavioural issues, such as opposition and stubbornness that provoke resistance to keep the CI in place and turned on for extended periods of time, can disrupt device usage, potentially causing delays or cessation of its use (Boerrigter et al., 2019). Thus, the intervention guidance might include a dedicated section addressing CI daily use in hours and its significance during the initial years of device usage.

Moreover, it would be essential to complement parents/caregivers reports of daily CI use with objective data derived from CI data logging. Evidence suggests that parents/caregivers often report more hours of device usage than the actual time the device is used by children with CIs, sometimes inflating usage up to 8 hours (Wiseman et al., 2021). In the characterisation and longitudinal study, over 75% of parents/caregivers reported usage as "Always" on question regarding CI use per day. Consequently, implementing a concrete intervention focus on the daily CI use could improve the average usage rate and, consequently the spoken language outcome results. In addition, it is important to note that increasing CI use also might require integrated complex work among health providers, education placements and family members.

In the policy context, Chilean regulations lack any specific section or recommendations regarding the extended use of CI for children (Ministerio de Salud, 2019). They only emphasise the importance of consistent and gradual use without a comprehensive program involving various specific actors, such as parents, family, teachers, educators and therapists, supporting children with CI. A noteworthy illustration of technical guidance within a national policy is the case of the UK (NHS, 2023), wherein the guidance includes a specialised section on services that accounts for the social dynamics among different parties supporting each child's CI usage during early stages. For example, the guidance describes a multidisciplinary team including clinicians, teachers, psychologies, and families as a core team monitoring the

CI use with specific facilities and services. Examples of this can be found in Chile in children with neurological and physical disability through Teleton Chile foundation. More recommendations in the policy context for this and other variables are integrated and available in section 7.4.

7.3.6. Sign language input not hindering spoken language development

Findings from the characterisation and longitudinal study yielded positive results in spoken language outcomes when children with CI were attending rich spoken language environments in education. Although the findings are in line with evidence suggesting that spoken language environments are positive for better results in spoken language outcomes (Archbold, 2014; Tait et al., 2007; Wiseman & Warner-Czyz, 2018), this should not be taken as evidence that any use of non-spoken language communication could be associated with harming the spoken language in children with CI. In this sense, the near-universal provision of cochlear implants is often accompanied by policies that restrict children's and parents' learning of sign language (Mauldin, 2016; Snoddon & Paul, 2020).

In several contexts, the perceived decline of sign language vitality is also linked to the shrinkage and closure of Special Schools for the Deaf (Murray et al., 2020; Snoddon & Weber, 2021). This poses a real challenge for children who cannot develop spoken language through using their CI and those who develop sign language alongside spoken language. Hence, it is crucial to advocate for the right to early language access, regardless of the modality used from an early age. This stance aligns with the linguistic rights of deaf individuals and the UN Convention on the Rights of Persons with Disabilities, which acknowledges sign language as a cultural heritage of the deaf community (Tardi & Njelesani, 2015). On the other hand, the average age of participants in both of the current studies raises the possibility that type of educational attendance in some specific centres might be the result of their spoken language proficiency rather than a variable influencing spoken language development.

It is important to emphasise that according to the sociocognitive approach to spoken language development, a rich spoken language input is required for consistent language acquisition. However, it is crucial to clarify that this does not imply that the presence of sign language interferes with spoken language acquisition (Hall, 2020). Furthermore, for children of formal education age, their placement might reflect their communication modality rather than directly affecting the developmental outcome.

7.4. Implications of findings for intervention and policies

7.4.1. Implications for intervention for children with CI in Chile and Latin America

This section will discuss how the intervention and policy implications of the findings could be extended to the broader region of Latin America. The following points are important supplements to consider in addition to those already discussed in the previous sections.

It is noteworthy that, in the characterisation and longitudinal studies, the number of children with CI who were not receiving any intervention was minimal. For instance, in the longitudinal study, only two children were not participating in any therapy or intervention sessions with professionals. This finding reflects strong service coverage, which is a comparative strength compared to access to professional services in other Latin American countries like Ecuador, Guatemala, and Venezuela, where there is less access to cochlear implants and intervention services (Emmett et al., 2016). Nonetheless, further analysis is required to better understand these services' quality and content. This requirement extends to other countries in the region where the shortage of professionals might pose challenges in delivering comprehensive intervention with limited resources. In this context, a particularly noteworthy finding pertains to the percentage of children who do not use a contralateral hearing aid, which was approximately 78% of the characterisation sample. It is imperative to acknowledge that the lack of a contralateral device due to child or family behaviour and availability of hearing aids could diminish expected outcomes from the subsequent CI usage. Moreover, effective intervention entails more than just weekly therapy’s attendance, taking in account the daily life of each deaf children and family. In this regard, it might be important to explore the costs of not using the contralateral device and the different costs parents/caregivers need to face for continuous intervention for the child with CI.

As discussed in chapter one, evidence from middle- or low-income countries indicates that deaf children with CIs demonstrate disparities in early CI intervention (Omar et al., 2022). While all intervention efforts strive for optimal outcomes based on evidence from high income regions, it remains critical to maintain a realistic perspective on program results and expectations, particularly in countries that house at least 80% of the global child population. This entails providing informed options to parents/caregivers with local progress estimations in language development, aligning expectations with actual outcomes considering late implantation ages and social determinants of health for each child with a CI. In addition to informed options, parents/caregivers, especially those in vulnerable situations, might actively participate in consultations regarding their child's intervention and the research process (Wickenden & Elphick, 2016). Access to information should ideally be supplemented with family and child’s perspectives on their expectations and priorities. Therefore, generating comprehensive evidence regarding best practices under challenging and unequal intervention circumstances seems to be an unquestionable need. The findings from the studies of this thesis contribute to the Latin American knowledge base concerning children with CI and serves as valuable insight from the similar regions.

A tangible step towards refining the intervention process involves offering technical guidance to various stakeholders involved in the care of deaf children. According to Leight (2016), the existence of evidence-based technical recommendations with detailed protocols could facilitate and formalise the health intervention process for children with disabilities. In the case of Chile, a national intervention framework exists, which is provided by the national health system (Ministerio de Salud Chile, 2018). However, the framework lacks specific measures as noted in this project's findings. For instance, while the framework underscores early implantation and continuous evaluation by the CI team, encompassing hearing tests, medical assessments, spoken language evaluations, and other clinical intervention requisites, it falls short by not providing protocols for CI utilisation, parental training, strategies for children facing additional difficulties, support for families residing in low and middle income areas, integration of educational services, and contingency plans for non-spoken language development. A practical approach might involve developing precise protocols and guidelines to address these aspects in addition to the standard specifications provided by high income nations.

7.4.2. Integrated policies for deaf children and children with disabilities

Considering the current findings, integrated policies that support early childhood development and families are ideally needed to address factors that impact outcomes. Policies encompassing child development, including health, education, and social interventions, are necessary (World Health Organization, 2021). This coverage does not solely pertain to the health service but also to the national social protection system in Chile. Social protection represents a set of integral measures aimed at addressing inequality and reducing poverty within specific groups. This is an integral part of sustainable development at the national level, as outlined by the Sustainable Development Goals (SDGs). The current findings emphasise the significance of enhancing service access through improved community development and increased involvement from parents and caregivers. These aspects could be reinforced through enriched education and services targeting disadvantaged groups. Parents/caregivers from marginalised backgrounds might lack confidence in understanding their role in CI intervention for their child. This lack of confidence is likely due to more than just a lack of training; it also reflects the influence of social determinants of health, which hinder equal engagement and education among parents/caregivers.

Within the project, all participants were beneficiaries of the same policy for deafness for children below four years of age (MINSAL, 2013). This policy provides robust technical guidelines for accessing CI, including clinical evaluations with the device and rehabilitation focusing on speech perception and spoken language development. However, these policies lack connections with other policies, such as labour adjustments for parents, economic support for families with children with disabilities, access to public services, protection for families during the intervention period, educational guidelines for specific centres, availability of facilities or public services during the intervention, and dedicated family training schedules, among other aspects.

Acknowledging the inherent complexity of creating a comprehensive policy that covers all the aforementioned needs for children with CI and their families, it is imperative to initiate a foundational level of equal access granted through social protection policies, which includes universal health coverage. Social protection mechanisms are vital in eradicating poverty and diminishing inequalities. These mechanisms function as safeguards against the direct and indirect costs of healthcare access. They are essential in guaranteeing the right to health and overcoming disparities in this domain (Gama, 2016). Within this context, specific adjustments are necessary for early intervention in deaf children with CI to allocate resources and design policies tailored to this group, thus improving CI outcome results and enhancing deaf children’s spoken language development.

To interpret these ideals in Chilean interventions, it would be necessary to have a social workforce working to integrate the current social protection measures such as Chile Crece Contigo, National Health Insurance, and other programs with a particular focus on children with CI (Bedregal et al., 2014). For example, evidence suggests that support through a direct cash transfer of resources are beneficial for parents engaging in caregiving for their children in Chile and Latin America (Ullmann et al., 2022) . This allows them to spend more time with their children and develop their skills in line with the expected outcomes. The national policy of Panama through the Angel Guardian Programme is aware of this special social protection measure for parents/caregivers, allowing leave of absence for one parent/caregiver who is receiving economic support during the intervention process for children with disabilities (ibid).

Social protection can also serve as a potent tool to reduce inequalities among people within a country (Cote, 2021). Chapter one reported that Chile and Latin America have long been associated with high levels of inequality, which have persisted despite the region's progress in various areas of social development (Flores et al., 2020). The chapter also underscored that more effective interventions and policies for deaf children and families must align with sustainable development. Therefore, in accordance with the Sustainable Development Goals of the UN 2030 Agenda (United Nations, 2015) and our current findings concerning children with CI, the concept of sustainable development and social protection measures might encompass various aspects relating to children with CI, including social, economic, and environmental considerations. Consequently, there are at least five elements to consider at this level (International Labour Organization, 2016):

1. Accessibility:

Accessibility refers to ensuring that children with CI, regardless of their socio-economic status or geographic location, have equal access to appropriate healthcare and educational services. In terms of health, this can include affordable and available cochlear implant programs, intervention therapy, and audiological support. To address this in Chile and Latin America, it would be necessary to establish public-private cooperation to reach underserved areas, offering a baseline of social protection measures with financial assistance to families who cannot afford the intervention and associated costs.

2. Inclusive Education:

Considering the existing dilemma regarding the best approach to providing education for deaf children, inclusive education tends to be a crucial topic. Inclusive education, through mainstream schools with inclusive programs, is part of the options aimed at creating a rich environment where children with CI can fully participate in the educational process. As mentioned, children with CI would benefit from the spoken language environment provided by mainstream schools, but this requires training for teachers and educational staff to understand the needs of deaf children and provide necessary accommodations, such as sign language educators or assistive technology. In Chile and Latin America, targeted efforts are necessary to ensure that even schools in disadvantaged areas are adequately equipped to support these children's education. This is particularly challenging due to geographical obstacles in the region.

3. Parent and Community Engagement:

Engaging parents and communities is essential to ensure the success of children with CI. Parents and the community surrounding the child with CI must have access to information and training resources. While workshops, support groups, and informational campaigns can empower parents and communities to participate in child development actively, continuous economic support from policies is vital to provide sufficient time and resources to achieve this objective. Additionally, it's worth noting that community involvement helps reduce stigmas and misconceptions about deafness, creating a more inclusive and supportive environment.

4. Capacity Building:

Capacity building in sustainable development involves training professionals within the healthcare and education sectors to provide specialised services for children with CI, adapting measures according to each child's context. This includes clinicians, speech therapists, educators, social workers, and other relevant professionals. While Chile might meet the requirements for professionals, Latin America faces a shortage of skilled personnel, revealing a regional necessity that should be considered in any policy recommendation (Boerrigter et al., 2019). Lastly, investing in training programs, scholarships, and partnerships with international organisations can help build a sustainable workforce capable of addressing the specific needs of children with CI.

5. Research and Innovation:

Research and innovation drive improvements in CI intervention, evidence-based developmental options, and procedure innovation, particularly in disadvantaged regions. As previously mentioned, fostering local research initiatives to tailor interventions to specific geographical and social contexts is crucial. Collaborations with international experts, incorporating successful global models, can introduce cutting-edge knowledge and resources to these countries. Additionally, promoting innovation in low-cost or accessible programs/strategies can make interventions more affordable and accessible to a broader population, especially in countries with high inequality. Research is also important for bringing global examples to the Chilean reality. Low-cost solutions, innovative interventions for remote areas, engaged programs for families and children, and integral interventions that do not solely focus on spoken language as the aim for children with CI can serve as good examples to follow.

In summary, addressing children's intervention from a policy perspective and considering sustainable development requires a multi-faceted approach focusing on the aforementioned areas and specific programs complementing social protection measures. When these elements are integrated, they might improve speech and language outcomes for deaf children with CI, ensuring that all children, regardless of their background, can reach their full potential.

7.5. Limitations of the studies and suggestions for further research

In response to Covid-19 restrictions in 2020, the originally planned project shifted data collection to an online format. Although one data source comprised clinical records of each child with CI from respective hospitals, the majority of information for both studies 1 and 2 originated from online surveys and input from parents/caregivers. This poses limitations due to potential bias introduced during survey completion in each study. Despite the insistence on having the closest child caregiver complete each survey, the decision ultimately rested with the child's designated contact person. However, this data was partially contrasted with data extracted from clinical records, which included a spoken language outcome derived from formal assessments of each child with CI. Future research needs to supplement parent/caregiver information with input from other sources, such as hospital therapists or school educators, to enhance the quality of evaluated outcomes for each child. A comprehensive evaluation of the language skills for each child with CI is also essential to ensure high-quality outcomes.

Given that data collection for these studies occurred during the Covid-19 emergency period, certain results related to treatment attendance, CI status, and other factors among parents/caregivers could have been impacted by the restrictions in place during the crisis. While this was addressed during the longitudinal study by incorporating a second time point after the pandemic, it is important to recognise that certain results may not be directly comparable to previous evidence unaffected by the pandemic. A potential impact of the pandemic on the progress of some children could contribute to the results of Study 2. Therefore, any analyses and findings must be interpreted within the context of the unique circumstances presented by the 2020 pandemic. However, it is worth noting that this study included information from clinical records, dating from before the pandemic and thus encompassing pre-pandemic socioeconomic and audiological variables.

The characterisation study provided a time-limited snapshot of children with CI within the Chilean public health system. The sample, comprising 107 children, encompassed a broad spectrum of chronological and hearing ages. This broad range might have affected the outcomes, a limitation that could be mitigated through future studies having a narrower range of participants which would allow for more extensive analytical evaluation, such as group evaluation and factor analysis. Additionally, it is important to acknowledge that as part of the Ministry of Health tender and research evaluating the Chilean public health system, the characterisation and longitudinal study did not encompass children who received cochlear implants through the private health system, which caters to approximately 18% of the Chilean population. However, it should be remembered that the current study was extremely representative, covering 70% of children implanted in the public health system from 2017 to 2019. Future research should consider including the private health system. Lastly, while efforts were made to provide detailed characterisation, certain aspects require more focused attention. For instance, refining inquiries related to aetiology, addressing additional difficulties, and incorporating objective measures of CI usage, such as data logging, would be beneficial.

In addition, future studies should contemplate expanding the sample size and possibly implementing additional evaluation measurements to comprehensively track developmental progress over time instead of relying solely on a follow-up assessment with merely two-time points. Moreover, additional evaluations might need to consider the perspectives from parents/caregivers (Wickenden & Elphick, 2016). Perspectives regarding children with CI development might include a comprehensive evaluation not only focused on the outcomes expected with the device, but also on outcomes expected from different dimensions of the child's life. Data related to social communication, community participation, literacy, friendship, peers relationship, and other abilities through quantitative and qualitative measures can be options to expand the approach for this group.

The primary outcome of the longitudinal study was the Mac Arthur Bates Version CDI adapted into a shorter Chilean version. While this assessment proved useful to evaluate participants' vocabulary comprehension and production, it is worth noting that the instrument did not standardise results in the same manner as its international versions. In addition, this study only considers spoken language as an outcome during the CDI administration. Further research can include information about any sign language in children with CI before or after the device implantation. The instrument has been widely used worldwide, including spoken and sign language, which can be considered a more comprehensive evaluation of language.

Various international versions yield results with differing approaches, including developmental age of language growth, comparisons with language measures of typically developing hearing children in the country, and utilisation of raw scores in specific sections, such as vocabulary. Consequently, the Chilean adaptation only provides raw scores for comprehension and production, thereby constraining the interpretation of outcome analysis. Nevertheless, vocabulary is appropriate as a spoken language outcome and for assessing spoken language progress over time. For future studies, it is advisable to encompass more comprehensive spoken language measures, potentially involving direct child evaluations with instruments adhering to standardised assessments.

Potentially anomalous outcome results in the Chilean CAPII, SIR, and CDI instruments might have introduced limitations to both studies, potentially introducing biases in evaluating the child's progress over time. Many parents and caregivers likely encountered difficulties while independently completing the surveys and did not fully utilise the continuous support offered by researchers and collaborators. This phenomenon may be attributed to researchers not providing sufficient training to parents for completing the surveys. The major difficulty in this regard lies in the fact that, in some cases, we may be evaluating parents/caregivers' abilities to complete a survey rather than focusing on the aim of the survey itself. Thus, more active support during the survey completion could be useful to ensure the accuracy of the results. Further studies also can consider apply surveys to child' teachers and therapists. Additionally, preliminary training in using the assessment could prove beneficial in achieving results more closely aligned with the child's actual developmental abilities. Future studies incorporating online assessments should potentially include a dedicated training section and active assistance for parents/caregivers.

Similar to the characterisation study, the longitudinal study could have used a more comprehensive evaluation of the social determinants of health. The socioeconomic variable associated with Social Health Insurance did not adequately reflect the broad spectrum of inequalities among deaf children in Chile, which the Borough Development Index more accurately depicted. Moreover, other measures can be taken to improve the reliability of the socioeconomic condition of a family, such as total monthly household contributions or, in Chile, household tax records through the Chilean tax division Servicio de Impuestos Internos (SII). These measures can show in detail the total income of each family in a more comprehensive manner.

Moreover, it is important to note that all participants came from the public sector due to the necessity of better representing the situation at this level in the country, considering that more than 80% of the Chilean population is there. However, it was not possible to collect data from the private sector due to the lack of unified national information from that sector. Although the private sector is very developed in the country with high standards of services, there is not a unified data source from that sector, especially for conditions with less prevalence or impact on mortality. Data from private sector can be very helpful to evaluate the impact of socioeconomic factors in children CI in the country and regional context. Further research needs to consider this sector and explore methods to collect national data from the private sector.

Likewise, for variables concerning parental engagement and CI usage over time, parents/caregivers tended to exhibit a high degree of proficiency or positivity in their responses regarding their parental roles, encompassing knowledge, confidence, and child CI use. In addition, engagement with the community or local stakeholders could be beneficial for parental support in the early stages. Therefore, more concrete measures such as the CI data logging could complement the parent reported results to yield more nuanced and reliable data about CI usage from children with CI. Moreover, an inherent bias can be identified in the relation between school placement attendance and spoken language development due to education programs usually do not prioritise spoken language in their curriculums.

Multiple hypotheses were formulated within a relatively small sample size of participants. While the sample size might be deemed substantial enough for a study centred on cochlear implants in children, it is essential to acknowledge that the sample size falls short from an inferential analysis perspective. Therefore, the sample size could have potentially impacted certain findings. Although this study used a survey completed by parents/caregivers, it had limitations in capturing their views on factors influencing their children's outcomes. Additional insights from parents/caregivers about essential elements in the intervention process and expected outcomes for children with CI might be needed.

This research project, from its inception, addressed the significant challenge of rigorously integrating various areas related to factors influencing spoken language in children with CI in Chile. This consideration encompasses the Latin American context and that of other regions where social context and local development exert even greater influence. The primary implication of this research for future investigations is the integration of the methodology employed in assessing the outcomes expected for children with CI towards a more multidisciplinary dimension. Within this framework, the policy aspect represents a complex yet valuable area capable of yielding implications across different levels of intervention. Instead of only proposing further research and improved interventions in children with CI in Chile, this policy perspective offers a crucial platform for providing recommendations and integrated approaches to address challenges that would otherwise be confined to specific contexts. This project sheds light on the potential to incorporate such perspectives, particularly through social policies assessing inequalities and those contributing for a better sustainable development (see section 7.4.2.).

The current study unveils further implications regarding the necessity for comprehensive tools and agreements among researchers, experts, and professionals involved in the progression of deaf children and children with CI across both health and educational domains. Although the spoken language instruments in this project are widely used for children with CI, there remains a lack of consensus regarding language development and its evaluation between health contexts, which emphasise in CI outcomes, and educational contexts, focusing on the holistic development of each deaf child. For meaningful recommendations to emerge, clinical tests/assessments need to mirror the actual evaluation practices in the daily lives of children with CI. Often, these evaluations are heavily segregated between health and education contexts for children with CI in many settings, which need to be considered for more comprehensive results.

Considering the advantages of establishing comparisons within the Latin American context, it would be important for further studies to encompass a deeper comparison with Latin American countries and realities, which was not possible in this project due to the lack of sufficient evidence regarding the national situation and evaluated outcomes for children with CI in regional countries and in low and middle income countries. Future research in this field must consider region-specific factors and evidence, which are crucial for conducting comprehensive and impactful studies. As noted in this project, the majority of evidence concerning children with CI originates from countries with unique conditions and outcomes, where factors such as social determinants of health and service accessibility are somewhat controlled. However, this reality does not represent the circumstances of approximately 80% of the global population, preventing them from replicating or achieving the expected outcomes observed in existing evidence. While the availability of evidence for children with CI in low and middle income regions is limited, further research should explore similar populations and interventions. This approach can offer valuable insights into the most effective strategies to adopt in specific regions. Acknowledging the particularities of different regions becomes essential for generating more accurate evidence regarding the factors influencing outcomes in children with CI

8. Conclusions

This project explored the factors influencing outcomes in deaf children with CI in Chile within the broader Latin American context. As a result of the global pandemic, the project pivoted to an online format. The project's aims were to characterise children with CI in Chile and assess their spoken language development and spoken language outcomes.

The characterisation of children with CI in Chile offered a national and Latin American perspective. Despite presenting lower levels of performance relative to international benchmarks, spoken language outcomes do align with the regional context. The finding of relatively low vocabulary understanding and production among children with cochlear implants pinpoints to an area of potential intervention and development, which needs to be assessed in detail in further studies.

Several factors were identified as crucial influencers of spoken language outcomes in children with cochlear implants. One of the key factors highlighted was the presence of additional difficulties, which was found to be an influential factor in predicting language progress in deaf children with CI. The age at which cochlear implantation occurred also emerged as a significant factor, underscoring the importance of early intervention strategies to maximise language development potential. Furthermore, social determinants of health were noted to exert an impact on language outcomes in children with CI, especially the influence of the Borough Development Index, indicating the role of socio-economic contexts in shaping language trajectories.

Parental engagement also emerged as a pivotal variable. The confidence about the CI intervention and language development was particularly influential, highlighting the crucial role of caregivers in fostering language growth and proficiency in children with CI. Moreover, high daily usage of the CI was identified as a highly critical variable linked to outcome results: children who used the device more than 8 hours demonstrated improved language outcomes.

These findings carry implications for further research with specific consideration to the territorial context, aligning health and education dimensions in comprehensive research assessments. The implications also include intervention strategies and policy formulation, with a notable resonance with the goals of Agenda 2030 (United Nations, 2015). The study highlighted the potential to contribute to the broader aim of reducing inequality in children with cochlear implants, which could be addressed with tailored social protection programs or strategies to support families, children, and communities during the intervention process.

The discussion generated from these findings should contribute to a deeper understanding of factors affecting outcomes in children with CI in the Latin American context, and offer meaningful directions for future research, interventions, and policies.

9. References

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10.Supplementary Material

Table of contents:

10.1. Assessments evaluating speech perception in this project

10.1.1. Assessments in the Geers and Moog Categories

GeersM Categories	Evaluation
Unable to perceive any speech sound (ling test)	Voice detection test / Ling test
Speech detection but unable to perceive even time-intensity pattern info in words with speech amplified	Prueba de Identificación de Patrones Suprasegmentales (PIP-S)
Time-intensity pattern perception in amplified speech (Above 70% in testing)	Early Speech Perception Test – Chilean Version
Word identification by basic spectral information (Same metric and time, but different consonants and vowels)	Early Speech Perception Test – Chilean Version
Word identification in a group by their vowels	Prueba de Identificación de Vocales (PIP-V)
Recognition of word in a group by their consonants	Prueba de Identificación de Consonantes (PIP-C) (PIP-C10, PIP-C20, PIP-C 50)
Word recognition by repetition	Oraciones en Formato Abierto (OFA-N) Mr. Potato Head Task
Spoken language comprehension	Test de Evaluación de Vocabulario (TEVI-R)

Reference: Information from Pallares de García (1993) and Cochlear Americas (2012)

10.1.2. English Adapted CAP II (*For a subsequent t*ranslation into Chilean Spanish)

English Adapted Categories of Auditory Performance Index (EA-CAP-II)
0 = No awareness of environmental sounds ***1= Awareness of environmental sounds*** *(Does your child react to sounds in the house or outside? For example, the doorbell, the dump truck, the sound from the TV?)*
2= Response to speech sounds *(Does your child show a response to speech sounds such as /a/, /m/, /s/, /sh/ /e/ /o/ in the SLT session or with you at home?)*
3= Recognition of environmental sounds *(Can your child identify some sounds from the house, pointing for example; the Doorbell, the door closing, the telephone ringing, animals such as a dog or cat?)*
4= Discrimination of at least two speech sounds *(Can your child discriminate between two sounds (such as hearing the sound 'woof woof' and pointing to/looking at the dog vs hearing the sound 'quack quack' and pointing to the duck, or his/her name vs some other word? sound?)*
5= Understanding of common phrases without lipreading *(Can your child follow a short instruction using only their hearing? For example, sit here, where is papa? collect your toys).*
6= Understanding of conversation without lipreading with a familiar talker *(Can your child maintain a conversation with some familiar people without the use of lip reading? For example, with some uncle or aunt, or his/her teacher?).*
7= Use of a telephone with a familiar talker. *Can your child use the telephone with a familiar speaker?*
8= Understanding/Following group conversations. *Can understand/follow group conversations? For example, in school? Or family meetings?*
9= Use the telephone with an unknown speaker in an unpredictable context. *Can I use the telephone with an unfamiliar person or unfamiliar topic/context?*

10.1.3. English Adapted SIR (*For a subsequent* translation into Chilean Spanish)

Adapted Speech Intelligibility Rating Scale (EA- SIR)
1. ***Connected speech is unintelligible. Pre-recognisable words in spoken language, the child's primary mode of everyday communication may be manual.*** *(Your child is communicating using gestures/pointing and some vocalisations)*
2. ***Connected speech is unintelligible; intelligible speech is developing in single words when context and lip-reading cues are available*** *(Your child is using any words that you recognise)*
3. ***Connected speech is intelligible to a listener who concentrates and lip-reads within a known context.*** *(You can understand your child's spoken phrases/sentences when you are focused, you know the background about, and you can lip-read)*
4. ***Connected speech is intelligible to a listener who has little experience of a deaf person's speech.*** *(Others who do not know your child can understand what she/he says).*
5. ***Connected speech is intelligible to all listeners. The child is understood easily in everyday contexts.*** *(Your child's speech is understood easily in everyday contexts.)*

10.2. The Chilean Ministry of Health Report on Policies (Extract in English)

Tender 757-35-L120 of the Undersecretary of Public Health

Final report (Automatic translation in English[1])

Characterisation of cochlear implant users who are beneficiaries of the GES, LRS and the MINSAL Cochlear Implants program of the Chilean public system.

Introduction

The Chilean Health System recognizes the relevance and impact that hearing loss or hearing loss, especially that considered disabling, has on people's quality of life . In Chile, this condition occurs in 1 to 2 per 1,000 live newborns (NVB), affecting between 4% and 6% of the population (WHO, 2014). Additionally, the national reality describes hearing loss values close to 6% of children and adolescents and 30% of adults with disabilities.

Therefore, this condition is included in the current reform to the health system called "Explicit Health Guarantees" (MINSAL, 2016). In this regulation, diagnostic and treatment procedures are defined based on standard criteria. Thus, since 2013, children with bilateral hearing loss under 2 years of age have been guaranteed by the law of explicit health guarantees (GES). Subsequently, this guarantee was extended to children under 4 years of age with moderate hearing loss, granting hearing aids and a cochlear implant (CI) according to medical indication. Additionally, an internal program of the Ministry of Health would cover some CI needs that cannot be included in the GES regulations. On the other hand, since 2018, unilateral cochlear implantation was also guaranteed through the Ricarte Soto Law (LRS) to those over 4 years of age with severe / profound bilateral post- lingual hearing loss .

In this context, it is of interest to know how the implementation of the CI device has been carried out in these programs at the national level and thus have objective information that contributes to decision-making and future actions that promote continuous improvement. of public policies. Tender 757-35-L120 of the Undersecretariat of Public Health seeks to contribute in part to said information by characterizing users with CI belonging to the GES and MINSAL 2017 and 2018 programs, together with the LRS 2018 and 2019.

This corresponds to the final report of the study in question and is divided into 5 relevant sections to respond to the objectives of the project:

1) Summary of products and proposed deadlines.
2) Public policies addressed and methodology used.
3) Results of characterization by public policy.
4) Approach of proposed objectives.
5) Consideraciones final and recommendations.

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[1] This text has been automatically translated without revision, and there may be mistakes in wording or sentences.

1. Summary of products and proposed deadlines.

The tendered project considers 12 activities during its development and 4 products. In *Table 1* extracted from the project, each activity and proposed times are detailed, along with columns where the status of the event and observations are detailed.

Activity	2020	Condition	Observations
Creation of surveys and data collection protocols for adults and children	Month 1-2	Accomplished	September 2020
Piloting the questionnaires	Month 3	Accomplished	December 2020
Presentation Committee of Ethics	Month 4	Accomplished	Ethics committee approved on December 9 (*Document Attachment 1*).
Delivery of the calendar of visits to centers and data collection	Month 4	Accomplished	All hospital centers have been contacted and notified.
Collaborative personal training	Month 5	Accomplished	December 2020
Product 1&2: Preliminary report deliver y .	Month 5	Accomplished	Report delivered on December 11, 2020
Data collection in clinical records of each Hospital	Month 5 - 6 -7	Accomplished	Process ended on April 22 , 2021
Data collection through digital platform or with interview support telephone	Month 7 - 8 - 9	Accomplished	Start December 13, 2020 after ethical approval. Completion March 31 , 2021.
Output 3: Delivery to results	Month 1 1	Accomplished	Excel document delivered on May 21 , 2021.
Product 4: Final report delivery (Project closure)	Month 1 1	Accomplished	Document in pdf format delivered in June 2021.
Data analysis for academic purposes	2021-2025	Pending	Objective after project closure.
Free use of data for academic purposes	2025	Pending	Objective after the closing of the Project.
Total months of the project: 12 Months			

10.3. Protocols and Survey to Children with CI parents/caregivers and Adults with CI.

10.3.1. Protocols for data collection during Study 1 and Study 2

PROTOCOLS FOR **STUDY 1and STUDY 2**
Training Guidelines for data collectors and interviewers

The aim of this document it to deliver guidelines for collecting data and doing interviews to the research staff of the characterisation study by the Chilean Ministry of Health (TCMH) and MPhil/PhD project from Mario Bustos in University College of London. The project aims to describe general, audiological and treatment information about children and adults with CI (CI users) from the Chilean public health system in the Metropolitan Region in Chile.

Previous to read this training, you need to know some documents for learning about who this is the project about. The description is below.

1. *List of participant (separated between children and adults):*
The list is given by TCMH and sorted by the researchers with the contact details of each participant. Additionally, this document will contain the missing data needed to collect in the telephone interview for each participant.

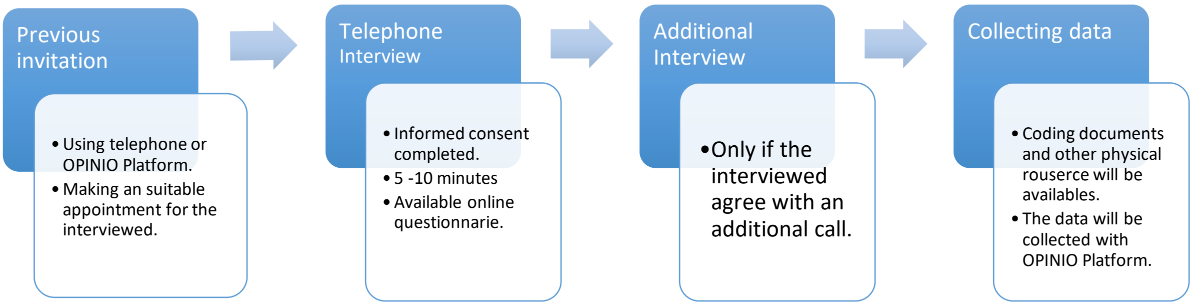
2. *The summary project in the Spanish version.*
For knowing the aims and consideration in the project.

3. The children and adult questionnaires for the telephone interview.
Questionnaire document for using for parents/caregivers. This document will be available for filling it in an Online Survey Platform, which will be the way for completing the data required.

4. *Spreadsheet with a Coding document.*
Although the Online Survey Platform will be the formal way to fill the information about each participant, there is a specific Spreadsheet with specific coding for each answer.

5. *Survey Platform for transferring data there.*
OPINIO Platform to use in each questionnaire and online surveys (Described in point 5

The process for collecting data from interviews has different steps summarised below:



1. Previous Invitation

A previous invitation to possible interviewees will be the first contact with the participants in this study. This invitation, which will be through telephone or e-mail, will contain the following information:

Dear XX

The Chilean Ministry of Health and UCL inform you about the first study of characterisation of Cochlear Implant Users Implanted by the public system in Chile. In this context, I am glad to request your help for completing this characterisation with the information about you as a parent/caregiver of a child implanted with GES (Popular Health Law) or you as an adult implanted with LSR (Ley Ricarte Soto High Cost Policy). If you agree to participate, we will invite you to take part in an interview to ask you about the characteristics of your family and your child, or you as an adult.

The interview will be through online and will take about 20 minutes. We will collect valuable information about your background and opinion, but considering the Chilean and British data regulation laws.

The results obtained will be useful to our understanding of the current situation in all users implanted in the public system. At the same time, at the end of the study, we can send you a summary report of the study results.
Additionally, this research has no harmful effects. And, as this study is not funded, we are unable to offer any financial compensation for the time you spend taking part. **This will be voluntary participation**. If you choose not to participate, you won't incur any penalty or loss of benefits to which you are otherwise entitled as a patient at the Hospital. Refusing will not affect the quality of care you or your child deserves.

If you have questions about your rights as a participant in medical research, you can follow the link that we will send you through e-mail with this consent and other details about this project.

The principal research is Mario Bustos Rubilar if you need contact with him at the end it is attached to his e-mail and telephone number.

Thank you, and we hope to have your help and opinion in this first national study

2. Telephone Interview

This step needs to be done after the allow to participate from the interviewees and in case participants cannot complete the OPINIO Survey online. The documents necessary up to this step are described in point 4.

The interview will be recorded (voice) and filled by the interviewer in the online platform OPINIO (Point 5). There are essential advices in case of CI users (children or adults):

1. *Previous requirements:*
- To read all documents.
- To sort the participant designed to each interviewer. It is necessary to check if the information and missing data are completed in each case.
2. *Practice Stage:*
- Each interviewer will practice the interview with one researcher at least 2 times at the beginning of the study.
- This work includes instructions to request information to participants and filling the data in a physical document and the online platform.
3. The time for calling always will be from 10:00 am to 5:00 pm from Monday to Friday. Only in exceptional cases, the calls can be in a different time (e.g. interviewed suggestion).
4. The propose in completing all the questionnaires in one call. If the participant requests another call, we can be flexible with them.
5. The ring need should last for no more than 30 minutes. However, and additional interview can be in place for completing the data required.

6. The call needs to be friendly and adapted to the participants. Still, the interviewer needs to follow the questionnaire all time, trying to collect as much as possible the clear opinion of interviewees, avoiding any suggestion or feedback.
7. The call need to be reordered (voice) from the informed consent until the end of the interview. An online app will be provided for this task.
8. In the case of the interviewer cannot answer the telephone interview, an online platform will be available for answering the questions.
9. The informed consent needs to be completed during the “Previous Invitation” through e-mail, or it is necessary to achieve in this step you need to read the document and record the voice according to the protocol.

The presentation and rapport are important at the beginning of the telephone interview (for avoiding any idea of scamming by the interviewees). We suggest an introduction as below:

“Hi, I am calling XXXXXX who is XXXXXXX from XXXXXX? Yes? How are you?... I am XXXXX, we are calling you from the Chilean Ministry of Health and UCL. Did you receive an e-mail/calling invitation? Let me remember you that we are evaluating different aspects through a questionnaire by telephone. This will be important information for improving the service given to you (or your child) *and future CI users in the country. The answer needs to be given by the closest person to the child in-home, and all will be confidential”.*

3. Additional Interview (Oral or online)

An additional interview could be possible with users with it was not possible to fill all information in one call, and with the user, which will use an online platform for completing all the protocol. It means people who need more time for answering the questions, people who cannot deliver answers by telephone and parents/caregivers who will need to answer the language inventory checklist online.

In the case of parents/caregivers, the protocol will be previously marked with the request of this information from the family surveyed.

4. Collecting data

The data for this characterisation will come from different sources of information described below:

Clinical records: Information collected from each hospital through the clinical record of each patient. This data includes personal information, family background, audiological and medical history, treatment information. Children will have completed more data than adults from this source. And this information will be collected by the researchers and SLT from each hospital. This information will be available in a data spreadsheet with a specific coding attached in the main project (There will be one for adults and one for children). This is not part of the current training, but it is necessary to know where this data comes from. Additionally, if there is crucial info missing from this section, this will be requested in the telephone interviews or online surveys.

Online Survey: two protocols will be in place for collecting missing data to the characterisation and information about performance with the device. In the case of children, there will be a special section in relation to some factors, which could be useful to give some approaches to the performance with the device in these users. Additionally, there will be a physical document for completing missing data from the clinical record at the beginning of the parent/caregivers interview in the case of children CI users.

5. Use of OPINIO as an online platform

The UCL will provide a specific survey platform for collecting data and do surveys to the participants. This platform will contain 3 different tools for using during this process.

1. Adults protocol with the options coded (Adult Survey): Survey available in the platform where each interviewer will add the data collected with the participants. This will have unique possibilities and space according to the original protocol document. Additionally, this protocol can be filled by the adult in the case of the telephone interview is not possible.

2. Children protocol with the options coded (C1 Survey): Survey available in the platform considering data to collect for parents and caregivers. This will have different sections according to the original protocol document. Additionally, in the case of missing data, this will be collected in the original paper document.

3. An online survey about language in children (C2 Survey): In some cases, the researchers will be marking some users, which will be required for completing a language inventory. This survey will be considered as an additional interview, which can be delivered in another telephone call or through a study in the OPINIO platform.

6. Researchers, collaborators and Staff:

The current project has been created in the MPhil/PhD Language and Cognition program and sponsored by TCMH. In this context, there is a different participant with different functions described below:

1. Researchers in the UK:
2. Prof. Merle Mahon: First Supervisor in the thesis project.
3. Prof. Fiona Kyle: Second Tutor in the thesis project.
4. Mario Bustos PhD Student

   Researchers in Chile:
5. Daniel Tapia Mora (MSc© Cs Language and Hearing, University of Chile):
    a. Researcher collaborator, project responsible in Chile.
6. Ximena Hormazabal (Catholic University):
    a. Researcher collaborator, methods and results reviewer in Chile.

Additional Protocol for data collection from Clinical Records (Spanish)
(Acknowledgement: Translation in English from Spanish. These instructions were formulated for collaborators in Chile who were helping with the data collection process).

The purpose of this document is to explain part of the sampling process for *Study 1* in an Excel file called "Spreadsheet *unique", which* consists of the characterization of children who use cochlear implants in 4 public hospitals in the country*.*

1. Transferring information using an **ID code**:
   To anonymize the data of your hospital and its users, we have provided simple encryption at this stage. The first step of this process is to complete a document (attached example called "Example Encryption") with the identification of each user in the hospital, this in order to control whose data is delivered in the event that this user needs to be monitored in Study 2. Each user characterized through their clinical record will have an ID (which you can review in the examples in the "spreadsheet unique" doc), which will be designated by each hospital using the code corresponding to each establishment. For example, there is a user with the code H1001, where H1 represents the hospital code (which will be given randomly to each hospital) and 001 which represents the identification of the user that each hospital designated for this study. This numerical value should not be sorted alphabetically. The document with the identification of each user must remain in each hospital and cannot be shared by email or other means.

2. With respect to the "Spreadsheet unique" document, each column represents a coded value, which you can review in the attached "Coding" document. The missing data of each user must NOT be FILLED IN the document, leaving a space, which must be marked with yellow indicating the absence of that information. In the case of a new piece of data, or something

missing from the coding sheet, you can mark the box with BLUE and write what happened in that coding as shown in the examples provided in "Spreadsheet unique".

3. There is a difference between a "missing data" which will be marked with yellow and something not done (marked with green), since the latter has a different argument, since it is a value of a test that was not performed because the user was diagnosed with another (Review the example document).

4. If they need to add relevant information about the user, they can do so after the last column where there will be a space to place observations.

5. The time should always be written in number of months in all columns where required. In the case of percentages, these should be transferred using the range 0-100. Finally, when filling in audiometric data in the "Audiogram Level" column, we must consider the number 125 (dB) as DOES NOT RESPOND TO THE MAXIMUM OUTPUT OF THE AUDIOMETER. Additionally, in the "Audiogram PostIC" column 95 (dB) will be used as DOES NOT RESPOND TO THE MAXIMUM OUTPUT OF THE AUDIOMETER USING IC (There are examples of both cases in the "spreadsheet unique").

10.3.2. Child with CI Survey 1 (C1 Survey)

This Interview Protocol Child with CI Survey 1 (Survey C1) was completed previous the translation and adaptation to Chilean Spanish. Some questions and options were changed.

PART 1 - INSTRUCTIONS AND SUMMARY SHEET
TELEPHONE INTERVIEW USING OPINIO PLATFORM

INSTRUCTIONS
This document must be used only by trained interviewers. This protocol has five sections:

- **Part 1** - Instructions and Summary Sheet
- **Part 2** - Informed Consent
- **Part 3** - Missing Data from Clinical Record
- **Part 4** - Data About Auditory and Language Abilities
- **Part 5** - Factors Data

The interview must follow the following steps as per the training *(For any question, you can check the interview instructions given in the training):*

1. Interviewer presentation and credentials.
2. Establish rapport with parents/caregivers giving details about CI user (Information about cochlear implant and Hospital).
3. Project presentation and digital link for additional information (Trust about the study).
4. Ask for the parent/caregiver closest to the CI user and request her/his participation.
5. Explain the interview, giving aim, duration of the interview and need for informed consent.
6. Read the information sheet and consent form and request his/her positive answer saying "Yes" and their complete name.
7. To deliver the protocol, i.e. ask the questions
8. Record the interview.
9. We are considering extra time for open-ended questions (Qualitative Data) in *Italic letters.*
10. Remember, do not read the titles of any section.
11. Remember, do not pre-empt an answer (Interview instructions).

PARENTS/CAREGIVER INFORMATION:
(Information need to be completed by the interviewer for cross-check information)
Name: ____.
Hospital: ____.
Phone/Mail: ____.
☐ Informed Consent given.
☐ Interview Protocol completed.

CI USER IDENTIFICATION
Personal Information about the CIu *(TCMH will provide this information)*
Anonymized ID: ______________. Date of Birth: _______________________.
Hospital: ____________________. Date of Switch on: ____________________.

Missing crucial data from the clinical record, which need to be collected (PART 3):
(The researchers will previously mark this information)
☐ Personal Information ____.
☐ Family Information ____.
☐ Audiological Information ____.
☐ Medical History ____.
☐Treatment Information ____.

OBSERVATIONS (Issues, pending action, missing data, etc.).
____
____
____

PART 3 - MISSING DATA FROM CLINICAL RECORD

1. TELEPHONE INTERVIEW QUESTIONS FOR PARENTS/CAREGIVERS OF CI USERS.

1.1 Personal Information:

1. Child's age: years______ months _____
2. SES / FONASA: A___. B ____. C____. D____.
3. Address:
____
4. Household composition: (* e.g. Nuclear family, only one parent, other, etc.)
5. ____
____
6. Mother/Caregiver Education Level (*e.g. Unknown, primary school, high school, etc.)
____

1.2 Medical and Audiological Information:

7. Additional Difficulties (*e.g. No known, Cerebral palsy, Learning difficulties, Psychomotor delay, etc.)
____
8. Medical History (*e.g. None, Grommets, Jaundice, Epilepsy, etc.)
____
9. Family History (*e.g. None, Hearing impairment, cognitive condition, etc.)
____
10. Date of birth _____________________ (Age of Diagnosis: _____ Months).
11. Age at first hearing aid issue: _____ Months
12. Age at CI implantation _____ Months.
13. Age of Switch on (CI) _____ Months.
14. Implant and hearing aid info (*e.g. Unilateral with or without Hearing aid, sequential implant, etc.)
15. Before of the CI, Did He/she use the hearing aid: freqtly____ s/times _____ rarely ____
16. CI condition now (*e.g. No problems, CI without use, technical issues, etc.)

1.3 Additional Information about treatment and language used (Mandatory field)

17. Is your child attending auditory or language therapy? Y____ N____
18. Where (Therapy): ____
19. Is the therapy Weekly, Monthly? ____
20. How much time do you spend in each session? 30 min____ 40min____ 60min or +____
21. Is it easy for you to get to the sessions? Yes___ No___ Why? (*) ______________________
22. Is it easy for you follow the guides given by the CI Staff? Y____ N____ Why? (*) ____
23. What communication mode is used in therapy:
sign lang ___, spoken lang ___, both mixed___, both separate ___.
24. Does your child attend nursery or school? Y____ N____. Where? ____________________.
25. How frequently does he/she attend the school/nursery?
How many days per week? _______. How many hours per day? 2h___ 4h____6___8or+___.
26. What type of school/nursery is it special education/ mainstream with PIE / mainstream with no special need support? (e.g. examples if they require them) ______________________________.
27. If he/she receives support for special need, who delivers this support? (e.g. therapist, interpreter, special education)

☐ Interpreter ☐SLT ☐ Audiologist ☐ S. needs Teacher ☐ AVT Therapist ☐ Psychologist

28. Did your child attend to auditory or language therapy before the current treatment? Y_ N_

PART 4 - DATA ABOUT AUDITORY AND LANGUAGE ABILITIES

2. AUDITORY AND LANGUAGE ABILITIES IN THE CHILD

2.1 COMMUNICATION

1. How do you communicate with your child?
☐ Sign L ☐Spoken L ☐ Mixed L ☐ Pre-Formal Com (e.g. as baby) ☐ Other ____________________
2. Can s/he communicate with unfamiliar people? Y____ N____
How (*) ____
3. Do your child use sign language at home/in the school/ or with friends? Y____ N____

4. CAP AND SIR
Please tell me if your child can do the following actions at home with the CI:

CAP

YES /NO	**Action (Possible questions for each scale step)**
	Does *your child react from the sound in the house or outside? For example, the doorbell, the dump truck, the sound from the TV?)*
	Do your child show a response to speech sounds such as /a/, /m/, /s/, /sh/ i/e/ /o/n the LST session or with you at home?
	Can your child identify some sounds from the house, pointing for example; the Doorbell, the door closing, the telephone ringing, animals (Such as a dog or cat)?
	Can your child discriminate between two sounds (such as hearing the sound 'woof woof' and pointing to/looking at the dog vs hearing the sound 'quack quack' and pointing to the duck, or his/her name vs some sound.
	Can your child follow a short instruction only by using the hearing? (For example, sit here, where is papa? collect your toys).
	Can your child maintain a conversation with some people familiar without the use of lip reading? (For example, with some uncle or aunt, or his/her teacher?).
	Can use the telephone with a familiar talker?
	Can understand/follow group conversations? For example, in school? Or family meetings?
	Can use the telephone with an unfamiliar person or unfamiliar topic/context?

5. **SIR:** Now, please tell me **how does your child communicate?**

YES /NO	**Action (Possible prompt questions for each scale step)**
	1. Is your child communicating using gesture/pointing and some vocalisations? (Pre-recognisable words in spoken language (the child's primary mode of everyday communication may be manual)
	2. Is your child using any words that you recognise? (Connected speech is unintelligible; intelligible speech is developing in single words when context and lip-reading cues are available)
	3. Can you understand your child's spoken Phrases/sentences when you are focused, you see the background, and you can lip-read? (Connected speech is intelligible to a listener who concentrates and lip-reads within a known context).
	4. Can you and others who do not know your child understand what s/he says? (Connected speech is intelligible to a listener who has little experience of a deaf person's speech; the listener does not need to concentrate unduly).
	5. Do your child is understood easily in everyday contexts? (Connected speech is intelligible to all listeners)

PART 5 – FACTORS DATA

3. FACTORS AFECTING THE SPOKEN LANGUAGE IN CI USERS.

3.1 CHILD'S COMPLIANCE WITH THE CI

1. Does your child use the Cochlear Implant? Y____ N____.
2. If the answer is no, Why? ____.

If the answer is Yes:

3. How many days per week, your child uses the CI?
   2 or less days_____ 4 or less days _____ 6 or less days____ All Days______
4. In the current time, how many hours a day does your child currently wear the aid(s)?
   Monday-Friday from_____ to_____ hrs Saturdays/Sundays from ______ to ______ hrs.
5. When your child wakes from sleep (morning or nap), how much *effort do you* exert to help him/her with the switch on of the device?
   Excessive effort___ Some Efforts___ Normal___ No effort ___.
6. Do you agree about this statement; "My child decides if she/he uses or does not use the device during the day". Y__ N__ Why? (*)____.

7. Are there any particularly challenging times or situations for you or the child for keeping the CI? (*)

8. If s/he does not use the device, what do you think is missing and how could this be improved? (*)
____

3.2. BEHAVIOUR ABILITIES IN CIU

1. Has your child been diagnosed with any behaviour issues? Y____ N ____
   (*e.g. behavioural problems, ADHD (Attention Deficit and Hyperactivity Disorder), Oppositional defiant disorder, etc).
   ____
2. Do you believe she/he currently has some behavioural problem, which need to be diagnosed? Y____ N____
3. In the case of "Yes". Are these conditions affecting the use of the CI in your child? Y____N____
   Why? (*)
   ____

3.3 SELF-ESTEEM AND WELLBEING

1. Is your child happy in the school/Nursery? Likert (Unhappy 0 to very happy 5)
2. Do you feel that your child is included in school and social life? Y____ N____

3. How many good friends has your child got? None__ 1 or 2___ 3 or +____
4. Some of them are deaf? Y____ N____
5 Does S/He have contact with some deaf activity or community? Y____ N____

If the answer is not, Why? ____

3.4. PARENTS/CAREGIVERS ENGAGE/KNOWLEDGE

1. Did you receive any education or training about hearing loss, devices or language development after the diagnosis of your child? Y____ N____.

What topic was considered? (*)____.

2. Who gave you that training?

Doctor___ Audiologist___ SLT___ SEN___ Other: ____ Where?______.

3. Did you receive specific training about CI (e.g. Device use, care of the device, etc) Y____N____

4. That training was:

During the child's session____ session only for this_____ written documents/instruction_____

6. How many sessions did you receive this training: 1 or 2_____ 2 to 4_____ more than 4 ______

7. Who have you guided you with instructions about the CI in your child? _______________________

8. Do your feel confident with the knowledge that you have about the CI?

Likert (Poor confident 0 to very confident 5)

9. Do you follow instructions given by professionals? All of them____ some of them____ No _____

10. Why? ____

11. Do you think that you have enough time for working in the rehabilitation process of your child? Y___ N___

If it is not, why? ____

12. If you receive some homework for your child with the CI. How many hours do you work on it?

No work in home ____ I do not set aside specific time for that _____ 1____ 2____ 3_____ 4 or more ______

13. How do you check if the Cochlear Implant is working? ___________________________________

14. Has the use of the device satisfied your expectations as a parent/caregiver?

High satisfied____ Satisfied ____ No Satisfied ____ unsatisfied____.

If the answer is not, why? (*)____

16. What recommendation would you give to:

the CI Staff?(*): ____

the nursery/School?(*): ____

This is the end of this interview. Thank you very much.

10.3.3. Child with CI Survey 1 Short Version (C1 SV Survey)

Interview Protocol Survey Child with CI 1 SHORT VERSION (Survey C1 –SV)

PART 1 - INSTRUCTIONS AND INFORMED CONSENT

Factors affecting outcomes in Deaf or Hard Hearing Children with Cochlear Implant in Chile considering the Latin-American context.
(This study has been approved by the UCL Language and Cognition Department Ethics Chairs, project number LCD-2020-13 and The Faculty of Medicine, University of Chile project number 167-2020)

Thank you for agreeing to continue to take part in this study about factors affecting spoken language development in children with CI in Chile. We appreciate your participation again in this survey after one year. We have shortened the survey we used last time. You should need now around 20 minutes for completing it. Please be sure that the person who responded last time also fills in the survey this time. You need to complete again each question about you and/or your child. It is strongly recommended that you complete the survey at one time. Some problems or loss of information could occur if you leave the survey uncompleted.

We need to get your informed consent again, giving specific details about your participation this second time. Please complete the information about your bank account at the end of the survey so that we can compensate you for taking part. Please read the following information and, if you agreed, completed the consent again at the end of this text. Thank you again for your participation!

Informed Consent:

You are reading the information sheet for collecting data through this survey. The purpose of this information is to help you decide for you and your child to continue to participate in the research. "
***The research objective** is to characterise the Chilean cochlear implant users from Public System Health implanted from 2018 and to investigate factors that affect children's language development.*
If you agree to participate, we will invite you to take part in a survey to ask you about the characteristics of your family and your child. The survey will once more be through OPINIO online platform, or if you need it, through telephone assistant. This will take about 20 minutes. We will collect information about your family, your child, their cochlear implant, their language used, their treatment and the education they received.
The information collected will be confidential and pseudonymised, according to Chilean and British law (Data Protection Act 2018) about protecting user data. It means that real names will not be used, and your child and this interview will have an ID number. Nobody in your Hospital will know any answer you give today. Only the research team will have access to the data.
The data will be analysed at University College London in the UK. All data transferred to the UK will be fully anonymised, and no personally identifiable data will be transferred to the UK.
***About benefits** – The results obtained will be useful to our understanding of the characteristics of cochlear implant users in the Chilean public system. Additionally, the information will contribute to improvement to the current cochlear implant programs in Chile. If required, at the end of the study, we can send you a summary report of the study results.*
***About risks** - This research has no harmful effects.*
***About compensations** – There will be 6200 Chilean pesos of compensation for your invested time in the survey filling. At the end of the survey, we will ask you for your bank account details. The deposit will be paid two weeks after you have completed the survey.*

***This will be voluntary participation** - Your participation in this research is entirely voluntary. It is up to you to decide whether or not to take part. If you choose not to participate, you won't incur any penalty or loss of benefits to which you are otherwise entitled as a patient at the Hospital. Refusing will not affect the quality of care you or your child deserves.*
*You need to add in the **Data Protection Privacy Notice** asset out in the information sheets in your original ethics application.*

***Questions** - If you have questions about your rights as a participant in medical research, you can contact with the principal research of this study.*

Name and Contact Details of the Researcher(s):

The principal research is Mario Bustos Rubilar, his mail mario.rubilar.18@ucl.ac.uk telephone 022-9786606.

Please fill in this informed consent form if you agree to participate:

YES / NO	*I confirm that I have read and understood the Information Sheet for the above study.
YES / NO	*I understand that I will be able to withdraw my data
YES / NO	*I consent to participate in the study. I understand that my personal information will be anonymised and used according to the aforementioned policies.
YES / NO	*I understand that my participation is voluntary and that I am free to withdraw at any time without giving a reason.
YES / NO	I understand the direct/indirect benefits of participating.
YES / NO	I understand that I will be compensated for the time spent in the study
YES / NO	I agree that research data may be used by others for future research.
YES / NO	I am aware of who I should contact if I wish to lodge a complaint.
YES / NO	I voluntarily agree to take part in this study.
YES / NO	I confirm I could be contacted at the future for a further research.

PART 2 – INFORMATION UPDATE

Questions from the previous survey will be asked in the next sections:

PARENTS/CAREGIVER INFORMATION:
(Information need to be completed by the interviewer for cross-check information)

- Borough
- FONASA Letter
- Education level of the parent-caregiver
- Work/Job(?)

DHH CHILD INFORMATION

- Aetiology
- Additional Difficulties

CI USER IDENTIFICATION

- Date of Surgery
- Day of Switch On
- Contralateral device use

TREATMENT-EDUCATION

- Attending to treatment session
- Proximity and difficulties to go
- Type of Nursery-Education

10.3.4. Adult Survey

ADULTS WITH CI SURVEY

Interview Protocol
Adults Cochlear Implant Users (CI users)
PART 1 - INSTRUCTIONS AND SUMMARY SHEET

INSTRUCTIONS

This document must be used only by trained interviewers. This protocol has five sections:

- **Part 1** - Instructions and Summary Sheet
- **Part 2** - Informed Consent
- **Part 3** - Personal and Audiological Data
- **Part 4** - Medical and Treatment History
  Part 5 - The International Outcome Inventory – Cochlear Implant

The interview must follow the following steps as per their training *(For any question, you can check the interview instructions given in the training):*

12. Interviewer presentation and credentials.
13. Ask for the participant and its availability to chat through the telephone. To offer the online survey If he/she cannot follow the interview.
14. Establish rapport with the participant (information about cochlear implant and hospital).
15. Project presentation and digital link for additional information.
16. Explain the interview, giving aim, duration of the interview and need for informed consent.
17. Read the information sheet and consent form and request his/her positive answer saying "Yes" and their complete name.
18. Deliver the protocol, i.e. ask the questions
19. Record the interview.
20. consider extra time for open-ended questions.
21. Remember, do not read the titles of any section.
22. Remember, do not pre-empt an answer (Interview instructions).

ADULT INFORMATION:
(Information need to be completed by the interviewer for cross-check information)
Name: ____.
Hospital: ____.
Phone/Mail: ____.
☐ Informed consent given.
☐ Interview Protocol completed.
☐ Data from TCMH completed.

DATA GIVEN FOR THIS PATIENT BY TCMH
☐ CI details
☐ Audiological Performance (Audiogram, CI Map, etc)
☐ Additional Data (Personal Data, Medical History)
Other: ____
____.

CI USER IDENTIFICATION
Personal Information about the CIu *(TCMH will provide this information)*
Anonymized ID: ________________. Date of Birth: ____________________________.
Hospital: ______________________. Date of Switch on: _________________________.

OBSERVATIONS (Issues, pending action, missing data, etc.).
(IMPOSSIBLE TO INTERVIEW BY TELEPHONE? ☐ USE OF ONLINE PLATFORM ☐)
____
____
____

PART 2 - INFORMED CONSENT

We need your consent for doing this interview. At the end, I will ask you about your understanding and if you want to join. Additionally, I will ask your name for the recording. **Remember that this interview will be recorded.**

The purpose of this information is to help you decide to participate or not - in the research: "**Characterisation of Cochlear Implant Users in Chile ".**

The research objective is to characterise the Chilean cochlear implant users from Public System Health implanted from 2017.

If you agree to participate, we will invite you to take part in an interview to ask you about you and your CI. The interview will be either face-to-face or on the telephone and will take about 20 minutes. We will collect information about you, your family, your cochlear implant, your treatment and use of the device

The information collected will be confidential and pseudonymised, according to Chilean and British law (GPDR) about protecting user data. It means that real names will not be used, and this interview will have an ID number. Nobody in your Hospital will know any answer you give today. Only the research team will have access to the data.

The data will be analysed at University College London in the UK. All data transferred to the UK will be fully anonymised, and no personally identifiable data will be transferred to the UK.

About benefits – The results obtained will be useful to our understanding of the current situation in all users implanted in the public system.

If required, at the end of the study, we can send you a summary report of the study results.

About risks - This research has no harmful effects.

About compensations - As this study is not funded, we are unable to offer any financial compensation for the time you spend taking part.

This will be voluntary participation - Your participation in this research is entirely voluntary. You can withdraw at any time without giving a reason. If you decide to withdraw you will be asked what you wish to happen to the data you have provided up that point.

It is up to you to decide whether or not to take part. If you choose not to participate, you won't incur any penalty or loss of benefits to which you are otherwise entitled as a patient at the Hospital. Refusing will not affect the quality of care you receive.

Questions - If you have questions about your rights as a participant in medical research, you can follow the link that we will send you through e-mail with this consent and other details about this project. At the same time, if you don't have e-mail, we will advise you at the end of this consent about the link in the internet and other ways that we have for giving all the information that you need.

The Ethics Committee from Faculty of Medicine of the University of Chile has approved this study.

Name and Contact Details of the Researcher(s):

The principal research is Mario Bustos Rubilar. if you need contact with him I can tell you at the end of this consent how we can do that.

Do you understand what we are asking you to agree to? ____ Yes _____ No

Do you agree to participate in this interview? ____ Yes _____ No

What is your name? ____.

PART 3 - PERSONAL AND AUDIOLOGICAL DATA

1.1. Personal Data

Date of birth:	*(dd / mm / yyyy)*	FONASA	TO ☐	B ☐	C ☐	D
Borough:		ISAPRE				
Level of education:	☐ Incomplete basic	☐ Primary completed	Other:			
	☐ Incomplete Secondary	☐ Secondary completed	☐			
	☐ Incomplete technician	☐ Training Completed				

☐ Incomplete university ☐ University Compleded

ccupation prior to hearing loss/CI:____

Current occupation: ____

1.2. Family information

Civil Status:	☐	Single	☐	Married	☐	Separated	
	☐	Divorced	☐	Widower	☐	Partner	
Household composition:						N°	☐
Hearing Loss in the family				☐	Yes	☐	No
Age-related hearing loss				☐	Yes	☐	No

1.3. Audiological information

Aetiology (e.g. to give an example) ________________________________ _____Unknown____.

Type of Hearing loss: (complete audiological diagnosis) __________________________________.

When did your hearing loss start date: ___________________?

Was this? Sudden_____ Progressive____ Both_____.

Use of Hearing aids in the pass: Y____ N____. Where? Left_____ Right_____ Both ears____.

Current use of Hearing aids: Y____ N____. Where? Left_____ Right_____ Both ears ____.

PART 4 - MEDICAL AND TREATMENT HISTORY

2.1. Medical History

Some doctor or health professional has told you that you have

☐	Diabetes or blood sugar	Is it checked regularly?	☐	Yes	☐	Not
☐	Hypertension or high blood pressure	Is it checked regularly?	☐	Yes	☐	Not
☐	Parkinson's disease or tremors	Do you take medicine for this?	☐	Yes	☐	Not
☐	Heart problem or heart attack	Is it checked regularly?	☐	Yes	☐	Not
☐	Depression	Do you take medicine for this?	☐	Yes	☐	Not
☐	Arthritis, osteoarthritis, or joint problem					

Other? ____.

Do you have any additional disability or sensorial impairment? Y___ N___ (Detail: _____________)

2.2. Treatment information

Currently, What are you receiving any treatment in relation with your CI? : Y____ N____

What type of treatment? Audiological Training____ SLT____ Psychological____ Other______

How many time per week? 1 Hr ______2 Hrs ______3 Hrs______ 4hrs or + _____

How long have you been receiving this support? 3 months_____ 6 months______ 1 year or +_____

Do you receive support from any of these professionals?
☐ Interpreter ☐SLT ☐ Audiologist ☐ SEN Teacher ☐ AVT Therapist ☐ Psychologist ☐ Other

Where? Hospital ____ Private – Paid _____Private – Free ____ Transport time from home____ min.

Frequency? ____Weekly ____Monthly_____Every 2 months_____Every 3 months or more

And at the PAST, did you receive any treatment in relation with CI or hearing aids? Y____ N____

What type of treatment? Audiological Training____ SLT____ Psychological____ Other______

How many times per week? 1 Hr ______2 Hrs ______3 Hrs______ 4hrs or + _____

How long did you receive that support? 3 months_____ 6 months______ 1 year or +_____

How long time ago? 1 year____ 3 years____ 5 years or + ____

2.3. CI Satisfaction

Have the results been as you expected?

In general: Much better___ Better ____As I thought ____No too much___Definitely Not___

In hearing/listening: Much better___ Better ___As I thought ___No too much___Definitely Not____

In my occupation: Much better___ Better ____As I thought ____No too much___Definitely Not___

Do you think that your abilities in your occupation has improved with the CI: Y____ N____?

How much the following conditions have changed after the CI?

Tinnitus: I don`t have this____. Nothing____ No too much____ Enough ____ Entirely____

Balance/Dizziness: I don`t have this____. Nothing____ No too much____ Enough ____ Entirely____

Do you think that the process offered by the hospital after your implantation was?

Very Good____ Good____ Enough_____ Poor ____ Bad

Based on your experience, how could the service provided by the hospital improve?

Interview Protocol
Adults Cochlear Implant Users (CI users)

PART 1 - INSTRUCTIONS AND SUMMARY SHEET FOR TELEPHONE INTERVIEW USING OPINIO

INSTRUCTIONS

This document must be used only by trained interviewers. This protocol has five sections:

- **Part 1** - Instructions and Summary Sheet
- **Part 2** - Informed Consent
- **Part 3** - Personal and Audiological Data
- **Part 4** - Medical and Treatment History

  Part 5 - The International Outcome Inventory – Cochlear Implant

The interview must follow the following steps as per their training *(For any question, you can check the interview instructions given in the training):*

23. Interviewer presentation and credentials.
24. Ask for the participant and its availability to chat through the telephone. To offer the online survey If he/she cannot follow the interview.
25. Establish rapport with the participant (information about cochlear implant and hospital).
26. Project presentation and digital link for additional information.
27. Explain the interview, giving aim, duration of the interview and need for informed consent.
28. Read the information sheet and consent form and request his/her positive answer saying "Yes" and their complete name.
29. Deliver the protocol, i.e. ask the questions
30. Record the interview.
31. consider extra time for open-ended questions.
32. Remember, do not read the titles of any section.
33. Remember, do not pre-empt an answer (Interview instructions).

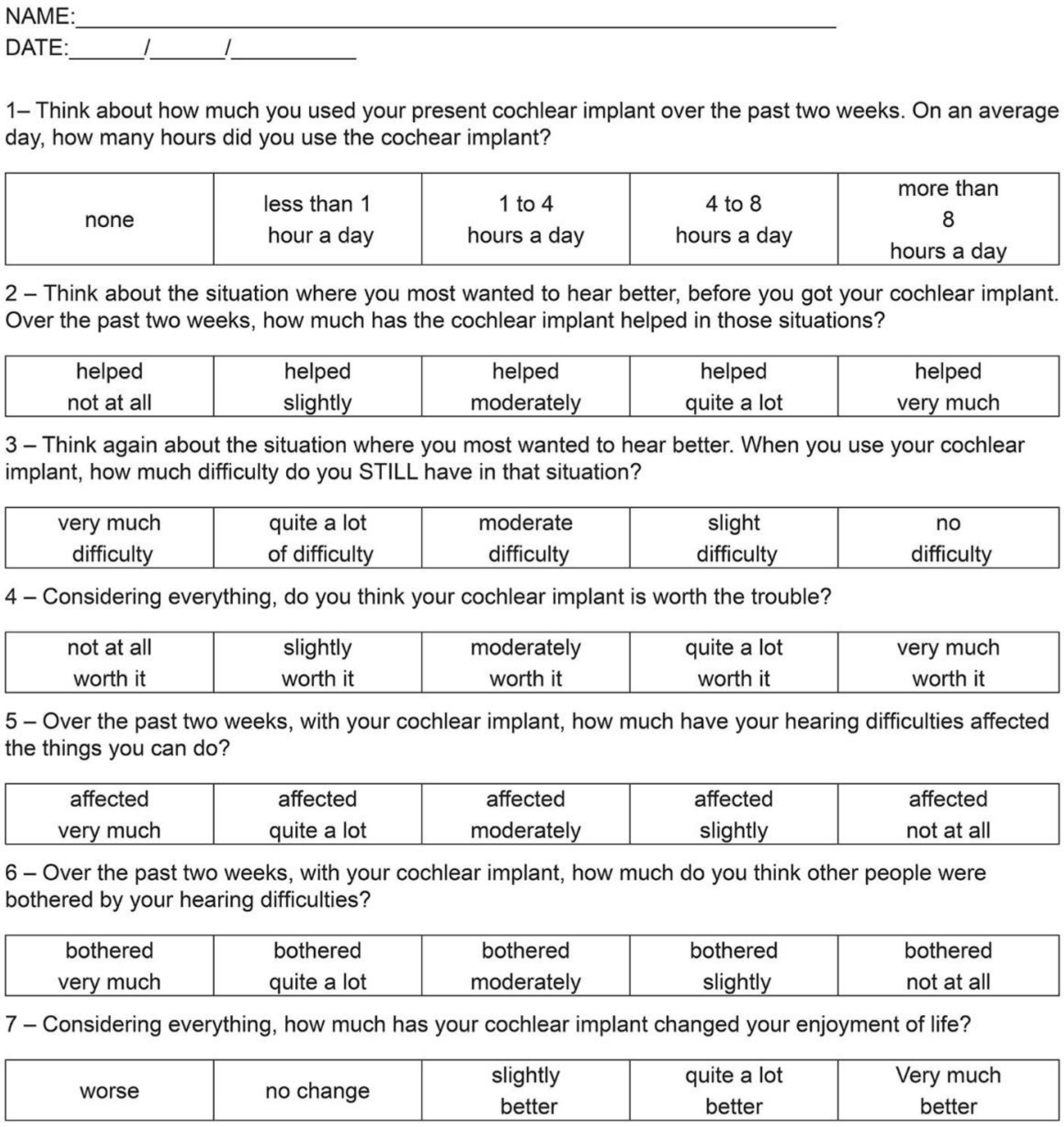
ADULT INFORMATION:
(Information need to be completed by the interviewer for cross-check information)
Name: ____.
Hospital: ____.
Phone/Mail: ____.
☐ Informed consent given.
☐ Interview Protocol completed.
☐ Data from TCMH completed.

DATA GIVEN FOR THIS PATIENT BY TCMH
☐ CI details
☐ Audiological Performance (Audiogram, CI Map, etc)
☐ Additional Data (Personal Data, Medical History)
Other: ____
____.

CI USER IDENTIFICATION
Personal Information about the CIu *(TCMH will provide this information)*
Anonymized ID: _______________. Date of Birth: _________________________.
Hospital: ____________________. Date of Switch on: _____________________.

OBSERVATIONS (Issues, pending action, missing data, etc.).
(IMPOSSIBLE TO INTERVIEW BY TELEPHONE? ☐ USE OF ONLINE PLATFORM ☐)
____
____
____

PART 5 - THE INTERNATIONAL OUTCOME INVENTORY – COCHLEAR IMPLANT



NAME:____

DATE:______/______/__________

1– Think about how much you used your present cochlear implant over the past two weeks. On an average day, how many hours did you use the cochear implant?

none	less than 1 hour a day	1 to 4 hours a day	4 to 8 hours a day	more than 8 hours a day

2 – Think about the situation where you most wanted to hear better, before you got your cochlear implant. Over the past two weeks, how much has the cochlear implant helped in those situations?

helped not at all	helped slightly	helped moderately	helped quite a lot	helped very much

3 – Think again about the situation where you most wanted to hear better. When you use your cochlear implant, how much difficulty do you STILL have in that situation?

very much difficulty	quite a lot of difficulty	moderate difficulty	slight difficulty	no difficulty

4 – Considering everything, do you think your cochlear implant is worth the trouble?

not at all worth it	slightly worth it	moderately worth it	quite a lot worth it	very much worth it

5 – Over the past two weeks, with your cochlear implant, how much have your hearing difficulties affected the things you can do?

affected very much	affected quite a lot	affected moderately	affected slightly	affected not at all

6 – Over the past two weeks, with your cochlear implant, how much do you think other people were bothered by your hearing difficulties?

bothered very much	bothered quite a lot	bothered moderately	bothered slightly	bothered not at all

7 – Considering everything, how much has your cochlear implant changed your enjoyment of life?

worse	no change	slightly better	quite a lot better	Very much better

10.4. Comparing descriptive statistics in subgroups considering anomalous results

Comparing descriptive analyses in all the sample (49), subsample without anomalies (35) and anomalies subsample (14).

1. Descriptive results

1.1. Dependant Variables - Outcomes

Type of Communication at time 1 and 2

1. All sample (N49)

Time1	Frequency	Percent	Time 2	Frequency	Percent
Other	2	4.1	**Other**	9	18.4
Sign L.	1	2	**Sign L.**	2	4.1
Mixed	34	69.4	**Mixed**	24	49
Spoken L.	12	24.5	**Spoken L.**	14	28.6

2. Subsample without anomalies (N35)

Time1	Frequency	Percent	Time 2	Frequency	Percent
Other	2	5.7	**Other**	4	11.4
Sign L.	0	0	**Sign L.**	2	5.7
Mixed	24	68.6	**Mixed**	16	45.7
Spoken L.	9	25.7	**Spoken L.**	13	37.1

3. Anomalies subsample (N14)

Time1	Frequency	Percent	Time 2	Frequency	Percent
Other	0	0	**Other**	5	35.7
Sign L.	1	7.1	**Sign L.**	0	0
Mixed	10	71.4	**Mixed**	8	57.1
Spoken L.	3	21.4	**Spoken L.**	1	7.1

1.1.3. CAP II at Time 1 and Time 2

All sample (N=49)

Time 1 Scale	Frequency	Percent	Time 2 Scale	Frequency	Percent
0	3	6.1	**0**	5	10.2
1	0	0	**1**	2	4.1
2	3	6.1	**2**	1	2
3	4	8.2	**3**	2	4.1
4	4	8.2	**4**	8	16.3
5	12	24.5	**5**	13	26.5
6	2	4.1	**6**	4	8.2
7	11	22.4	**7**	2	4.1

8	6	12.2	**8**	7	14.3
9	4	8.2	**9**	5	10.2
Total	49	100	Total	49	100

Scale= 0. No awareness of environmental sounds, 1. Awareness of environmental sounds, 2. Response to speech sounds ,3. Recognition of environmental sounds, 4. Discrimination of at least two speech sounds, 5. Understanding of common phrases without lip-reading, 6. Understanding of conversation without lip-reading with a familiar talker, 7. Use of a telephone with a familiar talker, 8. Understanding/Following group conversations, 9. Use the telephone with an unknown speaker in an unpredictable context.

Subsample without anomalies (N=35)

Time 1 Scale	**Frequency**	**Percent**	**Time 2 Scale**	**Frequency**	**Percent**
0	2	5.7	**0**	3	8.6
1	0	0	**1**	0	0
2	2	5.7	**2**	0	0
3	0	0	**3**	0	0
4	3	8.6	**4**	5	14.3
5	9	25.7	**5**	11	31.4
6	1	2.9	**6**	3	8.6
7	9	25.7	**7**	2	5.7
8	6	17.1	**8**	6	17.1
9	3	8.6	**9**	5	14.3
Total	35	100	Total	35	100

Anomalies subsample (N=14)

Time 1 Scale	**Frequency**	**Percent**	**Time 2 Scale**	**Frequency**	**Percent**
0	2	14.3	**0**	2	14.3
1	2	14.3	**1**	2	14.3
2	1	7.1	**2**	1	7.1
3	4	28.6	**3**	2	14.3
4	0	0	**4**	3	21.4
5	4	28.6	**5**	2	14.3
6	0	0	**6**	1	7.1
7	1	7.1	**7**	0	0
8	0	0	**8**	1	7.1
9	0	0	**9**	0	0
Total	14	100	Total	14	100

1.1.6. SIR at time 1 and 2

All sample (N=49)

Time 1 Scale	Frequency	Percent	Time 2 Scale	Frequency	Percent
1	23	46.9	1	16	32.7
2	3	6.1	2	8	16.3
3	3	6.1	3	2	4.1
4	15	30.6	4	15	30.6
5	5	10.2	5	8	16.3
Total	**49**	**100**	Total	**49**	**100**

Notes: Scale= 1. Connected speech is unintelligible. Pre-recognizable words in spoken language, the child's primary mode of everyday communication may be manual., 2. Connected speech is unintelligible; intelligible speech is developing in single words when context and lip-reading cues are available ,3. Connected speech is intelligible to a listener who concentrates and lip-reads within a known context., 4. Connected speech is intelligible to a listener who has little experience of a deaf person's speech, 5. Connected speech is intelligible to all listeners. The child is understood easily in everyday contexts.

Subsample without anomalies (N=35)

Time 1 Scale	Frequency	Percent	Time 2 Scale	Frequency	Percent
1	15	42.9	1	7	20
2	3	8.6	2	5	14.3
3	2	5.7	3	1	2.9
4	11	31.4	4	14	40
5	4	11.4	5	8	22.9

Anomalies subsample (N=14)

Time 1 Scale	Frequency	Percent	Time 2 Scale	Frequency	Percent
1	11	78.6	1	9	64.3
2	1	7.1	2	3	21.4
3	1	7.1	3	1	7.1
4	1	7.1	4	1	7.1
5	0	0	5	0	0

1.1.13. Table: CDI Numerical Outcomes

All sample (N=49)

Outcome	Mean	SD	p0	p25	p50	p75	p100	histogram
First phrases T1	12.37	6.04	0	9	14	17	19	▂▁▂▂▇
First Phrases T2	12.84	7.25	0	9	16	19	19	▂▁▁▂▇
Vocabulary Understand T1	102.775510	56.047326	0	55	124	150	160	▂▁▁▂▇
Vocabulary Understand T2	103.102041	63.498768	0	29	128	159	160	▃▁▁▂▇
Vocabulary Production T1	37.142857	48.419177	0	0	17	54	160	▇▂▁▁▁
Vocabulary Production T2	53.530612	56.414058	0	0	44	92	160	▇▃▂▁▂
First Gestures T1	6.53	2.56	0	5	7	9	9	▁▁▃▅▇
First Gestures T2	7.04	2.49	0	6	8	9	9	▁▁▁▂▇
Actions and Imitations T1	23.24	5.72	2	22	25	27	28	▁▁▁▂▇
Actions and Imitations T2	23.71	6.31	1	23	26	27	28	▁▁▁▁▇

Observation: Almost all without normal distribution.
Note: Total Score in 5 different CDI sub-sections.

Subsample without anomalies (N=35)

Outcome	Mean	SD	p0	p25	p50	p75	p100	histogram
First phrases T1	12.542857	6.213566	0	9.0	14	17.5	19	▂▁▂▂▇
First Phrases T2	14.342857	6.475941	0	15.0	17	19.0	19	▂▁▁▂▇
Vocabulary Understand T1	107.571429	57.090375	0	77.0	133	153.5	160	▂▁▁▂▇
Vocabulary Understand T2	117.685714	56.095387	0	109.0	142	160.0	160	▂▁▁▃▇
Vocabulary Production T1	45.457143	51.399441	0	3.5	25	66.5	160	▇▂▁▁▂
Vocabulary Production T2	66.400000	58.127244	0	8.0	48	130.0	160	▇▅▃▁▅
First Gestures T1	6.628571	2.766243	0	4.5	8	9.0	9	▁▁▂▂▇
First Gestures T2	7.200000	2.459077	0	6.5	8	9.0	9	▁▁▂▂▇
Actions and Imitations T1	23.514286	5.505994	2	22.5	25	27.0	28	▁▁▁▂▇
Actions and Imitations T2	24.200000	6.072116	1	23.5	26	27.0	28	▁▁▁▁▇

Anomalies subsample (N=14)

Outcome	**Mean**	**SD**	**p0**	**p25**	**p50**	**p75**	**p100**	**histogram**
First phrases T1	11.928571	5.797404	0	9.00	13.5	16.75	19	▂▁▇▅▇
First Phrases T2	9.071429	7.946594	0	0.00	11.5	15.75	19	▇▁▁▅▆
Vocabulary Understand T1	90.785714	53.456206	3	49.75	104.5	138.75	154	▅▃▁▆▇
Vocabulary Understand T2	66.642857	68.218661	0	0.75	56.0	130.25	160	▇▁▁▃▅
Vocabulary Production T1	16.357143	33.095682	0	0.00	2.5	17.00	122	▇▁▁▁▁
Vocabulary Production T2	21.357143	36.789646	0	0.00	0.0	28.00	123	▇▁▂▁▁
First Gestures T1	6.285714	2.016416	1	6.00	6.5	7.75	9	▁▁▁▇▅
First Gestures T2	6.642857	2.619664	1	5.50	7.5	8.75	9	▁▂▁▃▇
Actions and Imitations T1	22.571429	6.393678	4	21.25	24.5	26.75	28	▁▁▁▃▇
Actions and Imitations T2	22.500000	6.969715	4	21.25	25.0	27.00	28	▁▁▁▂▇

1.2. Independent Variables

1.2.1. Table Independent Variables At time 1 and 2

Independent Variable	**All sample (N=49)**	**SWA (N=35)**	**AS (N=14)**
Gender			
Female	22 (44.9%)	18 (51.4%)	4 (28.6%)
Male	27 (55.1%)	17 (48.6%)	10 (71.4%)
Age at Time 1 and 2			
Mean (SD) in months	63.7 (13.5)	66.3 (11.7)	57.3 (16.0)
Median [Min, Max] in months	67.0 [34.0, 83.0]	68.0 [42.0, 83.0]	59.5 [34.0, 82.0]
CI Surgery Age			
Mean (SD)	33.3(10.2)	34.4 (10.6)	30.6 (8.81)
Median [Min, Max]	34.0 [12.0, 55]	37.0 [12.0, 55.0]	28.5 [17.0, 52.0]
HSES			
A (Very low income)	17 (34.7%)	13 (37.1%)	4 (28.6%)
B (low income)	12 (24.5%)	8 (22.9%)	4 (28.6%)
C (middle low income)	7 (14.3%)	6 (17.1%)	1 (7.1%)
D (middle high income) + Higher Income	13 (26.5%)	8 (22.9%)	5 (35.7%)
Borough Index			

Mean (SD)	0.512 (0.0946)	0.501 (0.0910)	0.537 (0.102)
Median [Min, Max]	0.540 [0.300, 0.640]	0.535 [0.315, 0.640]	0.579 [0.300, 0.640]
Family Ed			
Primary School Incompleted	3 (6.1%)	0	3 (21.4%)
Primary School Completed	4 (8.2%)	0	1 (7.1%)
Secondary Incompleted	22 (44.9%)	3 (8.6%)	5 (35.7%)
Secondary Completed	1 (2.0%)	17 (48.6%)	1 (7.1%)
Training Incompleted	6 (12.2%)	3 (8.6%)	3 (21.4%)
Training Completed (In Chile from 2 to 3 years of formal education)	3 (6.1%)	2 (5.7%)	1 (7.1%)
University Incompleted	10 (20.4%)	10 (28.6%)	0 (0%)
Additional Difficulties			
Not recorded / Not declared	37 (75.5%)	28 (80.0%)	9 (64.3%)
Additional difficulties affecting language development (Recorded / Reported)	12 (24.5%)	7 (20.0%)	5 (35.7%)
CI Condition			
Operative-Without problems	37 (75.5%)	24 (68.6%)	13 (92.9%)
Operative but with some issues	9 (18.4%)	8 (22.9%)	1 (7.1%)
Not Operative - Current Techinical Issues	1 (2.0%)	1 (2.9%)	0 (0%)
Not in use from time ago	2 (4.1%)	2 (5.7%)	0 (0%)
CI Status			
Unilateral CI WITHOUT contralateral HA	42 (85.7%)	29 (82.9%)	13 (92.9%)
Unilateral CI WITH contralateral HA	3 (6.1%)	2 (5.7%)	1 (7.1%)
Bilateral CI	4 (8.2%)	4 (11.4%)	0
Rehabilitation Attendance			
Yes, face to face	25 (51.0%)	16 (45.7%)	9 (64.3%)

Yes, Hybrid	10 (20.4%)	7 (20.0%)	3 (21.4%)
Yes, Online	6 (12.2%)	5 (14.3%)	1 (7.1%)
No	8 (16.3%)	7 (20.0%)	1 (7.1%)
Attendance Proximity (Is it easy for you to get to the sessions?)			
Yes	36 (73.5%)	27 (77.1%)	9 (64.3%)
No	13 (26.5%)	8 (22.9%)	5 (35.7%)
Attendance Proximity Ordinal			
Very short time	1 (2.0%)	1 (2.9%)	0
Short Time	11 (22.4%)	7 (20.0%)	4 (28.6%)
Enough Time	13 (26.5%)	8 (22.9%)	5 (35.7%)
Long Time	8 (16.3%)	7 (20.0%)	1 (7.1%)
Very long Time	7 (14.3%)	4 (11.4%)	3 (21.4%)
Not attending	9 (18.4%)	8 (22.9%)	1 (7.1%)
Education			
The child do/did not attend any centre – the child is/was at home	6 (12.2%)	3 (8.6%)	3 (21.4%)
Special school for deaf students	6 (12.2%)	3 (8.6%)	3 (21.4%)
Regular school without PIE (Special needs team at school)	2 (4.1%)	2 (5.7%)	0
Regular school with PIE (Special needs team at school) – The child is/was attending the PIE	29 (59.2%)	24 (68.6%)	5 (35.7%)
Language Disorders School	5 (10.2%)	3 (8.6%)	2 (14.3%)
Nursery	1 (2.0%)	0	1 (7.1%)
CI use Likert			
Never	2 (4.1%)	2 (5.7%)	1 (7.1%)
Sometimes	1 (2.0%)	0	3 (21.4%)
Frequently	5 (10.2%)	2 (5.7%)	10 (71.4%)
Always	41 (83.7%)	31 (88.6%)	0
CI use in hrs.			
Mean (SD)	10.2 (3.62)	10.1 (4.01)	10.2 (2.52)

Median [Min, Max]	11.0 [0, 19.0]	11.0 [0, 19.0]	11.5 [5.00, 13.0]
Behavioural problems			
No	36 (73.5%)	27 (77.1%)	9 (64.3%)
Yes	13 (26.5%)	8 (22.9%)	5 (35.7%)
Frequency Rehabilitation			
Weekly	37 (75.5%)	27 (77.1%)	10 (71.4%)
Each 2 weeks	7 (14.3%)	4 (11.4%)	3 (21.4%)
Monthly	3 (6.1%)	3 (8.6%)	0 (%)
Less than once per month	2 (4.1%)	1 (2.9%)	1 (7.1%)
Parental Training			
No	14 (28.6%)	12 (5.7%)	2 8 (14.3%)
Yes	35 (71.4%)	23 (94.3%)	12 (85.7%)
Parental Confidence			
I do not know about this topic	1 (2.0%)	0	1 (7.1%)
Very Poor Confident	1 (2.0%)	1 (2.9%)	0
Poor Confident	3 (6.1%)	1 (2.9%)	2 (14.3%)
Somewhat Confident	22 (44.9%)	16 (45.7%)	6 (42.9%)
Very Confident	22 (44.9%)	17 (48.6%)	5 (35.7%)

Notes: Abbreviation= SWA: Subsample without anomalies, AS: Anomalies subsample.