



School of Psychological Sciences and Health

Speech and Language Therapy

**QUALITY OF LIFE IN
ADOLESCENTS WITH
REPAIRED CLEFT LIP AND PALATE
LIVING IN SRI LANKA**

INOKA UDAYANGANI SIRIMANNA

MIRIHAGALLA KANKANAMALAGE

A thesis presented in fulfilment of the requirements for the degree of

Doctor of Philosophy in Speech and Language Therapy

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DECLARATION OF AUTHOR'S RIGHTS

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A handwritten signature in black ink, appearing to read 'J. N. O. R. Y.', is written on a light blue rectangular background.

Date: 31.03.2023

DECLARATIONS OF PUBLISHED WORKS

Chapter 3, 5, 6, 7, 8, 9, and 10 of this thesis includes sections of previously published work.

Mirihagalla Kankanamalage, I., Cleland, J., & Cohen, W. (2022). Translation and validation of the Intelligibility in Context Scale into Sinhala for adolescents in Sri Lanka with cleft lip and palate. *Clinical linguistics & phonetics*, 1–17. Advance online publication. <https://doi.org/10.1080/02699206.2022.2120417>

For which I have been responsible. I was the first author of this work, taking the lead in planning the data collection, analysis and writing of the manuscript under the guidance of my supervisors.

Signed



Date 31.03.2023

COVID IMPACT STATEMENT: INOKA

MIRIHAGALLA KANKANAMALAGE

This study aimed to transculturally adapt and validate a quality of life (QoL) measurement and a speech intelligibility scale into Sinhala and investigate QoL in adolescents with cleft lip and palate (CLP) in Sri Lanka. The study planned to recruit typically developing adolescents' sample and adolescents with CLP sample from Sri Lanka after being granted ethical approval in both UK and Sri Lanka. Questionnaires were translated following a forward - backward - forward translation method and initially planned to assess reliability and validity including test - retest reliability. Moreover, initial plan was to broaden the QoL analysis of the adolescents with CLP using their cleft type, presence of fistula (Velo Pharyngeal Insufficiency - VPI) and surgical recommendations. The investigator planned to extract these details from patients' clinical notes with the help of the speech and language therapist (SLT). It was planned to include all these analysis results in this thesis. In order to succeed all these steps, the investigator planned to travel twice to Sri Lanka for the data collection purposes.

However, with Covid-19 related disruptions it was not possible to complete all those steps. The investigator travelled to Sri Lanka in October – November 2019 and applied for the Sri Lankan ethics, attended the ethics committee interview, and obtained local permission to conduct this study at Lady Ridgeway Childrens' Hospital, Sri Lanka. This was followed by liaison with the Department of Education to obtain permission to recruit typically developing adolescents from state schools. The typically developing data collection was completed while the investigator was in Sri Lanka

alongside partial completion of the CLP data. With the help of the SLTs, the remaining CLP data was also obtained. The initial data entering process was started in January 2020 and the plan was to travel in Spring 2020 to obtain another dataset from the same participants for test-retest reliability purposes, and to extract further necessary data from CLP participants' clinical notes to complete the data analysis.

Given the worldwide impact of Covid-19 in March 2020, both Sri Lanka and UK went into initial lockdown and travel restrictions were in place with subsequent lockdowns for nearly two years. All schools in Sri Lanka closed for nearly two years and face to face SLT clinics were also stopped. Hence, the investigator had to cancel the second data collection trip. This narrowed the QoL analysis as it was not possible to extract details from clinical notes because the SLT clinics were not functioning as usual and closed for most of the time during 2020-2022. Furthermore, as a mother of a young child, I had to allocate considerable amount of time to home school my daughter during lockdown periods. This coupled with supporting family members living in Glasgow who became unwell with Covid in July 2022 and my own Covid infection in 2022 and parents and brothers were became unwell with Covid in 2021 in Sri Lanka. Therefore, I lost some time from my studies to recover and look after family members in two countries. That was a very hard time as an international student with lots of psychological pressures.

For this reason, the following elements of the thesis were not possible to include:

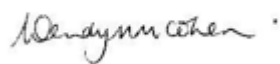
- Test-rest reliability
- More detailed QoL and speech intelligibility analysis in adolescents that would include details of the cleft type, presence of fistula and surgical recommendations.

I also applied for an extension to complete my thesis as I struggled to allocate full time to PhD work with family commitments during lock down periods.

A handwritten signature in black ink, appearing to read 'Inoka' followed by a stylized flourish and a period.

Inoka Mirihagalla Kankanamalage

30.03.2023

A handwritten signature in black ink, appearing to read 'Wendy Cohen'.

Wendy Cohen (First Supervisor)

30/03/2023

“Every child — no matter where they are born — has the right to smile”.

(Operation Smile)

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“Sometimes all what you want to know is that there are strong hands to pull you up when you fell steps on the PhD ladder”.

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I would like to offer special thanks to the original authors of the Intelligibility in Context Scale; Dr Sharynne McLeod, Child Oral Health Impact Profile; Dr Hilary Broder, Paediatric Quality of life Inventory; Mapi Research Trust and Professor Varni, Paediatric Quality of Life Inventory Sinhala translation author; Dr Manjula Danansuriya for granting me permission to translate assessments into Sinhala and use already translated assessments in my PhD study.

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Last but not least, my little daughter Melissa who has been growing with my PhD journey and asking the same question at least once a week during all these five years “When are you finishing your PhD mummy?”. Here’s promising your mum is almost there!

ABSTRACT

Introduction

Cleft lip ± palate (CLP) is the most common congenital abnormality in the craniofacial region. This condition impacts an affected individual's speech, hearing, appearance, and psychological wellbeing which can lead to long-lasting adverse outcomes for health and social integration. Children born with CLP typically need multidisciplinary care from birth to adulthood. Hence, the health and social integration difficulties, along with a lengthy treatment process, can have negative impacts on an individual's quality of life (QoL). Measuring QoL in people born with CLP is necessary in order to understand their feelings of satisfaction in areas that they consider important. Enhancement of QoL is now accepted as an important objective of health care and rehabilitation.

In Sri Lanka, where multidisciplinary services are provided for children with CLP from birth, psychological services are not widespread, and often QoL assessments are not undertaken. Speech and language therapists (SLTs), as one of the key professionals responsible for the care of people with CLP in Sri Lanka, play an important role in providing services to improve speech and enhance QoL. However, SLTs find providing these services challenging due to the limited resources available. Lack of standardised assessments validated with children and young people with CLP is one of the biggest challenges SLTs experience when treating children and young people born with CLP. This study aimed to address this gap by translating and validating assessments of speech intelligibility and quality of life into Sinhala, the main language spoken in Sri Lanka.

Method

A two-phase study was performed. The first phase aimed to translate and culturally adapt the English language version of the Intelligibility in Context Scale (ICS) and the Child Oral Health Impact Profile (COHIP) into Sinhala. In the second phase, this study aimed to 1. validate the new Sinhala ICS (ICS-SIN) and COHIP (COHIP-S) with both typically developing (TD) adolescents and adolescents with repaired CLP and 2. Compare QoL and speech intelligibility within and between groups.

The study employed mixed methodologies prioritising quantitative analysis. The first phase was conducted using “forward-backward-forward” translation method following cross cultural assessment adaptation guidelines. Qualified bilingual SLTs involved in the translation process and appropriate cultural adaptations were applied into the translated questionnaires after a reconciliation meeting. Thereafter, these questionnaires were piloted, and further changes were made where necessary. Finally, the ICS-SIN and COHIP-S was produced to develop the next stage of this study.

After transcultural adaptation, the COHIP-S was validated with 317 TD adolescents aged 12-15 years old and 38 adolescents aged 12-15 years with repaired CLP. The ICS-SIN was validated with 50 parents/carers of TD adolescents and 38 parents/carers of adolescents with repaired CLP. The psychometric properties of the COHIP-S and ICS-SIN were statistically analysed to determine the reliability, construct, convergent and discriminant validity. The adolescent participants also completed the Paediatric Quality of Life – Sinhala (PedsQL-Sinhala) generic QoL questionnaire together with the COHIP-S and the ICS-SIN. QoL responses to PedsQL-Sinhala and COHIP-S were compared between TD and CLP adolescents. Moreover, a descriptive analysis and a

correlational analysis were conducted to identify the most sensitive QoL measure for adolescents with CLP amongst generic and condition-specific questionnaires.

Results

The English COHIP and ICS measures were translated, culturally adapted, and piloted successfully. The COHIP-S was found to have good reliability (defined by Cronbach α), face validity, construct, and discriminant validity for both TD and CLP adolescents' groups. The PedsQL-Sinhala and COHIP-S findings highlighted that, adolescents with CLP had a lower QoL when compared to the same age TD adolescents. The descriptive analysis showed that COHIP-S was more sensitive in identifying QoL issues in adolescents with CLP than the generic PedsQL-Sinhala. The ICS-SIN was found to have good content, construct and discriminant validity and reliability for both TD adolescents and adolescents with CLP. Speech intelligibility ratings reported by the parents of adolescents with CLP were significantly lower than the TD parents' ratings. However, the parents' speech intelligibility ratings were not correlated with the QoL findings of the adolescents with CLP in this thesis.

Discussion

The findings of this study have the potential to enhance SLT practice in Sri Lanka. The validated ICS-SIN and COHIP-S are potential clinical resources which can be easily implemented in SLT clinics. This study suggests that QoL in adolescents with CLP is affected. SLTs, as a key member of the multidisciplinary team can integrate QoL assessment into the standard assessment process, identifying affected individuals and referring them for support where necessary. Moreover, the results emphasized the importance of using a condition specific QoL measures for people with CLP rather

than a generic QoL measure. Results also suggested that CLP adolescent's speech intelligibility was lower compared to TD peers, despite the participants being well into adolescence. Future research is needed to explore the relationship between speech intelligibility and quality of life in adolescents with CLP including analysis of speech samples and patients' perspectives. Moreover, further research should seek to clarify the validity and reliability of the ICS-SIN for younger age groups children with CLP and other types of speech disorders.

PUBLICATIONS AND PRESENTATIONS ARISING FROM THIS THESIS.

Peer reviewed publications

- Mirihagalla Kankanamalage, I., Cleland, J., & Cohen, W. (2022). Translation and validation of the Intelligibility in Context Scale into Sinhala for adolescents in Sri Lanka with cleft lip and palate. *Clinical linguistics & phonetics*, 1–17. Advance online publication.
<https://doi.org/10.1080/02699206.2022.2120417> (Appendix 1)

Peer reviewed conference presentations

- Mirihagalla Kankanamalage, I., Cleland, J., & Cohen, W. (2022, July). Validation of the Intelligibility in Context Scale (ICS) in Sinhala for use with children with Cleft Lip and Palate in Sri Lanka. Oral paper presented at the 14th International Cleft Congress (CLEFT 2022), Edinburgh, UK. (Appendix 2)
- Mirihagalla Kankanamalage, I., Cleland, J., & Cohen, W. (2022, July). An investigation into quality of life of adolescents with repaired cleft lip and palate living in Sri Lanka. Oral paper presented at the 14th International Cleft Congress (CLEFT 2022), Edinburgh, UK. (Appendix 3)
- Mirihagalla Kankanamalage, I., Cleland, J., & Cohen, W. (2021, June). Validation of the Sinhalese version of the Intelligibility in Context Scale. Oral paper presented at the International Clinical Phonetics and Linguistics Association online conference (ICPLA 2021). (Appendix 4)

- Mirihagalla Kankanamalage, I., Cleland, J., & Cohen, W. (2019, July). Cross cultural adaptation and validation of a health-related quality of life assessment (COHIP-Children's Oral Health Impact Profile) for adolescents with Cleft Lip and Palate in Sri Lanka. Poster session presented at the 59th Annual Meeting of the Japanese Teratology Society and the 13th World Congress of the International Cleft Lip and Palate Foundation – CLEFT 2019, Nagoya, Japan. (Appendix 5)

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LIST OF ABBREVIATIONS AND ACRONYMS

CLP - Cleft Lip ± Palate

TD – Typically Developing

QoL – Quality of Life

HRQoL – Health Related Quality of Life

OHRQoL – Oral Health Related Quality of Life

COHIP – Child Oral Health Impact Profile

COHIP-S – Child Oral Health Impact Profile – Sinhala

ICS – Intelligibility in Context Scale

ICS-SIN – Intelligibility in Context Scale – Sinhala

PedsQL – Paediatric Quality of Life Inventory

PedsQL-Sinhala – Paediatric Quality of Life Inventory – Sinhala

SLT – Speech and language therapist

SLTs – Speech and language therapists

FT 1 – Forward Translator 1

FT 2 – Forward Translator 2

MDT – Multidisciplinary Team

VPI – Velopharyngeal Insufficiency

WHO – World Health Organisation

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1 INTRODUCTION

Cleft lip and palate is among the most common congenital facial differences (birth defects) in children. The key treatment is surgery to repair the lip, palate, or both to separate the nasal and oral cavities to improve the child's ability to speak, swallow, hear normally and to achieve a normal facial appearance. Surgical management consists of several surgeries at different stages in infancy, childhood and adolescence and multidisciplinary team management is required to meet the individual child's needs. Hence, the treatment is a lengthy process that starts soon after birth and continues well into early adulthood with multiple surgeries and long term medical, dental, speech, orthodontic, and audiological care.

The multiple intervention procedures children will have to undergo until their older childhood can result in concerns related to physical, mental, emotional, and social functioning domains related to QoL (Broder et al., 2017). Therefore, it is important to investigate the QoL in these children and adolescents. However, investigating the impact of CLP on QoL is problematic due to limitations relating to a lack of validated measurement instruments in many cultures. This thesis focuses on children and adolescents living in Sri Lanka.

In Sri Lanka, 400 children with CLP are born annually and speech and language therapists are closely involved in the care plan from the beginning to provide feeding and speech treatments and advice. Children and families therefore work closely with SLTs in the Sri Lankan context. As psychological services are not well established in the country, and not included in the multidisciplinary care setting, SLTs are the most

involved professionals with families. This, together with the close therapeutic relationships SLTs have with their clients, makes them a good candidate for performing QoL screening using questionnaires. This will allow SLTs to direct clients to appropriate services.

This chapter will define and discuss CLP, impacts, and treatments and describe how services are established in the Sri Lankan context. This leads to a detailed literature review in chapter 2 of QoL in repaired CLP adolescents, including which measures are currently being used and what the contributing factors are.

1.1 Cleft Lip and Palate (CLP)

CLP is an umbrella term. CLP is a gap or split in the upper lip and/or roof of the mouth (palate). This birth difference occurs during early pregnancy. CLP is considered the most common congenital abnormality around the world, resulting in medical, psychological, and social problems in affected individuals and their families (A Oner & Taştan, 2020). Prevalence of CLP is estimated at approximately one in every 700 new-borns globally (Mossey & Modell, 2012), however, the incidence varies from 1 in 1000 to 2.69 in 1000 births depending on ethnic background, geographical origin, gender, and socio-economic status (Goodacre & Swan, 2008; Messer et al., 2010). For example, the incidence of CLP is 0.3 in 1000 births in African populations, 0.7-1.3 in 1000 births in European populations, 1.4-2.1 in 1000 births in Asian populations, and 3.6 in 1000 births in American populations (Brito et al., 2011). The epidemiological data on CLP in Sri Lanka are limited. According to a study by Amaratunga and Chandrasekera (1989), the prevalence of CLP is relatively low and estimated at 0.83 per 1000 births and the incidence of isolated cleft palate is 0.19 per 1000 live births.

A higher CLP incidence of 2.2 per 1000 live births was reported in Anuradhapura district (North Central province) of Sri Lanka (Alwis et al., 2008).

Clefts are classified based on the structures involved: lip, alveolus, hard palate and soft palate; and laterality: unilateral or bilateral; and severity. Clefts can be isolated or can occur in combination. The primary palate is the triangular area of the hard palate anterior to the incisive foramen and includes a portion of the alveolar ridge (Figure 1.1). The secondary palate consists of the remaining hard palate and all of the soft palate. As illustrated in Figure 1.1, CLP can occur mainly with three variations and approximate distribution as follows:

- cleft lip with alveolar involvement-22%
- cleft lip and cleft palate - 46%
- isolated cleft palate – 33%

Clefts can be complete or incomplete, unilateral, or bilateral, with unilateral clefts nine times more prevalent than bilateral clefts. In total 86% of bilateral cleft lips and 68% of unilateral cleft lips are associated with cleft palate congenital deformity (Goodacre & Swan, 2008). CLP can occur in isolation or as part of a syndromic disorder and appears as an associated feature in over 300 syndromes. Goodacre and Swan (2008), (p 283) stated that *“A total of 35% of cleft lip and/or palate patients and 54% of isolated cleft palate patients are associated with another anomaly”*. In Sri Lanka, study including 1190 non-syndromic subjects found out that 56% had unilateral cleft lip with or without cleft palate, 23% had bilateral cleft lip with or without cleft palate and 21% presented with isolated cleft (Wijekoon, 2009).

In common, biological males are most affected with CLP while biological females are commonly affected with isolated cleft palate (Goodacre & Swan, 2008). However, a study conducted in southern province of Sri Lanka highlighted that cleft palate is more common in females than males in Sri Lanka (Prabodha et al., 2012). Additionally, Wijekoon (2009) highlighted that males are mostly affected with unilateral or bilateral cleft lip with or without palate CLP, whereas females were mostly affected with isolated cleft palate in a study conducted in the central province of Sri Lanka, where one third of the cleft population in the country is managed. CLP has a complex aetiology in which both genetic and environmental factors play a role. Risk factors such as vitamin deficiency, especially folic acid deficiency, and maternal smoking, maternal alcohol consumption, drug use, and chemical exposure during pregnancy have been linked with cleft development (A Oner & Taştan, 2020). Hence, the causes of child born with a CLP is multifactorial involving genetic and environmental factors and there is a tendency for familial clustering. Unaffected parents who have a first child having a non-syndromic CLP, the risk of having a second child with non-syndromic cleft is 4%. This risk increases up to 9% for the third child. Moreover, if one parent has a CLP, the chance of having a child with non-syndromic cleft is 4%, while this increases to 17% for the second child (Goodacre & Swan, 2008). In Sri Lanka a positive family history has been identified in 9.1% of CLP subjects (Amaratunga & Chandrasekera, 1989).

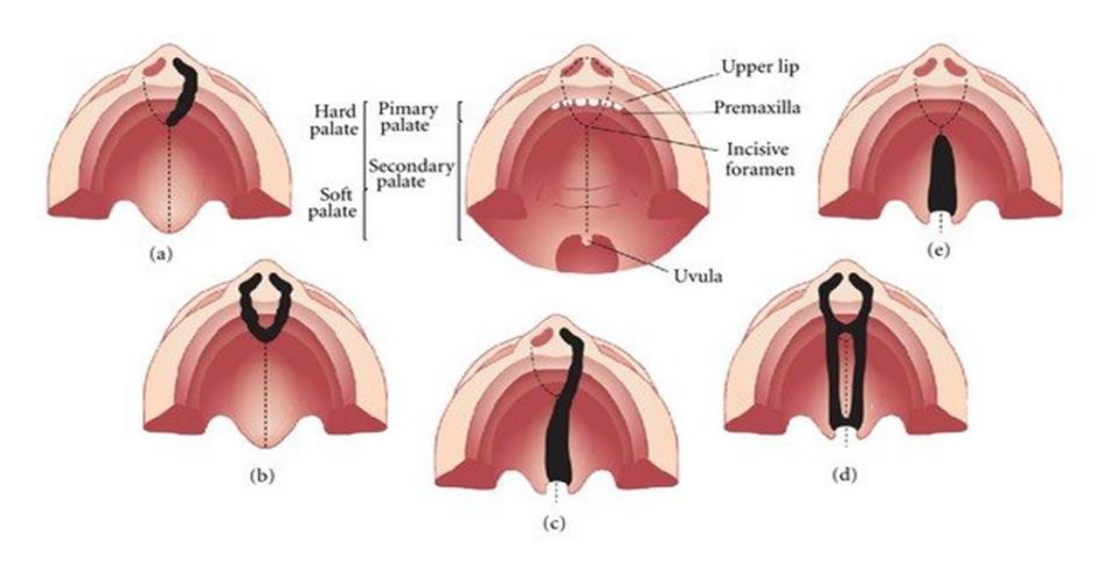


Figure 1.1: Common types of cleft lip and palate

Figure 1.1: Representation of the most common types of clefts affecting the palate. (a) Unilateral cleft lip with alveolar involvement; (b) bilateral cleft lip with alveolar involvement; (c) unilateral cleft lip associated with cleft palate; (d) bilateral cleft lip and palate; (e) cleft palate only (Brito et al., 2012).

1.2 Impacts of CLP

Individuals with CLP commonly presented with multiple problems such as early feeding difficulties, nutritional issues, developmental delays, disordered speech production, language development issues, impaired hearing, dentofacial and orthodontic differences, and facial appearance issues, which can lead to long-lasting complications throughout life (Nagarajan et al., 2009). In some cases, cognition can also be affected when CLP is associated with syndromes. A cleft in the secondary palate can lead to hypernasality and speech intelligibility disorders, ear infections, hearing loss and nasal regurgitation. Furthermore, cleft in the primary palate including the lip and alveolus is associated with facial disfigurements, dental anomalies and

learning disabilities (Broder et al., 2012). Even after early surgical intervention, children with CLP can exhibit “cleft speech characteristics” including abnormal nasal airflow, abnormal nasal resonance, atypical consonant productions, altered laryngeal voice quality and nasal or facial grimaces (Nagarajan et al., 2009). There can also be an impact on many psychological and social health dimensions such as anxiety, depression, inhibition, low self-esteem, reduced cognitive function and low achievement in school children (Klassen et al., 2012). These impacts can continue throughout life and result in social inhibition, low social competence, and overall lower QoL (Klassen et al., 2012). Despite rehabilitation with good quality intervention and care, the CLP condition inevitably poses a burden to the individual, and the family (Mossey et al., 2009). Findings of studies in the past have shown many children and their families are affected psychologically to some extent (Klassen et al., 2012; Mossey et al., 2009).

1.3 CLP impacts on speech

A CLP can affect speech and communication abilities in different ways. There is a wide variation in how speech and overall communication abilities in children are affected. Speech sound production problems can exist from the very early stages and may persist into later childhood (Lane et al., 2022), or throughout life. However, many children with CLP develop normal speech without speech and language therapy intervention. Disorders of speech have been the most salient problem encountered by clinicians when treating children with CLP (Pamplona & Ysunza, 2018). Depending on the cleft type, due to the structural abnormalities in the hard palate and the soft palate, there can be compensatory misarticulations when attempting speech and these

can lead to severely compromised speech intelligibility (Goodacre & Swan, 2012). Moreover, due to the low air pressure in the oral cavity, velopharyngeal incompetence (VPI) is a common feature associated with speech in CLP children. Components of VPI such as nasal emission, hypernasality, nasal turbulence and resonance can affect overall speech intelligibility (Goodacre & Swan, 2012). As well as articulation and intelligibility, language and cognition can be impacted in some children, and they may experience difficulties in higher organisational levels of language processing (Hardin-Jones & Chapman, 2011).

1.4 CLP Treatment

Although this birth condition is not life threatening, numerous intervention procedures are often necessary to reconstruct, rehabilitate and improve the outcomes of CLP. Treatment procedures are varied and individually planned. However, surgical interventions start from birth to correct the structural differences and are often repeated until early adulthood (Broder et al., 2014). Multidisciplinary care is vital in the management of this condition with the involvement of various disciplines including oro-maxilla facial surgery, plastic surgery, nursing, speech and language therapy, audiology, otolaryngology, counselling, psychology, genetic counselling, orthodontics, and dentistry. These professionals work collaboratively as a team from birth until young adulthood to accomplish comprehensive treatment plans for patients with CLP depending on individualised needs (Munz et al., 2011). The treatment of patients with CLP always aims to accomplish the full surgical revision to achieve more typical growth and development of the face, complete closure of the cleft, support speech development, normal hearing (in glue ear conditions) and, a good aesthetic

result all with the aim of encouraging socialising with others (Aravena et al., 2017). However, due to the lengthy involvement of many disciplines, surgeries, and interventions throughout childhood and into adolescence, there can be psychological impacts or an impact on QoL (Antonarakis et al., 2013). Hence, these children may need to access numerous services by multidisciplinary professionals throughout their childhood and even till adulthood. Services and treatment protocols for the management of children with CLP can differ remarkably between countries. The standard of care for both developed and developing countries for patients with CLP remains a cause of concern (Mossey et al., 2009). In the UK, the cleft lip surgery will be conducted within the first 6 months after the child were born and the cleft palate surgery will be performed between the age of 6 -12 months to close the palate (National Health Service, 2023). Depending on the severity, child may have to undergo further palatal surgeries to close the fistulas, jaw adjustments and orthodontic treatments until the young adulthood.

1.5 CLP care in Sri Lanka

1.5.1 Sri Lanka

Sri Lanka, formerly known as Ceylon, is an island country in South Asia. It lies in the Indian Ocean, separate from the Indian subcontinent. The total population in Sri Lanka was estimated at 21.92 million in 2020. Sri Lanka is a multinational state, and Sinhalese (74.9%) make up the majority of the nation's population. Sinhala is therefore the principal language spoken in Sri Lanka. The other official language is Tamil which is spoken by the country's largest minority group. English is used as a recognised language.

1.5.2 Sinhala Language.

Sinhala, sometimes called Sinhalese, is an Indo-Aryan language, primarily spoken by the Sinhalese people (largest ethnic group – 16 million) in Sri Lanka. Sinhala is also spoken as the first language by other ethnic groups in Sri Lanka (about 2 million). The Sinhala language has dialects and accents which are prominent in different regions of the country. The written Sinhala language differs from the spoken Sinhala language in many aspects. Spoken Sinhala distinguishes between a formal and a colloquial variety (e.g.- “Friends”- written Sinhala – /mituran/, spoken Sinhala – /jahaluwan/. Written language is used for all forms of literacy texts and formal spoken Sinhala is used in speeches, media presentations and newspapers, whereas colloquial spoken language is used in everyday communication in day today lives. In different regions of the country people speak different dialects of the Sinhala language although the base remains the same. For instance, people in the hill country use the word /appacci/ for father while low country people use the word /tatta:/. In the southern part of the country, there are differences in people pronouncing some words (e.g.- “what are you doing” will be pronounced as /makkej kəranne/ in south, instead of /møkədə kəranne/ in other parts of the country. The most important difference between the spoken and written Sinhala is that spoken Sinhala lacks the inflected verb form. The Sinhala script consists of 60 letters; 18 for vowels and 42 for consonants (Sinhala Language, 2023).

1.5.3 CLP treatments and services in Sri Lanka

Sri Lanka has around 400 children born with CLP every year. Children born with CLP will usually be seen by a paediatrician immediately after birth and referred to specialized professionals such as plastic surgeons, oral-maxillo facial surgeons, speech

and language therapists and nutritionists. However, where children are born in rural areas without access to speciality services, they will be referred to the closest general or teaching hospital. There are three specialised cleft units established in the country:

- Lady Ridgeway Children's Hospital – Colombo (capital of the country – Western province)
- Dental Institute – Kandy (Central province of the country)
- Teaching Hospital – Karapitiya (Southern province of the country)

It is not guaranteed that every child born with CLP will be seen at these institutions due to various transport and economic challenges faced by some families, however, most new born children receive specialized care at some stage of their lives from one of the above three cleft units as the Lady Ridgeway hospital itself provide care for 280-300 new born children with clefts per year (Lady Ridgeway Hospital for Children, 2020).

Children who have not been referred to one of these three specialized units are referred to an oro-maxillofacial surgeon at their local hospital or closest general hospital for primary surgery as soon as possible. There are approximately 24 oral and maxillofacial units in different regional hospitals in the country (Ministry of Health, Sri Lanka, 2012).

If the child with CLP is in good health and free from other concerning medical factors, surgery for lip closure will be carried out between birth and six months and the primary palatal surgery will be carried out from 9-12 months onwards in most cases, following the world recognised surgery time frames (National Health Service, UK, 2023).

The specialized cleft units all have facilities to carry out CLP surgeries and are equipped with well trained staff. All three centres have multidisciplinary cleft teams and clinics that provide services for children with CLP from birth until 18 years and in some units, they receive services until adulthood. National health service is free in Sri Lanka, and there are no age restrictions for accessing these services (Lady Ridgeway Hospital for Children, 2020).

1.6 Overview of Speech and Language Therapy services in Sri Lanka

Speech and language therapy is a young profession in Sri Lanka. The first group of nine speech and language therapists (Wickenden et al., 2003) started to work in three general hospitals and a few private sectors in 2000 (Walpita & Ginige, 2014). Since then, there have been a small number of SLTs added to the service up until 2008. SLT training was included in the national university recruitment system as a four-year BSc degree training 30-40 SLTs annually afterwards. The country now has approximately 400 SLTs providing services to 22 million people. Most of the government general and basic hospitals across the country have at least one SLT and there are established SLT departments in all teaching and general hospitals. However, due to the country's national health service structure, the SLT service is not well established in the community and educational settings in every part of the country.

1.7 SLTs involvement with CLP patients.

SLT services in the country follow the World Health Organisation guidelines on global strategies to reduce the health care burden of craniofacial anomalies (Programme,

2002). In the teaching hospitals where the specialized cleft units are established, children born with CLP will be immediately seen by the SLT for feeding advice. Thereafter the SLT will remain involved with the family supporting feeding until 6-9 months of age. Focus on speech intervention usually starts when the infant is nine months. The first step is indirect therapy involving parents, explaining to them about the possible speech difficulties their child may experience in the future and advising on encouraging babbling and early language development. Then, when the child attends multidisciplinary clinics, the SLT will monitor the child's speech and language development and provide necessary intervention following assessment. Children will see the SLT more often if they have persistent speech and/or language difficulties, hence the SLT is the most approachable contact for the child and parents to discuss their concerns regarding treatment, speech, and other aspects such as schooling, peer-interaction, and social issues. In Sri Lanka, there are no established psychological support systems integrated into the government medical system. Therefore, children will not receive any advice or intervention from those professionals. Hence, the QoL aspect for these children, adolescents and adults will not be formally assessed at any time during the treatment process. Because SLTs work intensively with these children and adolescents, they may be able to identify QoL issues in these children and adolescents and refer them for necessary services and help. SLTs usually see children until they become adolescents and depending on the severity of the problems, they will be moved to adults' clinics after the age of 18 years and continue treatments. QoL is a complex construct and children's understanding about this concept will be questionable at their young age. Hence, most of the QoL questionnaires will be answered by parents, or answers will be influenced by parents. As children grow into

adolescents, they experience changed appearance, can comprehend more, and are capable of answering a questionnaire containing different aspects of QoL. Moreover, children may become frustrated or withdrawn if they are not understood leading to reduced QoL, and therefore speech treatments may impact QoL. A condition specific self-administered QoL assessment would therefore be a very useful tool in SLT clinics as then SLTs can gain an overview of how QoL is affected by CLP, and if there are any associations between speech problems and QoL ratings. For example, should a listener find it difficult to understand a child because of unintelligible speech, so the SLT can prioritise these areas in intervention. Moreover, if there are any issues in school, SLT can contact the teacher, If the child is experiencing pain, SLT can refer to them to multidisciplinary team and if overall QoL is reduced the SLT can refer the child to a psychologist. A QoL measure developed for older children/ adolescents is appropriate for SLT clinics, because the adolescents can self-administer it and SLTs can gain valuable insights into the child's own feelings and worries rather than a proxy version where parents complete a measure on behalf of their child.

1.8 Rationale for this study

I graduated as an SLT following an undergraduate SLT degree from Sri Lanka. During this time (2001) the SLT profession was a very new profession and only one batch of nine SLTs were working in the whole country. The SLT profession was established as a collaborative project with the Great Ormond Street Hospital (GOSH) - UK because the Cleft team from GOSH were visiting the country once a year to train multidisciplinary professionals for cleft care at that time. As an output of the GOSH project, cleft care professionals were trained and a university course for training SLTs

was initiated to produce professional SLTs to work in the country. Following graduation, I joined the Sri Lankan Government Health Service and served as an SLT for nearly ten years in a leading teaching hospital. During this time, I experienced working with children and adolescents with CLP and identified a lack of resources that were needed to provide comprehensive SLT care for CLP population was a major issue. Validated Sinhala assessments are a main priority to enhance the quality of the SLT service. Hence, I decided to translate and validate two English questionnaires (COHIP & ICS) into Sinhala for use in SLT clinics. Translating and validating speech assessments from a different language is complex work as the Sinhala language is linguistically very different from English. The ICS is a parent report speech intelligibility rating scale that can be translated with minimal language adaptations as it does not involve any speech sample analysis. SLTs can use this as a valuable screening, reporting and outcome evaluation tool in clinical settings where there are only a limited number of assessments available.

QoL in patients with CLP needs to be investigated, as this aspect is not assessed by any professionals in Sri Lanka but can have significant impacts on children's and adolescent's lives. Health Psychologists' and counsellors' involvement is very limited within CLP care units in the national health system in Sri Lanka. Therefore, SLTs, as the people who have regular contact with the children and adolescents and their families, and build close therapeutic relationships are the best people to screen for QoL in Sri Lanka and then refer to expert services as required.

1.9 Adolescents

This study investigates QoL in adolescents. Adolescence is a major transition period in the individual's life. There are many biological, behavioural, and psychological changes happening to an individual during this time and children are expanding their social engagement with family members, extended relatives, friends, and teachers (O'Donohue et al., 2013). When children reach adolescence, they become more conscious about their appearance and become more independent, hence, they become more concerned about relationships, appearance, socialising behaviour, and attitudes (Herbert, 2006). Hence, adolescents with CLP may experience problems relating to appearance, relationships socialising as a result of their birth condition which can have impacts on QoL. Children, when they grow into the adolescence age may be good in expressing themselves about impacts of CLP, treatment experiences and social integration problems rather than when they were small. Moreover, majority of adolescents with CLP often experience orthodontic issues and receive treatments to maximise growth and development of the maxillary region, improve functional efficiency and facial appearance (Markovic, 1986). Thus, by this age the QoL impacts are more directly related to their craniofacial condition and treatments rather than milk teeth falling and the appearance of permanent tooth issues.

1.10 Quality of life (QoL)

There is an increasing interest in the QoL in health care and amongst health researchers (Fayers & Machin, 2015). A traditional medical assessment of health can have many limitations, hence an expansion in the use of QoL measures can add pertinent details on how people perceive their own health and disease along with subjective aspects of health (Gomes et al., 2020). *“Quality of life is an individual’s perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns”* (Whoqol, 1994, p.1405). Hence, it is an all-inclusive, broad concept, affected in a complex way by the individual’s physical health, psychological state, level of independence, social relationships, personal beliefs and their relationship with salient features of their environment (Whoqol, 1994). Health-related quality of life (HRQoL) is one dimension of QoL (Bowling, 2005) and can be interpreted as impacts or effects of a health status, disease, or treatment on different aspects of individuals’ life (Queiroz Herkrath et al., 2015). Oral-health related quality of life (OHRQoL) is a more specific quality of life concept, defined as the impact of oral health problems on an individual’s daily life activities (Locker & Allen, 2007). Therefore, OHRQoL is relevant to children and adolescents with CLP as it is associated with their condition. However, while QoL, OHRQoL and HRQoL are defined differently, they are interlinked as they aim to capture subjective perception and assessment of a patient’s health and well-being. Hence, QoL in children born with CLP has been discussed in the literature using all three terms. In this study, the broad term of QoL is used in the literature review. Where appropriate, the terms HRQoL and OHRQoL also used when discussing evidence from the literature in order to be consistent with individual study findings.

In summary, the facial differences, impacts and lengthy treatment process can impact QoL in children and adolescents with CLP. Therefore, QoL in CLP children and adolescents is an important aspect to address while providing care for these children and adolescents. In Sri Lanka, QoL aspects of adolescents with CLP had not been given adequate attention and there have no systematic reports available related to how speech treatments impacting their QoL. In the Sri Lankan context where psychology services are limited in CLP clinics, a QoL assessment could be administered at SLT clinics to screen and identify QoL impacts. However, this is not possible without a validated QoL measurement in home language. The following literature review will explore QoL in adolescents with CLP and discuss how QoL can be measured in this group.

The next chapter (Chapter 2) outlines a narrative review of the available literature to explore health related and oral health related quality of life findings in adolescents with CLP and QoL measurements used around the world. Subsequently, in Chapter 3 speech intelligibility in CLP and measurements used to assess speech intelligibility will be discussed. The Chapter 4 lays out literature gap leading to the research questions, research study hypotheses and null hypotheses. Next, the Chapter 5, 6 and 7 of the thesis present the transcultural adaptation method, results and discussion as outlined below:

- Chapters 5 – Transcultural adaptation of the assessments – Method
- Chapter 6 – Transcultural adaptation of the assessments – Results
- Chapter 7 – Transcultural adaptation of the assessments – Discussion

Afterwards, the next chapters of the thesis consist of details of validation of the translated questionnaires into Sinhala, investigate QoL and speech intelligibility in adolescents with CLP when compared to TD same age peers, exploring the relationship between QoL self-ratings and parents' speech intelligibility reporting's followed by limitations, future research suggestions and conclusion for this thesis as outlines below:

- Chapter 8 – Methodology
- Chapter 9 – Results
- Chapter 10 – Discussion
- Chapter 11- Conclusion

2 NARRATIVE REVIEW

Health-related & oral health-related quality of life of adolescents with cleft lip and palate and how it's being measured: A narrative review.

2.1 Overview

This narrative literature review explores HRQoL and OHRQoL in adolescents with repaired CLP. The literature search was carried out between 1st January 2013 and 31st August 2022. The search yielded 25 published articles that investigated QoL in children and adolescents with CLP aged 8-18 years. This narrative review includes an Introduction (2.2), methodology (2.3), results (2.4), discussion (2.5), limitations (2.6) and a summary (2.7) section.

2.2 Introduction

As the most common congenital structural abnormality in the oro-facial region, “*The quality of life with individuals with craniofacial diseases is challenged throughout life, given the conditions themselves and the treatments needed to be done*” (p.2).(Elmouden et al., 2020). CLP can affect the individual's well-being in many ways, such as appearance, talking, eating, emotions, social relations, and confidence. Individuals with CLP experience a wide variety of aesthetic and functional problems as a result of their anatomical differences which have significant impacts on physical and psychosocial functioning, as well as the quality of life of the individual (Ruiz-Guillén et al., 2022). Despite early surgical treatments to correct structural

abnormalities, some children with CLP have nasolabial aesthetics with visible scarring that can contribute to differing facial appearance (Klassen et al., 2012). Speech and language problems can persist throughout life and there is an increased incidence of middle ear infections and hearing impairments (Sharma & Nanda, 2009). Even with surgeries administered at different time points, there can be persisting issues such as oral fistula, high arched palate and orthodontic issues which will result in velopharyngeal insufficiency and articulation problems leading to unintelligible speech. Moreover, these structural issues can lead to problems with eating such as nasal regurgitation and high food residues in the mouth. Taken together, there can be issues that affect a person's physical functioning, hence ongoing medical and dental treatments may interrupt the individual's daily living (Sundell et al., 2017).

Moreover, individuals may experience difficulties with self-image, self-esteem, anxiety, depression, and social stigma sometimes or throughout their lives (Klassen et al., 2012). These psychosocial problems may affect their educational and social opportunities (Klassen et al., 2012). Additionally, social relationships during school can be affected as a result of teasing and bullying (Antonarakis et al., 2013) and these together with any societal stigma and unwanted questioning (Antonarakis et al., 2013) can be stressful. Children and adolescents with CLP are at increased risk of anxiety and depression due to these negative interactions and experiences (Richman et al., 2012). These can be more extensively negatively impacted when a speech disorder or hearing impairment is also present (Munz et al., 2011).

Therefore, it is evident that individuals can have problems related to physical and psychosocial functioning. Thus, their life can be disrupted in many ways due to different medical and surgical procedures, assessments and evaluations, psychosocial

problems and social issues, all of which when combined can directly affect the person's HRQoL across the functional, emotional, and social wellbeing domains.

The impact of CLP on QoL is varied for affected children depending on their age, geographical region, services, and resources available to them (Queiroz Herkrath et al., 2015). Early surgical intervention, speech and language therapy, dental treatments, and other supportive treatments such as counselling and access to dieticians can minimise the impacts of CLP on an individual's life, however these services can be geographically dependent (Sharratt et al., 2020).

Available literature reports discrepancies concerning the outcome of CLP care and individuals' QoL (Defabianis et al., 2022). To date, there is no definitive answer to what extent the QoL is affected in individuals with CLP. Previous studies conducted to evaluate QoL in CLP children and adolescents have given varying results, with some studies reporting lower, other similar, and again others higher, HRQoL and OHRQoL when compared to non-cleft peers.

Augsornwan et al. (2011) reported high QoL in Thai patients aged 8-18 years with CLP measured with the WHOQoL (WHO, 1998) and Zhan (Zhan, 1992) model. Moreover, a further two studies (Munz et al., 2011; Reddy et al., 2012) reported good QoL outcomes. The study conducted by Munz et al. (2011), in 27 participants with an average age of 18.74 years, using the Michigan oral health-related quality of life scale; reported a quite positive OHRQoL after treatment completion in young patients with cleft lip and palate. Reddy et al. (2012) reported an average to good HRQoL result with differences in the levels of satisfaction in an $n=724$ sample with a mean age of 16.8 years measured by the modified SF-36 questionnaire (Ware & Sherbourne, 1992).

Conversely to the above findings, similar QoL in children with CLP compared to children with no health conditions has also been reported. Wogelius et al. (2009) found no significant differences between cleft patients ($n=21$) aged 11-14 years and healthy school children ($n=154$) of the same age. However, a significant number of reports have highlighted that the QoL in adolescents with repaired CLP is lower when compared to their typically developing peers. Christophe et al. (2020) reported a lower OHRQoL in children aged on average 7.74 years with CLP than their healthy peers. A systematic review by Eckstein et al. (2011) generally concluded that children and adolescents with CLP tend to have a lower QoL, however, the results should be interpreted carefully as the conclusion is based on a small number of papers. Furthermore, Topolski et al. (2005) using a generic QoL measure (Youth Quality of life Research Version) included 11-18 years adolescents ($n=56$) with facial differences (24 CLP included in this sample) and reported lower QoL when compared to 116 healthy sample.

In addition, Queiroz Herkrath et al. (2015) reported the presence of CLP negatively affected some dimensions of HRQoL in children and adolescents while there was a significant difference in adults with CLP when compared to controls. In Queiroz Herkrath et al. (2015) a meta-analysis of four studies (Warschausky et al., 2002), (Damiano et al., 2007) (Kramer et al., 2009), (Collett et al., 2012) compared HRQoL overall and dimension scores between adolescents with and without CLP. Though there was significant heterogeneity found out, this meta-analysis pointed out emotional wellbeing and functional wellbeing as the most influenced OHRqoL dimensions in children and adolescents, whereas physical health is the least affected for all groups. The impacts of CLP on HRQoL and OHRQoL is discussed due to the functional,

aesthetic, and psychosocial impairments and differences of QoL findings were discussed in relation to the use of different QoL instruments in this meta-analysis.

Likewise, a systematic review by Klassen et al. (2012) synthesised evidence of QoL in CLP from 26 studies included participants age from birth till 21 years of age and identified a number of health concerns of CLP patients in different domains such as physical health, psychological health and social health. In this systematic review Klassen et al. (2012) identified that there are 28 different questionnaires have been used to measure QoL in CLP population.

Numerous different “generic” and “health-related”, and “oral health-related” quality of life outcome measures had been used in studies published to date, nonetheless, there remains very limited “condition-specific health-related quality of life” assessment available for measuring the domains of HRQoL in adolescents with CLP. It can be argued that generic QoL assessments used in previous studies to measure condition-specific impacts were inadequate to identify differences. Queiroz Herkrath et al. (2015) highlighted that QoL measures have been used as indicators to evaluate the effectiveness, efficiency, and impact of distinct treatments for different diseases or health disorders. Moreover, Eckstein et al. (2011) and Klassen et al. (2012) pointed out in both of their systematic reviews, that there are limited comprehensive, valid and reliable patient report outcome questionnaires for CLP.

Due to the complex nature of impacts associated with CLP, QoL might be affected by demographic determinants, cleft type, severity of the cleft, other associated medical conditions such as a syndrome or hearing impairment, and socioeconomic factors. It has been argued that cleft type has a significant impact on the QOL outcome in relation

to the severity of the cleft (Prahl & Bos, 2011). Spencer (2006) and Houben-van Herten et al. (2015) studied the relationship of these factors in CLP adolescents and reported several demographic, socioeconomic and family environmental determinants that contribute to the child's HRQoL. Dak-Albab and Dashash (2013), Broder et al. (2017), and Wehby and Cassell (2010) found that socioeconomic status can negatively affect the level of QoL of CLP patients and patients from lower socioeconomic backgrounds are more prone to develop more emotional and social problems. Speech intelligibility can be severely affected in CLP individuals as a result of palatal fistulas which is a common complication (Lighthall & Sidman, 2015) that may cause problems with nasal air escape, nasal regurgitation, speech unintelligibility, articulation errors and halitosis. Therefore, any tool used to evaluate the QoL in this population needs to encompass all these areas.

The QoL conceptualization is understood with regard to children and adolescents with CLP and it is important to integrate it into the CLP treatment and assessment protocol of the SLT services. The majority of cleft patients are continuing speech therapy treatments until their late childhood, hence SLT may be the best person to identify QoL issues at preliminary stages. The impacts of the CLP on QoL (including HRQoL and OHRQoL) are expected and reported due to aesthetic, functional and psychosocial impairments. However, there were disagreements between the previous studies that focused on the QoL of individuals with CLP. Hence, a narrative review using a systematic approach is necessary.

The objectives of the present narrative review were to:

- Investigate the QoL in adolescents with CLP aged between 8 -18 years and explore differences in QoL between CLP and typically developing (TD) older children and adolescents.
- Identify the most affected dimensions of QoL (considering HRQoL & OHRQoL)
- Identify generic and condition specific QoL assessments used within the CLP population.
- Identify demographic factors that might impact the QoL of individuals with CLP.

2.3 Method

A detailed systematic review on QoL of children with CLP was conducted by Klassen et al in 2012. In their review, they searched PUBMED, CINHALL, EMBASE, and PsycINFO databases from inception to July 2010. Subsequently, Queiroz Herkrath et al. (2015) conducted a systematic review and meta-analysis to compare HRQoL and OHRQoL between non syndromic cleft and non-cleft individuals. Their literature search was conducted using PUBMED, EMBASE, LILACS, ScieELO, SCOPOUS, Web of Science, PsycINFO, and Cochrane Library data bases up to the 31st of December 2012. Moreover, Raposo-do-Amaral et al. (2011) conducted a critical review to identify measurement instruments in the literature that are used to assess comprehensive aspects of QoL among children with CLP. They searched literature on PubMed published between 2001 to 2011. Finally, Antonarakis et al. (2013) published another review, but only including three papers exploring the QoL in children with CLP. Therefore, the current narrative review searched the databases from 1st of January

2013 to 31st of August 2022 to avoid the repetitive analysis of QoL findings in adolescents with CLP and instruments used to assess QoL and to update the information as a means of finding out what might be appropriate for the Sri Lankan context.

The PRISMA statement (Figure 2.1) was used as guidance to analyse the literature using a systematic method (Aveyard, 2019). University of Strathclyde “SUPremo” data base (which incorporates Web of Science, PsycINFO, MEDLINE, PUBMED and EMBASE electronic databases) was used for the literature search from 1st of January 2013 to 31st of August 2022. Inclusion and exclusion criteria were applied in data extraction from databases. One data base (Web of Science) search string is attached in the appendices this thesis (Appendix 6).

The inclusion criteria were:

- The study sample of cleft lip and/ or palate participants
- Studies reported QoL outcomes.
- QoL outcomes were reported by the patient or patient and parent/ caregiver
- Studies included cleft lip and/or palate patients between the ages of 8 -18 years old.
- Papers written in English.

The exclusion criteria were:

- Studies that did not separate cleft from other craniofacial anomalies
- Papers published in non-English.
- Systematic or narrative reviews

The key words “cleft”, “cleft lip”, “cleft palate”, “quality of life”, “young adults”, “adolescents”, “older children” were combined using Boolean operators “AND” and “OR”. Symbol * was used to find possible endings of the keywords during the search (eg- adoles*). Once the relevant literature was identified using the key word search as a first step, further filtering was carried out combining the keywords to extract the most appropriate study papers for the final analysis. Firstly, screening of the study title was completed followed up by manual examination of paper abstracts, then full text analysis of all papers.

The CASP tool (CASP, 2024) was used to critically evaluate each paper selected for inclusion, with each paper critically appraised using the specific CASP tool according to the research design. Following the in-depth critical appraisal process, irrelevant papers that had not been excluded during abstract screening were discarded.

Basic data from each study, including the author, year, country where the study was conducted, study design, participant numbers, age of the sample, respondent details and assessments used to measure QOL, and cleft types were extracted as shown in **Error! Reference source not found..**

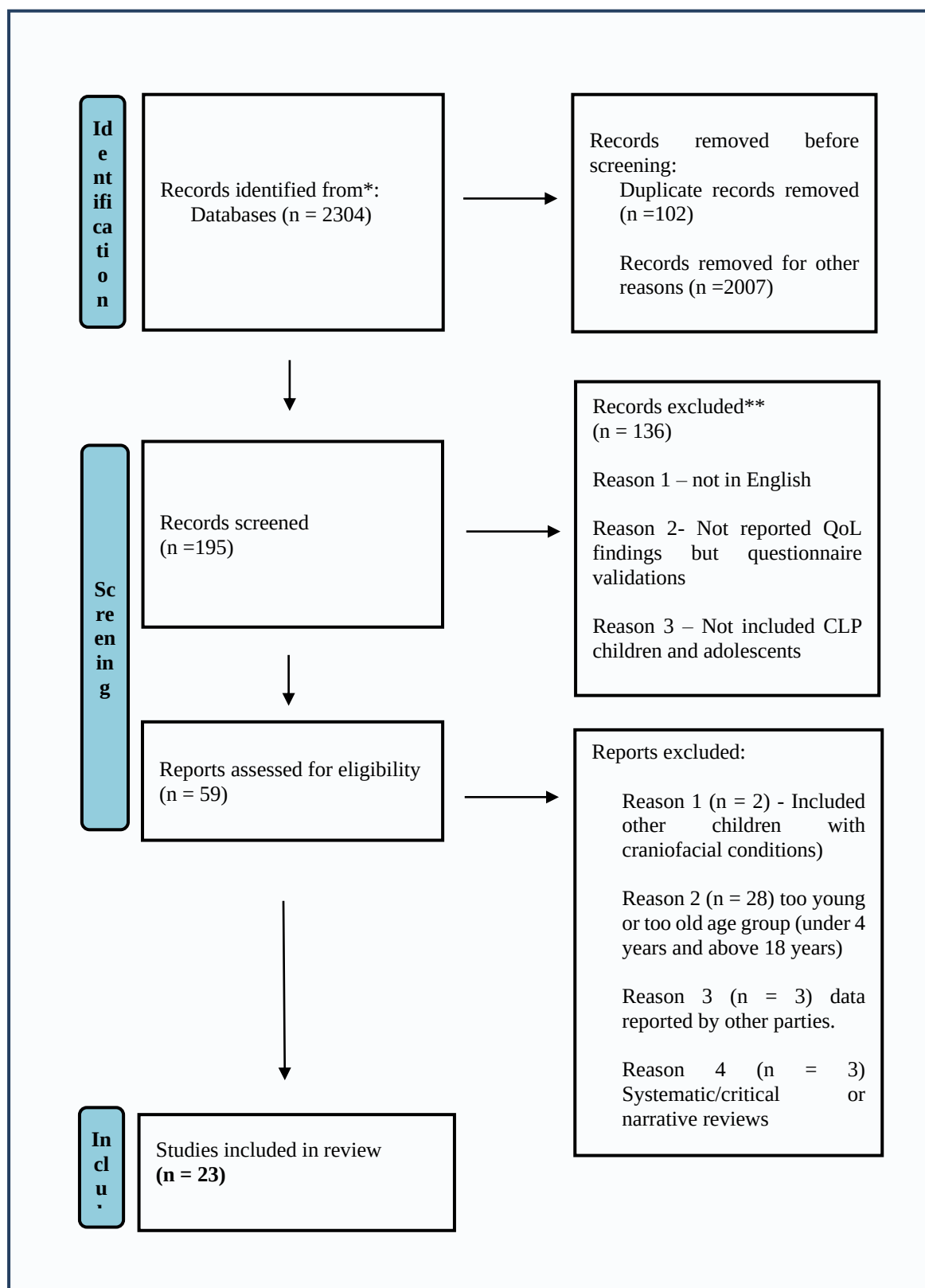


Figure 2.1: Flowchart summarizing the selection process of papers for the narrative review using Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA, 2009)

2.4 Results

2.4.1 Results of the selection process

Through analysis of the University of Strathclyde “SUPrimo” database, a total of 2304 publications were identified. After inclusion and exclusion criteria were applied, 195 publications were listed for abstract screening. After abstract screening, a total of 59 publications were identified as most suitable for this review. The remainder were excluded due to QoL outcomes not being reported in relation to CLP or not published in English. Following the review of the 59 studies in full, a further 36 were removed as some studies included participants younger than 8 years old or older than 18 years old; included other oro-facial conditions; and respondents were other people instead of participant or parents. Therefore, 23 publications qualified for this narrative review. Details of the screening process following the PRISMA statement (Moher et al., 2009) is shown in

Figure 2.1.

2.4.2 Study Characteristics

Key details and characteristics of each of the 23 publications are included in **Error! Reference source not found.** In terms of study design, there were eight case control studies (Ali et al., 2021; Aravena et al., 2017; Christophe et al., 2020; Defabianis et al., 2022; Glener et al., 2017; Kortelainen et al., 2016; Pisek et al., 2014; Ward et al., 2013), three cross sectional studies (Corcoran et al., 2020; Oka et al., 2022; Ruiz-Guillén et al., 2022), one prospective blind study (Nolte et al., 2019), three descriptive studies (Abebe et al., 2018; Eslami et al., 2013; Konan et al., 2015), two longitudinal

studies (Broder et al., 2014; Broder et al., 2017), one survey (Bickham et al., 2017), and one observational investigation study (Broder et al., 2014) were included. There were four studies (Crepaldi et al., 2019; de Oliveira et al., 2015; Elyaskhil et al., 2021; Lin et al., 2020) that did not report the exact study type but were included in the review after screening the content. Research papers in this review comprised studies that included CLP patients in 14 different countries: USA, Italy, Japan, Sudan, Malaysia, Cameroon, Hungary, China, Ethiopia, Thailand, Netherlands, Chile, Finland and Iran.

2.4.3 Study participants

The number of participants in the study samples ranged from 41 (Abebe et al., 2018) to 1200 (Broder et al., 2014). Eight of the studies included control groups and the number of controls ranged from 30-333. Age groups of individuals and participants' cleft types varied substantially among the studies. As shown in **Error! Reference source not found.**, study participants age range varied from 8 to 18 years and most of the studies included both children and adolescents with CLP. One study (Aravena et al., 2017) included children with isolated cleft lip. Eight of the studies included children with both isolated cleft lip and those with isolated cleft palate or both and assessed them in subgroups according to the cleft types (Defabianis et al., 2022; Oka et al., 2022). However, some of the studies ($n=17$) did not define the subgroups. Some studies involved patients with either unilateral or bilateral cleft palate only, excluding cleft lip only patients (Eslami et al., 2013). Some studies included parents and caregivers along with patients to measure the parents' perspectives of QoL constructs of their child. In this review there were eight studies that recorded both parent/caregiver and patient responses (using questionnaires or interviews) regarding

the QoL of adolescents with CLP (Abebe et al., 2018; Bickham et al., 2017; Broder et al., 2017; Defabianis et al., 2022; Konan et al., 2015; Nolte et al., 2019; Ward et al., 2013).

2.4.4 Quality of life assessments

Out of these 23 studies, 22 used standardised questionnaires and one study (Glener et al., 2017) did not clearly specify the standardization or validation of the questionnaires they used. While there was a range of questionnaires that measure the QoL used in the studies, seven different standardised health-related, or oral health-related quality of life assessments were identified. The most frequently used assessment to measure QoL was the Child Oral Health Impact Profile (COHIP) (Broder & Wilson-Genderson, 2007), used within 14 studies (Abebe et al., 2018; Ali et al., 2021; Aravena et al., 2017; Broder et al., 2017; Broder et al., 2014; Christophe et al., 2020; Defabianis et al., 2022; Eslami et al., 2013; Konan et al., 2015; Lin et al., 2020; Nolte et al., 2019; Sischo et al., 2017; Ward et al., 2013). The second most used QoL measures were OHIP -14 (Slade, 1997) and PedsQL (Varni et al., 2001). Other QoL questionnaires such as VQOL-FD-AX, QoL Ado Cleft, OIDP, CPQ (11-14) were also used in some studies as shown in Table 2.2. The PedsQL generic QoL assessment was used by Bickham et al. (2017) and (Gomes Moreira & Butini Oliveira, 2021).

Table 2.1: Details of the publications included in the review and the QOL findings.

Author, Year of Publication	Country	Study Type	Age/ Mean age of participants, Cleft Type	Cleft/Control n	QoL measurement instrument	Reported negative influence of CLP on QoL	Respondent	Impacted domains & Associated factors
Defabianis et al. (2022)	Italy	Cross sectional/ case control study	8-18 years CL/P	71/71	COHIP	Yes	Child & parent	Experienced poorer OHRQoL in comparison to their non-cleft peers. Care givers reported worse scores in the peer interaction and functional well-being domains than their children did. There were negative impacts of CLP on self-image sub domain, and this was greater between 12–18-year-olds. Gender, type of cleft and type of surgical protocol also contributing factors.
Oka et al. (2022)	Japan	Cross sectional study	11-18 years CL/P	69	VQOL-FD-AX	Yes	Child	There are individual differences in QoL concerning facial appearance. QoL vary in different age groups: 15-18 years old QoL > 11-14 years old QoL. All subdomains followed the same pattern. Influenced by age, but not by sex or cleft type
(Ali et al., 2021)	Sudan	Cross sectional/case control study	11.3 +2.5/ 11.4+ 2.6 CL+_P	75/150	COHIP	Yes	Child	Adolescents with cleft lip and/or palate reported significantly lower scores on the overall and all subscale scores when compared to adolescents without CL/P. Age, gender

								differences had no impact on the OHRQoL.
Gomes Moreira and Butini Oliveira (2021)	Italy		8-18 years old CL/P	348	PedsQL 4.0	Yes	Child	13-18 years old had a better QoL and a positive impact than 8-12 years old.
Elyaskhil et al. (2021)	Malaysia		13-16 years CLP		OHP-14	Yes	Child	Malocclusion can have negative impacts on QoL. Prominent in psychological discomfort and psychological disability domains. Higher in females than males. Low quality of life is associated with severity of malocclusion.
Ruiz - Guillén et al. (2022)	Italy	Cross sectional study	8 -18 years	60 CL, CP, CLP	QoL Ado Cleft patient	Yes	Child	QoL improved with treatments.
Christophe et al. (2020)	Yaounde, Cameroon	Cross-sectional/ case control study	7.74 +_ 0.7 8.03 +_ 0.7	27/30	COHIP	Yes	Child	Children with repaired CLP have a lower OHRQoL than healthy peers. Functional well-being, self-esteem and emotional well-being domains are mainly affected. Overall COHIP score for boys were higher than girls, particularly for functional well-being and self-esteem subscales, but the difference was not significant. Visible facial difference impacting on QoL.
Corcoran et al. (2020)	Northern Finland	Cross-sectional study	18 years	63	OHIP-14	Yes	Child	Even though they received comprehensive treatments, still experience lower OHRQoL, more pronounced in physical pain and psychological discomfort.
Lin et al. (2020)	China		8-15 years old	120	COHIP	Yes	Child	Older children had poorer OHRQoL. Functional well-being and emotional

								well-being domains are mostly affected. Girls had poorer emotional well-being. CLP & CP poor in overall COHIP, functional well-being and school subscales. There were significant differences in OHRQoL regarding gender, age and cleft type.
Nolte et al. (2019)	Netherlands	Prospective blinded questionnaires	8-18 years CL/P	170	COHIP Patient and parent	Yes	Child/ parents	High OHRQoL overall, with some areas of differences. Females rated better OHRQoL on “functional well-being” and “school” subscales. More complex results found in CLP cohort where overall COHIP, “functional well-being and “school” domains are affected. Children and adolescents with more complex bilateral CL/P had a significantly lower HRQoL score on functional well-being, school and overall COHIP.
Crepaldi et al. (2019)	USA		15:11 +_ 1:2 CL, CP, CLP	57	SF-36 patient	No	Child	CLP type did not affect the HRQoL of adolescents.
Abebe et al. (2018)	Ethiopia	Descriptive study design	8-17 years OFC	41	COHIP Patient & parent	Yes	Child/parents	OHRQoL is high at children and adolescents who received multidisciplinary care. OHRQoL in children and adolescents with OFC are at similar levels in other international populations. Parents and children's responses are similar. When evaluating OHRQoL.
Aravena et al. (2017)	Chile	Cross sectional study	8-15 years	48 /48 CL	COHIP	No	Child	OHRQoL in CLP is similar to the control group. However, a lower QoL observed items associated with speech and being understood by other people.

Hillary L. Broder et al. (2017)	USA	Longitudinal study	7.5 years to 18.5 years	1196 CLP	COHIP	Yes	Child/caregivers	Youths who were surgical candidates had a lower QoL. Surgical intervention improves OHRQoL. Youths with high number of surgical interventions had lower OHRQoL. Caregiver proxy ratings appears to provide similar findings with the exception of incrementally improved OHRQoL after surgery.
Bickham et al. (2017)	USA	Survey		108 CLP	PedsQL, SLT perceptual speech analysis, QoL in neurological disorders	Yes	Child/ parent	Patients and parents had different perceptions about quality of child's speech and differed from SLT's perceptual analysis. Both SLT and patient, parent responses analysis correlated with important aspects of QoL. Patient speech perception was correlated with depression and difficulty with peer relationships.
Glener et al. (2017)	USA	Cross sectional study	9.9 – 17 years	176/333 CL/P	Psychosocial questionnaire	Yes	Child	Social implications associated with CL/P are high in middle school and less in primary or high schools. Middle school children were more affected by aesthetic concerns, bullying and difficulties with friendship and social interaction. CL/P reported more aesthetic related concerns than children with CL+ Alveolus, but experienced similar speech related distress. Cleft type affects degree and pattern of social consequences of CL/P.
Kortelainen et al. (2016)	Finland	Comparative study	11-14 years	51/82	CPQ (11-14)	Yes	Child	The CPQ ₁₁₋₁₄ total, and oral symptoms, functional limitations, emotional well-being, and social well-being sub scores were poorer

								among patients with CLP than among school children without CLP.
Konan et al. (2015)	Thailand	Cross sectional descriptive study	8-15 years	140 CLP patients and parents	COHIP	No	Child / parents	Young adolescents with CLP had generally positive OHRQoL. No significant difference in OHRQoL among cleft types. Impacts of age and gender were similar.
H. L. Broder et al. (2014)	USA	Longitudinal study	7-19 years	1200	COHIP	Yes	Child	Youth recommended for surgery had high OHRQoL than those with no surgical recommendation. Older females had lower QoL than males. Unmet clinical needs significantly affect the QoL.
H. Broder et al. (2014)	USA	Observational investigation	7-18 years	CP-282 CLP - 918	COHIP	Yes	Child	Depressive symptoms were negatively, and self-concept and self-efficacy were positively associated with OHRQoL.
Pisek et al. (2014)	Thailand	Cross sectional case control study	10-14 years	68/118 CLP	OIDP	Yes	Child	Cleft adolescents had higher levels of dental caries gingivitis and have poorer oral hygiene compared to controls. Cleft adolescents had lower quality of life than the controls in most performances with different perceived causes.
Eslami et al. (2013)	Iran	Descriptive study	8-15 years	50 CLP	COHIP	Yes		HRQoL did not change with the age. Impacts were same in unilateral and bilateral groups. Girls were more affected than boys.
Ward et al. (2013)	USA	Cross sectional case control study	8-18 years patient & caregivers	75/75 CLP	COHIP	Yes	Child/ caregiver	Children and adolescents with orofacial clefts had statistically significant lower QoL scores than control subjects. Overall scores, functional well-being and social

								emotional well-being domains were mostly affected. The social-emotional well-being impact is greater in 15-18 years than younger age groups. Caregivers, children and adolescents' responses were very similar.

¹

¹ Cleft type; CLP=Cleft Lip and Palate, CP=Cleft Palate, CL=Cleft LIP, CL/P=Cleft lip and/or Palate

Table 2.2 : HRQoL & OHRQoL assessments used in previous studies to measure QoL in CLP adolescents.

Study details	Country	HRQoL/OHRQoL assessment used in the study
Aravena et al., 2017	Chile	COHIP
Abebe et al., 2018	Ethiopia	COHIP
Ali et al., 2021	Sudan	COHIP
Broder et al., 2014	USA	COHIP
Broder et al., 2014	USA	COHIP
Broder et al., 2017	USA	COHIP
Corcoran et al., 2020	Northern Finland	OHP-14
Defabianis et al., 2022	Italy	COHIP
Eslami et al., 2013	Iran	COHIP
Glener et al., 2017	USA	Psychosocial questionnaire
Gomes Moreira & Butini Oliveira, 2021	Brazil	PedsQL
Kortelainen et al., 2016	Finland	CPQ (11-14)
Konan et al., 2015	Thailand	COHIP
Lin et al., 2020	China	COHIP
Marghana et al., 2021	Malaysia	OHP-14
Nolte & Pharl, 2019	Netherland	COHIP
Oka et al., 2022	Japan	VQOL-FD
Pisek & Pitiphat, 2014	Thailand	OIDP
Ruiz-Guillen et al., 2020	Italy	QOL-ADO-CLEFT
Thainara Alves et al., 2019	USA	SF -36
Ward et al., 2013	USA	COHIP

2

² COHIP- Child Oral Health Impact profile, PedsQoL – Paediatric Quality of Life Inventory, OIDP – Oral Impact on Daily Performance, SF-36 - Short Form Survey 36, OHP-14 – Oral Health Impact Profile-14, QOL-ADO-CLEFT-Quality of life Adolescent Cleft Questionnaire, VQOL-FD-The Youth Quality of Life Instrument-Facial Differences Module, CPQ (11-14) – Child perception Questionnaire

2.4.5 Analysis of QoL findings

Based on the findings of the reviewed publications, a considerable number of research studies have been carried out investigating QoL aspects and constructs in children and adolescents with CLP. However, the impacts of CLP for QoL in children and adolescents are not consistent in the 23 publications included in this review. Most of the studies pointed out that QoL in children and adolescents with CLP are impacted when compared to non-CLP children and adolescents, however a handful of studies reported that there's no impact on QoL (Konnan et al., 2015; Crepaldi et al., 2019; Aravena et al., 2017). A range of QoL measurement instruments and other perceptual assessments were used in those 23 studies to assess impacts of CLP on those individuals, however priority has been given to assess HRQoL and OHRQoL. Among those QoL measurement instruments, nearly all of them are standardised and have proven reliability in the CLP population. Most of the instruments are designed to measure the oral health condition specific QoL impacts, but some studies used general QoL measurements such as PedsQL, SF-36 as well. The most frequently used QoL measure was COHIP, and this was used in 13 out of 23 reviewed studies showing that COHIP is widely used to assess OHRQoL in children and adolescents with CLP. The studies that used COHIP as a QoL measurement instrument reported impacts within its five domains: oral health, social-emotional well-being, functional well-being, school environment and self-esteem. Other studies reported QoL impacts covering various other constructs such as speech, psychological discomfort, pain, oral hygiene and caries, peer relationships, difficulties with social, aesthetic concerns, depressive symptoms and surgical recommendations. Based on the review findings, QoL aspects and constructs assessed or discussed in each study could be categorized under a

framework covering physical health and psychosocial interaction health (psychological health and social health) domains as shown in **Figure 2.2**. It is apparent that most issues were reported in psychological health and social health domains compared to the physical health domain. Therefore, the psychosocial health domain seems to be the most affected and is mostly assessed and reported in children and adolescents with CLP. The least affected QoL subdomain in children and adolescents with CLP was physical health. However, difficulties associated with oral health condition such as speech intelligibility, impacts on smiling, speech and communication difficulties were commonly reported compared to impacts on general physical activities such as walking, running, or doing a sports activity in physical health subdomain.

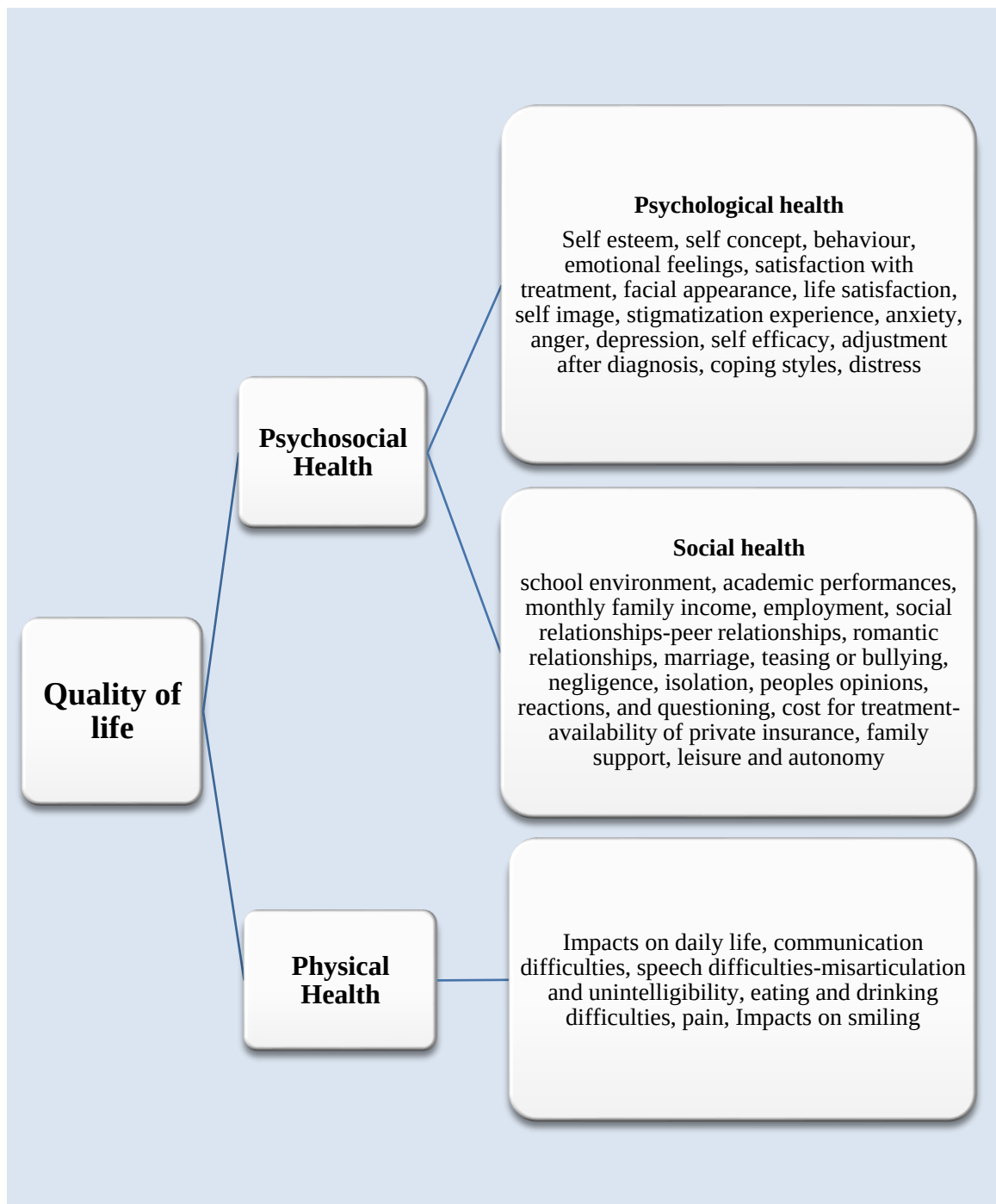


Figure 2.2 : Quality of life constructs analysed in previous studies selected for the narrative review.

Some of the publications also discussed how QoL varies in different sex groups and age groups. Though the findings were not consistent in all studies, there was a general trend observed that girls experienced more impacts relating to their facial appearance, smile and speech, hence, they tend to have a low QoL when compared to same age boys. Interestingly, most studies reported that the QoL impacts were greater when children mature while few studies pointed out that there was no change observed in QoL when children become adolescents or into young adults. Other factors such as surgical recommendations, socio economic factors, ethnicity and unmet clinical needs were highlighted as contributing factors for low QoL in some studies. Therefore, the constructs that can affect QoL in children and adolescents with CLP discussed in these 23 publications included in this narrative review can be analysed using the ICF-CY holistic framework (Figure 2.3) for understanding health, functioning and disability (World Health Organization, 2007). In summary, body functions (changes in anatomical structures), activities and participation together with environmental and personal factors outlined in Figure 2.4 in children and adolescents with CLP were identified as negative contributors leading to low/reduced QoL.

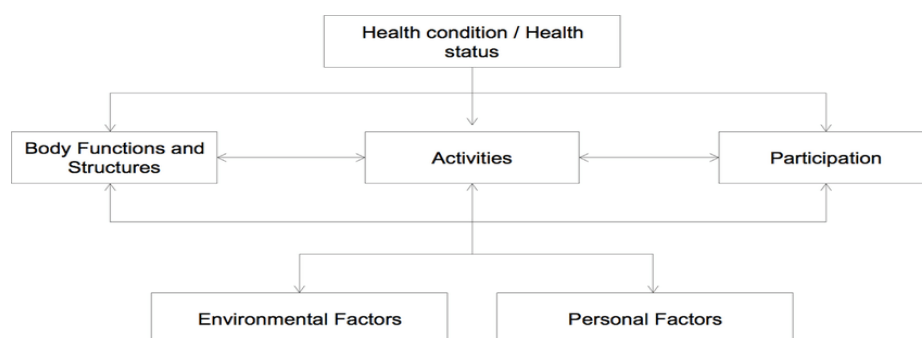


Figure 2.3 : The International Classification of Functioning, Disability and Health: Children and Youth Version (ICF-CY; World Health Organization, 2007)

2.5 Discussion

HRQoL is a multidimensional concept that includes domains related to physical, psychological and social health. A person's well-being is mainly assessed by QoL measures reflecting positive aspects of that individual's life such as positive emotions and self-reporting of life satisfaction. Specific HRQoL assessments already exists for some health disorders; however, this concept is relatively recent within the CLP population and not largely used in assessments in adolescents with CLP. In the literature, it was argued that the expected negative impacts on QoL is high as children with CLP undergo multiple surgeries and multidisciplinary interventions from birth to adulthood as a result of aesthetic, functional, psychological and social health issues associated with CLP (Defabianis et al., 2022).

However, there have been disagreements between previous studies and the results are varied in the QoL outcomes of adolescents with CLP, thus these controversies and identified gaps warranted the current narrative review. The two previous systematic reviews and meta-analysis conducted by Klassen et al. (2012) and Queiroz Herkrath et al. (2015) analysed the frequently measured QoL constructs in CLP children in the literature. However, Klassen et al. (2012) did not clearly comment on the overall QoL outcome in CLP children and adolescents, even though it included the papers of sample populations aged between 2-21 years. Queiroz Herkrath et al. (2015) conducted a meta-analysis and concluded that HRQOL in adults with CLP was lower compared to peers without CLP, but they did not conduct it for the adolescence group due to insufficient number of studies. However, in their meta-analysis they highlighted that

emotional wellbeing and functional wellbeing domains were affected in CLP children and adolescents when compared to non-CLP adolescents.

This review focused on QoL in adolescents (8-18 years) with CLP. According to the findings of this review, there are disparities between the QoL outcome findings in the publications sourced, nonetheless the majority of the studies showed evidence that CLP negatively affected or influenced the adolescents' QoL, HRQoL, OHRQoL or its constructs when compared with non-cleft adolescents or in non-comparative studies, even after they received specialist multidisciplinary intervention and rehabilitation. These results collaborate the findings of Antonarakis et al. (2013) systematic review of three papers that concluded children with CLP tend to have lower OHRQoL than individuals without cleft.

Self-esteem, self-concept and self-image constructs were assessed in most of the studies and discussed in most publications as highly affecting QoL dimensions in adolescents with CLP. A study was conducted with 5 -12-year-old Brazil children and adolescents with CLP (Tannure et al., 2013) compared with non-cleft controls, measured with the AUQUI questionnaire, reported that QoL was similar to the non-cleft group. However, some studies reported a positive or higher QoL for children and adolescents with CLP when compared to the non-cleft controls. As examples, positive OHRQoL has been reported in 8-11- and 12-15-year-old Thai children and adolescents with CLP measured with COHIP, a questionnaire designed to evaluate OHRQoL (Konan et al., 2015).

CLP impacts on different QoL constructs were categorised into two broad areas covering psychosocial (psychological + social) health and physical health. The most

impacted QoL domain in adolescents with CLP appears to be the psychosocial domain and physical health is the least affected domain. In the psychosocial domain, psychological impacts are greater than social impacts. These results are in agreement with the previous systematic review by Klassen et al. (2012), who analysed QoL issues in a similar way using a conceptual framework of QoL issues in CLP population. In addition, QoL issues in CLP identified in this narrative review broadly support the findings of the systematic review by Klassen et al. (2012) and systematic review and Meta-analysis by Queiroz Herkrath et al. (2015).

Moreover, the narrative review findings were analysed using the ICY-CY (World Health Organization, 2007) framework. There were QoL constructs that could be listed under each category: body structure (defined as anatomical parts of the body) & body function (physiological functions of the human body) , activity and participation (difficulties that individual may have in executing activities that can cause restriction in participation), personal (constituting the special background of an individual's life) and environmental factors (physical, social and attitudinal environment in which people live and conduct their lives; further classed as facilitators or barriers) that can negatively influence QoL in CLP children and adolescents. Factors identified in this narrative review analysis under each of these constructs are similar to those reported by Neumann and Romonath (2012) identified CLP relevant terms relating to ICY-CF domains.

CLP is a condition which leads to a range of problems including facial and functional impairment (Konan et al., 2015) that continue even after the surgical construction, individuals' communication, and understandability of speech due to articulation problems, VPI associated with the condition (Baghban et al., 2021; Ward et al., 2013).

These facial and functional problems and ongoing treatment interventions may have a significant influence on the CLP person's psychological and social life. This review identified issues related to speech (Aravena et al., 2017), facial appearance (behaviour, emotional well-being, some constructs of psychological health such as self-esteem, self-concept, life satisfaction, distress (Ward et al., 2013) and social health issues such as school environment (Nolte et al., 2019), peer relationships (Defabianis et al., 2022), employments and income that are negatively affected in CLP children and adolescents. These results are consistent with Aravena et al. (2017), who pointed out that the QoL observed as low in areas of functional well-being and school environment in Chilean CLP adolescents. However, there are some studies that reported contrary findings stating that QoL in CLP is equal to normal developing peers in their studies (Aravena et al., 2017; Konan et al., 2015). This review further points out that there are some constructs, such as cognition, family function and social support which appeared to be not investigated in detail. Therefore, it will be beneficial to study how these constructs correlate with QOL in CLP adolescent population.

Children and adolescents perceptions of their HRQoL could be influenced by many aspects, such as demographic factors (age, gender), personal and family characteristics, along with their socioeconomic status (Gaspar et al., 2012). This review's results identified cleft type, age and gender as three key determinants, that were investigated in relation to HRQoL and/or OHRQoL outcomes in most of the included publications and agrees with Klassen et al. (2012) systematic review findings. Some studies investigated these determinants individually and concluded with varied results. Chen et al. (2021) found that there is an association between cleft type and QoL nonetheless Wehby et al. (2010) highlighted that there is no association between

the cleft type and QoL in adolescents. This review also showed mixed findings on the effect the cleft type on QoL findings as some studies reported that there is an association between cleft type and QoL.

Biological sex also factors in HRQoL with females appearing to be more affected in constructs such as facial appearance, forming relationships and speech than males and reported lower QoL. These results differ from Nascimento et al. (2022), but are broadly consistent with earlier findings by Gomes et al. (2017) and de Oliveira et al. (2015).

Apart from these demographic determinants, this review identified further factors that can affect to QoL findings such as surgical intervention (Broder et al., 2017), ethnic minority, speech problems, orthodontic treatments, and family income/status. Spencer (2006) stated that socio-economical determinants and parental education/family wealth determinants contribute to the states of the QoL of the individual. A parallel study finding was published by Houben-van Herten et al. (2015), explained several demographics, socioeconomic, family/environmental determinants that contribute to a child's HRQoL and similar determinants affecting adolescents' QoL were also supported in this review. Moreover, the World Health Organisation (WHO) also highlighted the importance of assessing socioeconomic factors when assessing QoL, because these factors are significantly relevant to understand QoL outcomes (Correa de Queiroz Herkrath et al., 2015). Nevertheless, these factors are not widely investigated in the existing literature, and it would be valuable to conduct future studies to evaluate the relationship with these factors with QoL outcome in adolescents with CLP.

As synthesised in this narrative review, the QoL questionnaires were completed by children and adolescents and their parents. Among the 23 studies, seven studies included proxy ratings while other studies ($n=16$) included only children and adolescents' responses. Most of the parents' responses were matched with children's responses (Abebe et al., 2018; Ward et al., 2013), however there were some studies where parents' scores were lower than their children's scores (Bickham et al., 2017; Defabianis et al., 2022). These differences may be due to over expectations in parents about their child's treatment or potentially the influence of parental presence on adolescents' responses particularly when striving for independence is a key factor in adolescence. Several studies in this review addressed this as a limitation as they consider response bias of when the patient and parent fill the questionnaires in the same clinic room or at home. Bickham et al. (2017), in their study, highlighted this as a limitation because patient and parent both completed the questionnaire in the same room and there were differences between children/adolescents and proxy answers, indicating parents tend to record their ratings more negatively when compared to children. Hence, they highlighted there may be a possible response bias in their study even when the children or adolescents and parents were encouraged to complete the questionnaires independently. Moreover, Defabianis et al. (2022) stated that parents cannot replace children or adolescents when assessing their OHRQoL, but parents' responses can be used as complementary information.

In the past, most health care providers used to assess outcome success using conventional methods such as the reporting of problems, difficulties, radiographic evidence, or photo analysis (Klassen et al. 2012), which represent mostly the evaluations of the health care providers. Even though these methods and data could

contribute important information for deciding multidisciplinary interventions and outcome evaluations, in most cases these are not sufficient to gain a comprehensive outcome analysis of the patient. Therefore, it is vital to assess how the individual perceives their own physical and mental health, and how satisfied the individual is. Most of the studies in this review used HRQoL or OHRQoL questionnaires and found out that the overall QoL (HRQoL/OHRQoL) or its domains are affected in adolescents with CLP. Thus, it is crucially important to measure the QoL, using health related / oral health related assessments which can comprehensively assess the physical, psychological, and social constructs of these individuals. The condition specific assessments appeared to be more sensitive in recording data in CLP children and adolescents than generic QoL assessment as it captures more CLP condition specific information than a generic health assessment.

This review identified different data collecting procedures such as using standardised QoL assessments, questionnaires, SLT perceptual speech analysis and interviews to measure different constructs of QoL domains used by different studies. Most of the studies measured the QoL or it's constructs in CLP children and adolescents using a range of standardised generic QoL assessments such as PedsQL (Bickham et al., 2017; Gomes Moreira & Butini Oliveira, 2021), or condition specific QoL assessments such as COHIP, OIDP, OHP-14 (Abebe et al., 2018; Ali et al., 2021; Aravena et al., 2017; Broder et al., 2017; Broder et al., 2014; Defabianis et al., 2022; Eslami et al., 2013; Konan et al., 2015; Nolte et al., 2019; Ward et al., 2013). According to this review analysis, the most frequently used OHRQoL assessment with CLP children

and adolescents was the Child Oral Health Impact Profile (COHIP) (Broder & Wilson-Genderson, 2007). The most frequently used generic QOL assessment was Paediatric

Quality of Life Inventory (PedsQoL). However, the majority of studies did not use a condition specific HRQoL assessment tool designed for CLP children or adolescents and there was no published assessment designed only to measure QoL in CLP at the time this narrative review was conducted. Although one study used CLEFT-ADO-Q, this is not just a QoL questionnaire, and it includes pre and post treatment aspects. Even though, generic QoL assessments used in studies including CLP children and adolescents, it is uncertain how accurately a generic assessment measures QoL in patients with CLP with regard to the condition specific characteristics. Hence, this review results confirmed that presently there is a lack of purely a patient reported quality of life outcome assessment developed to capture the specific concerns of cleft lip and palate patients/adolescent group though there are assessments that have QoL component included in the questionnaires. Klassen et al. (2012); Eckstein et al. (2011), also pointed out the similar results regarding lack of PRO - CLP specific assessment to measure QoL and Correa de Queiroz et al., 2015, p.170) stated that “*general OHRQoL and HRQoL instruments may be not sufficient for the cleft lip and palate client group, because of the low sensitivity of these assessments to capture individuals’ perceptions of health status with regard to subtle features related to CL/P*”.

This study results revealed that COHIP had been the most frequently used condition specific questionnaire to measure QoL in the CLP adolescent group. This questionnaire is specifically designed to study the impact in adolescents across oral health conditions and it assesses the oral health, functional wellbeing, social-emotional wellbeing, school environment and self-image of the affected individual (Broder et al., 2012b) and is a sufficiently validated (Eckstein et al., 2011). Broader et al. (2014) emphasised that the COHIP is a condition specific instrument to measure oral health-

related quality of life in children and includes both positive and negative constructs. It was validated with a large diverse sample including CLP children and adolescents; therefore, it appears to have increased sensitivity to treatment effects which eventually increased the patient responsiveness. This review findings also agree with these conclusions, given that the COHIP was used in many studies in different parts of the world (Defabianis et al., 2022; Italy, Ali et al., 2021; Sudan, Nolte and Phrahl., 2019; Netherlands, Broder et al., 2014;2017, Ward et al., 2013; USA, Eslami et al.,2013; Iran, Konan et al., 2015; Thailand) and demonstrated good reliability in this CLP age group (Arabic validation – Ali et al., 2021, Amharic (Ethiopia) validation – Abebe et al., 2018) and also it appears to be a sensitive outcome measure.

Correa de Queiroz Herkrath et al.'s systematic review (2015), also highlighted that the COHIP was a commonly used OHRQoL assessment within the CLP population. Moreover, Klassen et al. (2012) stated range of questionnaires have been used to find the QoL in CLP patients and COHIP was commonly used among them.

It can be argued that a broad, generic QoL instrument is appropriate to use when attempting to find out condition-specific characteristics and impacts of individuals with CLP as it captures the overall health status of the individual. These generic measures will also allow comparisons across different conditions and populations (Meadows, 2011). On the other hand, generic HRQoL instruments may be inadequate to detect the impacts of CLP on QoL due to their low sensitivity to capturing CLP individuals' perceptions of health status regard to the subtle features related to CLP (Herkrath et al., 2015). A condition-specific instrument might capture the health and quality of life elements relevant to specific patient groups and probably have the capacity to identify important changes resulting from treatments (Meadows, 2011).

Hence, the QoL findings of the adolescents with CLP could differ depending on the instrument used in the studies as some generic assessments might not capture the condition-specific impacts on QoL.

All publications included in this review discussed or measured QoL concepts or its constructs, in cleft lip and/or palate in adolescence. The findings varied significantly depended on different factors. There were eight case control studies where adolescents with CLP were compared to non-CLP controls (Ali et al., 2021; Aravena et al., 2017; Christophe et al., 2020; Defabianis et al., 2022; Glener et al., 2017; Kortelainen et al., 2016; Pisek et al., 2014; Ward et al., 2013). In this narrative review the reported QoL findings were not consistent because some studies reported that HRQoL or OHRQoL in children and adolescents with CLP is affected and lower than typically developing children and adolescents but on the other hand some studies reported that QoL in adolescents with CLP is not affected or relatively high. In line with this findings, Antonarakis et al., 2013; Sischo et al., 2017; Stock et al., 2016 concluded varied QoL outcomes in their systematic and narrative reviews, pointing out that presence of CLP could result at least some degree of negative influence on QoL. The descriptive (Abebe et al., 2018, Eslami et al., 2013), survey (Bickham et al., 2017) and longitudinal studies (Broder et al., 2014, Broder et al., 2017) also concluded varied QoL results in CLP as shown in Table 2.1. Four case control studies (Pisek et al., 2014, Aravena et al., 2017, Glener et al., 2017, Ward et al., 2013) reported low QoL in CLP patients compared to normal non-CLP adolescents. Conversely, two case control studies reported QoL or its constructs in CLP was equal to the control group (Pisula et al., 2014). This could be possibly due to the range of assessments/measurements and methods used in those studies, because there is no condition specific QoL assessment available for CLP. The

CLEFT- Q assessment was published in 2018 as a CLP condition specific assessment to measure consequences of the condition. However, this is not only a QoL assessment, but this has a section of seven questions to rate quality of life. CLEFT ADO QoL was reported as another condition specific QoL assessment for CLP population, however this was validated for the older age groups (18-29), hence there were not many evidence available in the literature using it with adolescent population.

2.6 Limitations

This review was performed in accordance with the PRISMA Statement and CASP tool was used to identify to analyse the limits and strengths of the studies. The literature search was conducted for a wide age range and there 23 publications matched the inclusion criteria. Hence, this narrative search was comprehensive; however, there were few limitations. Firstly, the selection of only papers published in English was a one limitation. Secondly, this review excluded publications that included other craniofacial anomalies along with CLP. Thirdly, this review only included publications from 2013 onwards. Finally, this literature review was conducted by a sole researcher and only searched the institution database, therefore did not fulfil the criteria of a systematic review.

2.7 Conclusion

This narrative review supported the widely available finding in the literature, that quality of life/health related quality of life/oral health related quality of life in children and adolescents with CLP are lower than their typically developing peers. Additionally, the review findings identified COHIP as the widely used oral health

related quality of life measurement used within CLP adolescents' population. The COHIP tool was able to identify how CLP is impacting QoL in adolescents in physical, emotional well-being, functional well-being, social and school subdomains. Hence, there is very few specific QoL questionnaires available for children and adolescents with CLP, COHIP found to be the most reliable, condition specific questionnaire and commonly used assessment within this age group to measure QoL in children and adolescents with CLP by the time this narrative review was initiated. It was noted that a cleft-specific patient reported outcome measure: CLEFT-Q (Klassen et al., 2018) was published in 2018 as a wide measure to use with CLP patients including some questions relating to HRQoL, however, a lack of QoL impacts only questionnaire specifically designed for CLP population is a gap within CLP services and there's a vital need to develop CLP condition specific QoL assessment tools. Moreover, this review results highlighted that the majority of studies concluded that CLP could have a significant impact on QoL in adolescents, therefore, it is very crucial to assess this aspect and provide necessary intervention or help as required. The most affected subdomains are psychological and social subdomains, so those areas need to be assessed comprehensively in CLP adolescents and intervention targeted to these areas should be considered. Also, this review findings supported that the severity of cleft palate could negatively impact QoL in CLP adolescents, therefore, it is important to look at this aspect. In addition to that, socioeconomic factors also associated with the QoL and adolescents who have a higher socio-economic background tend to have a higher QoL when compared to adolescents from lower socioeconomic backgrounds. Moreover, age and gender were also identified as determinants of QoL in this review. This literature review included publications covering 10 years since 2013. There were

18 different countries conducted investigations on QoL in adolescents with CLP and published their results. But there are very limited countries in the South Asian region investigated this aspect. Thus, future research investigating QoL aspects of CLP children and adolescents in those countries can contribute to address this literature gap.

Narrative review findings summarised numerous factors that can affect QoL in CLP children and adolescents using ICF-CY framework. Among those speech difficulties, misarticulation and unintelligibility were categorised as factors that can limit activities and participation in adolescents with CLP. Cleft children are at high risk of having problems with speech at the early childhood and some may persist until adolescence and adulthood. In Sri Lanka, where a speech and language therapy services are at developmental level, CLP children may receive limited services, especially people living in rural areas of the country. Thus, persisting speech problems relating to speech clarity, articulation, listeners find it difficult to understand their speech may impact their overall QoL. In the next chapter, speech intelligibility in children and adolescents with CLP and questionnaires available to measure this construct will be explored in detail.

3 SPEECH INTELLIGIBILITY

Authors' Declaration of publications

This chapter includes previously published work.

Mirihagalla Kankanamalage, I., Cleland, J., & Cohen, W. (2022). Translation and validation of the Intelligibility in Context Scale into Sinhala for adolescents in Sri Lanka with cleft lip and palate. *Clinical linguistics & phonetics*, 1–17. Advance online publication. <https://doi.org/10.1080/02699206.2022.2120417>

3.1 Overview

Speech intelligibility, how clearly a person speaks so that his or her speech is comprehensible to a listener, is a key component in communication (Hopf, 2017). Reduced speech intelligibility can cause frustration, misunderstanding, loss of interest by communication partners and poor social interaction (Coppens-Hofman et al., 2017). These physical abnormalities in the articulatory region directly affect speech. The speech of children with CLP is frequently associated with resonance, articulation and phonatory disorders. These aspects can adversely affect overall speech intelligibility (Van Lierde et al., 2010). Therefore, speech intelligibility is an important aspect to consider when providing treatments for children with CLP. There are various methods of measuring intelligibility in speakers with CLP. Perceptual evaluation is the most common method because the aim of interventions is to achieve speech that is perceptually accurate (Lohmander & Olsson, 2004). The gold standard approach, phonetic transcription, can be used to record a speaker's productions which can then be analysed to determine, for example, percentage consonants correct. This in turn is

used to quantify either the degree of difficulty or any improvements in speech over time (Roxburgh et al., 2015). While this is a common approach, there have been calls for a more functional approach which measures outcomes that matter to patients and their families: that is, how well the speaker is understood by others. The International Consortium for Health Outcomes details a list of suggested outcome measures for CLP (Apon et al., 2021). Amongst the set of suggested outcomes for measuring articulation and intelligibility is the Intelligibility in Context Scale (ICS) (McLeod et al., 2012). This is a parent report scale focuses on the child's functional speech intelligibility with seven different communicative partners. The aim of this section is to discuss how speech intelligibility can be affected in adolescents with CLP and the importance and appropriateness of the ICS as a parent reporting assessment/ diagnostic tool among this population.

3.2 Speech Intelligibility in CLP

It is widely accepted that people with unoperated cleft palate have severely disordered speech (Sell et al., 2001), so the development of normal speech is a principal goal of interventions for this population, starting with surgical procedures to correct the structural abnormalities. There is no universal agreement regarding the best surgical techniques and optimal timing of cleft palate repair to attain optimal speech and to avoid abnormal maxillofacial growth after repair (Howard & Lohmander, 2011) as the structural abnormalities and associated medical conditions varies from child to child. Surgery itself for many individuals with cleft includes a series of interventions over an extended time period, causing structural and functional changes to the speech apparatus throughout the period of speech development (Vyas et al., 2020). However,

some proportions of the structural and functional abnormalities CLP children were born with may persist after surgical intervention. Hence, these structural differences and changes can significantly impact speech development and speech production in CLP children and adolescents.

The impaired production of speech, abnormal nasality, nasal air emission, nasal turbulence, and speech quality are the principal speech disorders associated with CLP (McWilliams et al., 1990). Hypernasality in speech is the most common resonance disorder resulting from the VPI in this group. Speech characteristics of cleft speech include resonance, articulation and phonatory disorders (Van Lierde et al., 2010). Abnormal consonant production can adversely affect overall speech intelligibility. Hence, speech intelligibility is an important parameter in cleft palate intervention. The success of cleft palate surgery in children is determined by overall intelligibility and subsequent speech characteristics (Van Lierde et al., 2010). According to previous published studies exploring speech outcome of children with CLP, a high variability of intelligibility has to be anticipated. However, Sell et al. (2017) reported that the use of intelligibility alone as an outcome measure in speech studies is controversial with its definition, difficulties in its application and dependency on the nature of the listener. As a result, in addition to research studies that have speech intelligibility as the primary focus, many other studies within the field of CLP use, intelligibility as an outcome measure to evaluate different surgical techniques, the timing of surgery, speech therapy, or other treatment interventions may use a variety of speech outcome measures, including physiological, instrumental, and perceptual (Whitehill, 2002).

Copeland (1990) described one hundred participants following very early palate repair (before 6 months) in terms of intelligibility using audio recorded speech samples at 5-

year clinical review rated by the reviewing speech therapist. He described the features of articulation, nasality and nasal escape separately as these may have a significant effect on overall intelligibility. The terms “acceptable” and “unacceptable” were used to describe the degree of intelligibility. Results showed that 87 participants had “acceptable” speech; 58 were “very easy to understand and 29 were “easy to understand”. Thirteen participants had “unacceptable” speech; seven were difficult to understand and six were very difficult to understand. Moreover, six participants had symptoms of VPI, nine were considered to have poor articulation, nine had moderate to severe nasal emission and seven had moderate to severe nasality.

Sell et al. (2001) summarised the speech outcomes in two hundred and sixty-eight, 5-year-old and two hundred and sixty-seven 12-year-old children and adolescents born with unilateral cleft lip and palate in the UK using standardised audio-video recorded speech samples. Speech intelligibility was analysed using a five-point scale and results indicated that majority of 12-year-old (81%) were judged to have intelligible or slightly different speech that was unlikely to cause a comment, despite one fifth (19%) of five-year-olds were judged to have speech that was “only just intelligible to strangers” or impossible to understand. They also reported nasality and consonant errors. Overall, half of the 5-year-olds and 20% of the 12-year-olds had speech that was different enough to provoke comment even with speech and language therapy interventions.

Van Lierde et al. (2002) measured and compared the effect of a unilateral cleft lip and palate and bilateral cleft lip and palate on overall speech intelligibility, nasalance and nasality including thirty-seven children and adolescents aged 4 years to 16.11 years with normal cognitive and motor functions and normal hearing levels. Both subjective

and objective assessments were used to assess cleft types of effect on speech intelligibility including a perceptual analysis of connected speech of each subject by three speech and language pathologists. Speech intelligibility was rated as significantly poorer than normal in both cleft type subjects, although no difference in overall speech intelligibility according to the cleft type was found.

Hodge and Gotzke (2007) evaluated the construct and concurrent validity of speech intelligibility probe in children with cleft palate using five children with cleft palate (age range; 39 to 82 months) and ten children with typical speech development without any craniofacial abnormalities. Each child was asked to imitate single words and a 100 word sample of spontaneous speech also recorded. The results showed that the group of children with cleft palate had significantly lower intelligibility scores. Further there was a strong positive correlation was found between the intelligibility scores from the intelligibility probe (cleft palate group) and spontaneous speech sample.

Azadeh et al. (2016) evaluated speech intelligibility in 3 - 5 years children with repaired CLP who had not received any SLT early intervention. The speech of thirty-two Persian children with repaired CLP compared with age and sex matched control group. Speech intelligibility was assessed using Persian single word Speech Intelligibility test validated for 3–5-year-old children. The study findings highlighted that 3–5-year-old children with repaired CLP who had not received any SLT intervention had moderate speech intelligibility. Intelligibility analysis results further revealed that more than half of the subject's speech was unintelligible to the listeners. 90% of the children with cleft palate had mild to severe hypernasality and there was a strong relationship found between the severity of hypernasality and speech intelligibility in children with CLP.

The above studies provide evidence that speech intelligibility is affected in a proportion of children with CLP even after surgery and other multidisciplinary interventions. CLP individuals with structural deficits may have significantly reduced intelligibility in speech due to hypernasality, audible nasal air emission and weak oral pressure consonants. Even though the primary aim of the surgical and therapeutic intervention of individuals with CLP is improvement in speech intelligibility, several other factors such as presence of oral nasal fistulae, hearing impairment, dental abnormalities, misarticulation, velopharyngeal inadequacy and learning difficulties may affect speech production and impact intelligibility (Whitehill & Chau, 2004). Hence, the individual's speech intelligibility will be determined by these individual factors and the interaction of these can directly affect speech intelligibility.

Assessing speech intelligibility in children with CLP is a principal procedure as it can evaluate the surgical and therapeutic intervention success, estimate the overall speech production capability of an individual with CLP and signpost professionals for further treatments. The perceived speech quality is the main criterion for evaluating the speech outcomes following surgical or therapeutic management procedures in children with CLP. Gnanavel (2012) (p-33) emphasised "*The perceptual speech assessment is a global measure to judge the presence of nasality or other speech problems*". They also pointed out scaling measures and item identification tasks as most frequently used measures to assess speech intelligibility. In clinical settings speech and language therapists mostly evaluate speech in CLP children using the auditory-perceptual method.

A systematic review on methods of assessing speech intelligibility in individuals with CLP was conducted by Whitehill (2002). The keywords for this study search were

“intelligibility” and “cleft.” She identified 57 articles on methods of assessing intelligibility in individuals with CLP. According to the results, only two studies focused specifically on intelligibility. Thirty-eight articles (66.7%) used intelligibility as the speech measure of interest. Almost half of the studies (47.4%) utilized a rating scale as a method of measuring speech intelligibility in CLP. The length of rating scales used ranged from 3 to 10, but a seven-point rating scale was the most frequently used (40%). Eight studies (14%) used another global measure such as severity, speech acceptability, speech proficiency and eleven studies (19.3%) used articulation measures to measure the speech outcome. Her study highlighted that there have been improvements over the years in measuring speech aspects of speakers with CLP and emphasized the importance of valid and reliable measures of speech performance such as speech intelligibility.

3.3 Speech Intelligibility and International Classification of Functioning, Disability and Health (ICF)

Reduced intelligibility can significantly affect the overall quality of speech. Traditionally assessment and intervention with children with a speech impairment has focused on the level of impairment (McLeod & McCormack, 2007). The WHO’s International Classification of Functioning, Disability and Health (ICF) and the derived version for Children and Youth (ICF-CY) in 2007 (World Health Organization, 2007), recognise the role of environmental factors in the creation of disability as well as the relevance of associated health conditions and their effects. This model ensures the holistic understanding of people in context. Applying ICF and ICF-CY to children with speech impairment requires consideration of every component:

body functions, body structures, activities and participation, environmental and personal factors (McLeod & McCormack, 2007). Considering speech intelligibility is influenced by two factors: production factors (body functions) and contextual factors (environmental factors). McLeod et al. (2012) highlighted that the previous research in intelligibility only focused only the production factors but both production and contextual factors are equally important when aiming to holistically document children's intelligibility.

3.4 Intelligibility in Context Scale (ICS) (McLeod, 2012)

The ICS is a parent reporting subjective rating scale of how well their child's speech is understood in daily life by different communication partners. Thus, it aims to capture "activities" and "participation" level functioning within the ICF framework (McLeod, 2015). The ICS assesses functional intelligibility, by asking parents or caregivers to rate their children's intelligibility in relation to seven communication partners differing in levels of authority and familiarity. Communication partners are parents themselves, immediate family, extended family, friends, acquaintances, teachers and strangers. It consists of a five-point rating scale to mark the degree of intelligibility for each listener: 5 (always), 4 (usually), 3 (sometimes), 2 (rarely), 1 (never). The ICS is a relatively quick scale to use, all seven questions must be answered, producing a maximum possible score of 35. An average score is then reported for the seven items, with a higher total score indicating a higher speech intelligibility rating (McLeod et al., 2012). The original ICS (English) questionnaire has high internal reliability ($\alpha = .93$), construct validity and sensitivity (McLeod et al, 2012) and it has been translated into 60 languages to date, including Arabic, German, Russian, Welsh, Finnish, Chinese

and was shown to be reliable and valid in cross-cultural adaptations (McLeod, 2020). To date, there are 18 published validation studies of the ICS (Table 3.1) of 4235 children and adolescents in 14 countries speaking 14 languages (McLeod, 2020). SLTs find the ICS is an easy tool to use and a useful component of the assessment process, especially where communication barriers exist between the SLT and the parents/carers (Pascoe, 2016).

Though the ICS has been mainly used with pre-school children, there is evidence to support that the ICS can be used within the older age groups to measure intelligibility (Hashemi Hosseinabad et al., 2021; Hopf, 2017). Furthermore, ICS is used in studies involving atypical children and found to be a valid and reliable tool. The ICS has been used as a screening and outcome measure in research studies involving children with speech sound disorders (Cleland et al., 2023; McLeod & Verdon, 2017), children with cleft lip and palate (Hashemi Hosseinabad et al., 2021; Seifert et al., 2021) and with adults who speaks other languages (Blake et al., 2020).

Seifert et al., (2019) analysed 412 completed ICS responses from mothers of 3-year-old children with cleft palate. The participants were recruited from the Cleft Collective British Cohort study (bristol.ac.uk/cleft-collective). The average age of a child at response was 38 months (SD=2.06). The mean average ICS score for all cleft subtypes was 3.75, SD=0.76 (sometimes-usually intelligible) of a possible score of 5 (always intelligible). Children's speech was reported to be most intelligible to their mothers (M=4.33) and least intelligible to the strangers (M=3.36). There were variations reported in intelligibility across different cleft subtypes. Moreover, this study concluded that children born with a cleft lip palate associated with a syndrome were found to have low intelligibility when compared to the non-syndromic cleft lip and

palate children. The ICS therefore shows potential as a suitable tool for measuring intelligibility in CLP.

Moreover, Hashemi Hosseinabad et al. (2021) used ICS in a prospective study with 20 Native American English-speaking children and adolescents aged 4-12 years with different degrees of VPI due to different cleft types. In this study parents' intelligibility ratings were correlated with speech pathologists' ratings and the study results emphasized that ICS is a relatively accurate and practical measure of speech intelligibility in children and adolescents with VPI.

“Parental concern about speech is a good indicator of speech status” (Sell et al., 2017, p27). In Sri Lanka cleft lip repair is normally carried out sometime between birth - 6 months and palate repair typically takes place between 9 - 12 months depending on the child's other medical conditions. Even with these surgical corrections, many children with cleft palate continue to experience difficulties with speech. Speech and language therapy is a young profession in Sri Lanka and there are limited cleft specialised SLT's available within the country. Children with CLP visit specialised cleft centres where multidisciplinary support is available and cleft specialised therapists will not see them very often. Thus, parents' perspective about their child's speech intelligibility is a helpful measure for the SLT's to get an idea about child's functional speech in day-to-day contexts and develop a working hypothesis to plan intervention.

The International Consortium for Health Outcomes Measurement (ICHOM) was set up to design a standard set of outcome measures that aim to encompass the cleft palate and its complexities (Apon et al., 2021). They considered the importance of measuring

intelligibility and recommend the use of the ICS (McLeod et al., 2012). To date there is no parent reporting intelligibility screening tool in Sinhala available for cleft services in Sri Lanka to use.

Sinhala is an Indo-Aryan Language, written in the Sinhala script. It has around 16M speakers, mostly concentrated in Sri Lanka. There are few validated questionnaires or standardised assessments for the evaluation of speech in Sinhala. There is only one published assessment: the Common Token Test (COT), a measurement of speech perception in children with cochlear implants (Jeyaraman et al., 2016). There are also few single-word articulation or phonology assessments validated in Sinhala for different age groups. It is therefore clear that an easy-to-use parent/carer reported measure of intelligibility translated into Sinhala for use with speakers with CLP, and potentially other types of speech sound disorder, would be a valuable addition for SLTs and researchers in Sri Lanka. Furthermore, there are no validation study evidence available using ICS in adolescents with CLP and this will be the first study to address this gap. The current study is a translation and validation of the ICS into Sinhala, the main language spoken in Sri Lanka.

Table 3.1: Summary of the psychometric properties of Intelligibility in Context Scale (ICS) across eighteen studies.

Author (year)	ICS language	Participant's country & spoken language(s)	Age range (years)	Sample size (N)	Typical Sample size	Atypical sample size	ICS total mean (SD)	ICS Typical mean (SD)	ICS Atypical mean (SD)	Internal reliability	Construct validity
(Ng, 2014)	ICS: Traditional Chinese	Hong Kong, China Cantonese	3;0-6;0	72	39	33	-	4.56 (0.48)	4.14 (0.65)	-	range $r = .56$ to $r = .89$, $ps < .001$
(Ching Eugena Kok & To, 2019)	ICS: Traditional Chinese	Hong Kong, China Cantonese	2;4-6.9	789	642	147	3.96(0.71)	4.03 (0.70)	3.63 (0.66)	-	-
(Tomić & Mildner, 2014)	ICS: Croatian	Croatia Croatian	1;2–7;3	486	-	-	Parents 4.44(0.59) Teachers: 4.52 (0.62)	-	-	$\alpha = .98$	-
(Van Doornik et al., 2018)	ICS: Dutch	The Netherlands Dutch	4;0–6;11	67	48	19	-	4.50 (0.44)	4.01 (0.56)	-	-
(McLeod et al., 2012)	ICS: English	Australia English	3;11–5;8	120	11	109	-	4.69 (0.51)	3.85 (0.49)	$\alpha = .93$	range $r = .48$ to $r = .86$, $ps < .001$
(McLeod, 2015)	ICS: English	Australia English	4;0–5;5	803	525	278	4.4 (0.7)	4.6	3.9	-	-
(Hopf, 2017)	ICS: English	ML-Fiji, Fiji English (FE)	5;3–10;5	65	-	-	ML: 4.6 (0.6); FE: 4.4 (0.5)	-	-	ML: $\alpha = .83$; FE: $\alpha = .79$	ML: $r = .31$ to $.78$, all $ps < .05$; FE: $r = .29$ to $.68$, all $ps < .05$
(Washington, 2017)	ICS: English	Jamaica English (E) + Jamaican Creole (JC)	3;3–6;3	145	145	-	-	E: 4.43 (0.63)/ JC: 4.50 (0.56)	-	$\alpha = .91$	range $r = .42$ to $r = .81$, $ps < .001$

(Sprunt & Marella, 2018)	ICS: English, Fijian, Fiji-Hindi	Fiji Not reported	5–15	463	257	71	-	4.0–5.0	1.0–2.43	-	-
(Neumann et al., 2017)	ICS: German	Germany German	3;0–5;11	181	151	30	4.40 (0.76)	4.49 (0.47)	3.97 (0.63)	$\alpha = .94$	$r = .71$ to $r = .93$ $ps < .001$
(Piazzalunga et al., 2020)	ICS: Italian	Italy Italian	3;0–5;11	364	356	8	Mothers: 4.51 (0.47) Fathers: 4.46 (0.50)	-	-	Mothers: $\alpha = .918$ Fathers: $\alpha = .917$	Mothers: $r = .409$ to $r = .847$ Fathers: $r = .465$ and $r = .871$
(Lee, 2019)	ICS: Korean	Korea Korean	2;6–6;5	178	145	33	4.46 (0.59)	4.64 (0.41)	3.67 (0.62)	$\alpha = .945$ range $r = .541$ to $r = .827$	range $r = .656$ to $r = .943$, $ps < .001$
Kim et al. (2016)	ICS: Korean	New Zeland Korean	3;0–5;11	33	33	-	4.44 (0.42)	4.44 (0.42)	-	-	-
(Lousada, 2019)	ICS: European Portuguese	Portugal Portuguese	3;11–6;2	76	51	25	4.50 (0.60)	4.78 (0.36)	3.91 (0.59)	$\alpha = 0.96$	-
(Kogovšek & Ozbič, 2013)	ICS: Slovenian	Slovenia Slovenian	1;6–6;6	104	-	-	4.56 (0.51)	-	-	-	-
(Lagerberg et al., 2021)	ICS: Swedish	Sweden Swedish	4;1–10;1	30	-	30	-	-	3.99 (0.64)	‘moderate to strong’ $r = .56$ – $.90$	$r = .40$, $p < .05$
(Phạm, 2017)	ICS: Vietnamese	Viet Nam Vietnamese	2;0–5;11	181	148	33	4.43 (0.62)	4.63 (0.67)	3.96 (0.70)	$\alpha = .94$	-

3.5 Summary

Intelligibility can be considerably reduced as a consequence of having CLP. In clinical settings, speech intelligibility is an important measure to determine both plans for intervention and to evaluate outcome measures in children and adolescents with CLP. Several methods have been used to measure intelligibility in speakers with CLP and rating scales are quite a popular method among those. ICS is a parent reporting scale focusing on perception of intelligibility of their child's speech by different communication partners. It has been translated into more than 60 languages to date with high validity and reliability in 18 published studies across the world. The ICS rating scale has been previously used with studies included CLP children and adolescents, hence chosen for translating and validating for use in Sri Lanka.

4 LITERATURE GAP

4.1 QoL findings in Sri Lankan young children & adolescents with CLP

This narrative review was not able to identify any QoL studies based on adolescents with CLP in Sri Lanka. However, a grey literature search was conducted to find available reports. There are only a handful of studies conducted in Sri Lanka to explore the QoL in CLP children and adolescents to date. Prabodha et al. (2012) investigated the psychological status of children aged over 5 years with CLP in the southern part of Sri Lanka and reported psychological problems associated with CLP, such as fear of talking in public, aggressive behaviour, and unusual behaviour. Their study further emphasized the importance of addressing psychological aspects of people with CLP, alongside surgical treatments to enhance their quality of life. In addition, K. Senavirathne et al. (2022) reported that speech problems were the most common disability in children with CLP, hence a multidisciplinary approach is vital. PedsQL, a HRQoL measurement was validated into Sinhala, but this was only tested with children with medical conditions such as Asthma. The PedsQL-Sinhala questionnaire has to date not been used with children and adolescents with craniofacial conditions in Sri Lanka.

4.2 Paediatric Quality of Life Inventory (PedsQL) -

Sinhala

The PedsQL is a 23-item short, practical, generic Health Related Quality of Life (HRQoL) measure suitable for use with healthy children and adolescents and those with acute and chronic health conditions. This is a validated instrument published by Varni et al. (2001) and consists of parent and child forms that assess five domains of health: physical functioning, emotional functioning, psychosocial functioning, social functioning, and school functioning in children and adolescents ages 2 to 18. The PedsQL measurement model consists of developmentally appropriate forms for children ages 2-4, 5-7, 8-12, and 13-18 years. In this assessment, the paediatric self-report is measured in children and adolescents aged 5-18 years, and parent proxy-report of child HRQOL is used for children and adolescents ages 2-4 years. The PedsQL scales have already been translated into multiple languages, including Sinhala, the principal language spoken in Sri Lanka for the use with adolescents aged 12-15 years old (Danansuriya & Rajapaksa, 2012).

Oral health related quality of life measurements such as the Oral Impact Daily Performance (OIDP) and Short Form of Child Health Questionnaire 11-14 (CPQ 11-14) were translated and validated into Sinhala, however none of these were validated with the CLP population or used in the studies including CLP participants. The OIDP contains only eight questions to record oral impacts on an individual's ability to perform eight daily activities. As this is a relatively short questionnaire, a detailed questionnaire that includes different QoL domains would be of benefit to identify QoL issues in adolescents with CLP. Hence, this study's results will contribute to

addressing this gap by investigating the QoL in CLP adolescents' population and validate a OHRQoL questionnaire for adolescents with CLP in Sri Lanka.

According to the narrative review findings, it was highlighted that a condition specific QoL measure is more sensitive in identifying more issues related to QoL in children and adolescents with craniofacial conditions. OHRQoL questionnaires contains questions that directly connect to the issues associated with the oro-facial condition, hence, a person with CLP finds that questions are more related to their condition and highlight concerns relevant to them. The narrative review results identified COHIP as the most frequently used oral health related QoL questionnaire with the CLP population. Therefore, this can be considered as a condition-specific questionnaire commonly used with adolescents with CLP that has not been translated into Sinhala. Even though, the OIDP and CPQ 11-14 oral health related questionnaires are available in Sinhala, these are relatively short. The CLEFT- Q (Klassen et al., 2018) is a condition-specific questionnaire that can be used with children and adolescents with CLP, however, it only includes one section on QoL. The QoL Adolescent Cleft questionnaire (QoL Ado Cleft) was identified as another condition-specific measure used with CLP. However, it's psychometric properties and feasibility of use across ages remains unclear (Ruiz - Guillén et al., 2022) as it was only tested with young adults with CLP aged 16-24 years. (Piombino et al., 2014) and is not much used in studies. Also, for the QoL-Ado-Cleft there are pre-surgical and post-surgical impacts to report as well. Thus, these two questionnaires not only focus on QoL in CLP and adolescents may find them difficult to complete. Therefore, COHIP was found to be a detailed, QoL focused questionnaire that is suitable for the need in Sri Lanka. Moreover, it was argued that condition-specific assessment is more appropriate to use

when assessing QoL in adolescents with CLP as it can capture condition related health issues better than a generic HRQoL. The generic QoL assessment - PedsQL is validated into Sinhala, however, it can only capture limited issues relating to oral health in CLP. Hence, it is extremely beneficial to validate a condition specific QoL assessment to use in the Sri Lankan context as there are none validated with adolescents with CLP to date. Hence, COHIP is chosen for the translation and validation as a condition-specific measure to use with CLP adolescents given these reasons.

4.3 Child Oral Health Impact Profile (COHIP)

Child Oral Health Impact Profile is an instrument that was developed by Broder and Wilson-Genderson (2007) to measure oral health-related quality of life in children and adolescents. It measures oral health, functional-well-being, socio-emotional well-being, school environment and self-image as well as the overall oral health related quality of life of the child (Broder & Wilson-Genderson, 2007). The COHIP contains 34 questions: 28 questions on negative impacts and six questions on positive perceptions of oral health and health outcomes (Y. S. Ahn et al., 2012) divided over five subscales. The COHIP questionnaire was designed to be used from 8 to 15 years across various oral health conditions including CLP (Broder and Wilson-Genderson, 2007). The psychometric properties of the English instrument were tested in children and adolescents between the ages of 8 and 15 years old in the United States and Canada (Broder & Wilson-Genderson, 2007). The reliability and validity of this instrument has been established across a wide age range (8-15 years), different ethnicities and various oral health conditions (Broader & Wilson-Genderson, 2007). It has been translated

into several languages including Dutch (Geels et al., 2008), French (Osta et al., 2015), Korean (Ahn et al., 2012), Persian (Asgari et al., 2013), Vietnamese (La et al., 2021). With consideration of issues important to craniofacial and/or orthodontic needs including confidence and attractiveness and a specific dimension for school environment (Osta et al., 2015), the COHIP is the most widely used health related QoL self-report questionnaire within the CLP population (Broder & Wilson-Genderson, 2007; La et al., 2021; Li et al., 2014; Osta et al., 2015).

This instrument is important compared to the other health related quality of measures because it includes positive aspects of OHRQoL such as confidence and attractiveness (Osta et al., 2015). Moreover, the COHIP includes a specific dimension (the school environment) that is well suited to evaluate OHRQoL in school aged children. As this instrument has shown its ability to discriminate children and adolescents between groups depending on their experience of dental decay and their perceptions about appearance (Osta et al., 2015) this measurement is well suited to use with children and adolescents with oral-facial differences. The transcultural adaptation of this instrument will be discussed in Chapter 5-7 and the validity and reliability of the COHIP Sinhala translation will be discussed in Chapter 8-10 of this thesis.

4.4 Speech related quality of life impacts in CLP individuals

Most individuals with CLP will have problems with speech and language development, hearing, dentures, or facial appearance at some point in their lives. Amongst these impacts, it is speech development and production which can be most

significant and cause problems with day-to-day communication. Speech disorders in CLP affect mainly articulation, resonance and voice (Nagarajan et al., 2009). Due to the structural abnormalities, even after surgeries, individuals' speech can be characterised by speech production errors, nasal emission, hypernasality, hyponasality, nasal turbulence and nasal grimace (Bruneel et al., 2017). The underlying cause of most of these speech errors is velopharyngeal insufficiency which is caused by inadequate velopharyngeal closure due to anatomical or structural differences caused by CLP. These speech related issues result in the individual's speech being unintelligible, or perceived as different, to listeners. This can limit their social interaction and communication participation and can negatively impact their QoL. Sell et al. (2015) pointed out that approximately 20% of children with CLP had unintelligible or barely intelligible speech at the age of 5 years and 4% were unintelligible at the age of 12 years (Sell et al., 2001). Bruneel et al. (2019) highlighted that targeting speech features in therapy leads to the greatest impact on patients' HRQoL. Hence, measuring speech intelligibility is valuable as it evaluates severity of the impact of speech difficulties, as well as contributing to outcome measurement. Perceptual speech analysis based on phonetic transcription has been considered as the "gold standard" approach in the past, but this has limitations as is strongly listener dependent. In healthcare, the current trend focuses on providing patient centred care. For care to be patient centred we must capture patients', or, where appropriate their parents/carers perspectives using patient outcome measures. Therefore, it is vital to have standardised measures in clinical practice to gather information to facilitate patient oriented care. The ICS is a commonly used rating scale to measure intelligibility in children with communication impairments. The ICS was developed

by McLeod et al. (2012) in accordance with the ICS-CY environmental factors to take account of the range of contexts / listeners and communication partners with whom children communicate. McLeod et al. (2012) stated that *“Specifically, the seven items of the ICS draw on the relevant contexts identified in Chapter 3 of the ICF-CY, “Support and Relationships”: “immediate family”; “extended family”; “friends”; “acquaintances, peers, colleagues, neighbours, and community members”; “people in positions of authority ... such as teachers”; and “strangers”* (World Health Organization, 2007, P.205)”. Therefore, ICS can be used as an assessment that gathers information about how well a child is able to convey their message to different conversation partners in a range of contexts. This questionnaire can be used by parents, teachers, or therapists to give an initial impression about the child’s speech and as a screen to administer further necessary formal assessments and intervention. Moreover, it can be used as a treatment evaluation measure. It is a short, straightforward questionnaire that parent/carers with basic language skills can administer in clinical settings or at home in a relatively short time. Therefore, this would be a good screening tool to use in SLT clinics in the Sri Lankan context.

4.5 Summary

The available reports from Sri Lanka highlight that the most common difficulty in the Sri Lankan CLP population is speech problems (Senavirathne et al., 2022). Again, there are not many reports, even in the non-peer reviewed literature, available regarding speech intelligibility in Sinhala speaking CLP children and adolescents. Thus, this area needs to be prioritised and a Sinhala speech intelligibility assessment as a screening tool and outcome measure will be an immensely useful tool in clinical

practice. The ICS is not validated into Sinhala to date; thus, translation and cultural adaptation of the ICS will address this gap and provide important findings about speech intelligibility in adolescent CLP population.

From these considerations, and based on the results of the narrative review, aim underpinning this study was to translate and culturally adapt the COHIP and ICS into Sinhala; test the reliability and validity of these measures; and investigate QoL in adolescents with CLP in Sri Lanka.

The research questions, research hypotheses, and null hypotheses are as follows:

4.6 Research questions, research hypotheses and null hypotheses

4.6.1 Research question (RQ1)

What are the psychometric properties (reliability, convergent and discriminant validity) of the COHIP-S in 12–15-year-old TD and adolescents with CLP?

Research hypothesis 1 (HO1)

COHIP-S translations will demonstrate acceptable psychometric properties; good reliability (defined by Cronbach's alpha above 0.7) and validity (face, convergent and discriminant validity) in order to consider them as appropriate tools to use with TD adolescents and adolescents with CLP in Sri Lanka.

Null hypothesis 1 (NH1)

COHIP-S translation will not demonstrate acceptable psychometric properties; poor reliability (defined by Cronbach's alpha below 0.5) and poor validity (face, convergent and discriminant validity) and not consider as appropriate tools to use with TD and adolescents with CLP in Sri Lanka

4.6.2 Research question (RQ2)

Does quality of life investigated using a condition specific oral health related quality of life assessment (defined by COHIP-S) differ between TD and adolescents with CLP?

Research hypothesis 2 (HO2)

There will be a statistically significant ($p < 0.05$) difference with TD scores $>$ CLP COHIP-S scores and the COHIP-S higher scores shows a better (condition specific) oral health related quality of life in TD and CLP in Sri Lanka.

Null hypothesis 2 (NH2)

There will be no statistically significant ($p > 0.05$) difference between TD and CLP COHIP-S scores ($TD \leq CLP$).

4.6.3 Research Question (RQ3)

Does quality of life investigated using a generic health related quality of life measure (defined by PedsQL-Sinhala) differ between TD and adolescents with CLP?

Research hypothesis 3 (HO3)

There will be a statistically significant ($p < 0.05$) difference between TD and CLP PedsQL-Sinhala scores ($TD > CLP$), indicating that CLP also experience issues assessed by a generic health related quality of life measure (higher scores indicate better QoL).

Null hypothesis 3 (NH3)

There will be no statistically significant ($p > 0.05$) difference between TD and CLP PedsQL-Sinhala scores ($TD \leq CLP$) indicating that adolescents with CLP are not experiencing issues assessed by a generic quality of life measure.

4.6.4 Research question (RQ4)

What measure is best suitable to assess quality of life related to the oro-facial condition in adolescents with CLP; generic (PedsQL-Sinhala) or condition specific (COHIP-S)?

Research hypothesis 4 (HO4)

The QoL information gathered by COHIP-S and PedsQL-Sinhala will positively correlate ($r > +1, p < 0.05$) to show that both questionnaires measure similar concepts, but the COHIP-S identifies more oral health related quality of life issues showing more sensitivity in adolescents with CLP.

Null hypothesis 4 (NH4)

The QoL information gathered by COHIP-S and PedsQL-Sinhala will negatively correlate ($r > -1, p > 0.05$) with each other to show that measurements are not measuring similar concepts, and COHIP-S will not be able to identify oral health related issues in the CLP group as a condition specific quality of life measure.

4.6.5 Research Question (RQ5)

What are the psychometric properties (reliability, convergent and discriminant validity) of ICS-SIN in 12–15-year-old TD and adolescents with CLP?

Research hypothesis 5 (HO5)

ICS-SIN translations will demonstrate acceptable psychometric properties; good reliability (defined by Cronbach's $\alpha > 0.7$) and validity (good face, convergent and discriminant validity) to consider as an appropriate tool to use with TD and adolescents with CLP in Sri Lanka.

Null hypothesis 5 (NH5)

ICS-SIN translation will not demonstrate acceptable psychometric properties; poor reliability (defined by Cronbach's $\alpha < 0.5$) and poor validity (face, convergent and discriminant validity) and not consider as appropriate tools to use with TD and adolescents with CLP in Sri Lanka.

4.6.6 Research Question (RQ6)

Do intelligibility ratings (defined by ICS-SIN score) differ between TD and CLP groups?

Research hypothesis 6 (HO6)

There will be a statistically significant ($p < 0.05$) difference in ICS-SIN TD scores > CLP scores indicating adolescents with CLP have low speech intelligibility.

Null hypothesis 6 (NH6)

There will be no statistically significant ($p > 0.05$) difference in ICS-SIN scores between TD and adolescents with CLP (speech intelligibility in CLP $\geq$ TD).

4.6.7 Research Question (RQ7)

Is there a correlation between parents' ICS-SIN ratings and the QoL in adolescents with CLP?

Research hypothesis 7 (HO7)

There will be a positive correlation ($r > +1$, $p < 0.05$) between speech intelligibility scores and quality of life scores in adolescents with CLP.

Null hypothesis 7 (NH7)

There will be a negative or no correlation ($r \geq -1$, $p > 0.05$) between speech intelligibility scores and quality of life scores in adolescents with CLP.

4.6.8 Summary

In order to answer the research questions 1-7, a two-stage study was necessary. The first stage (Chapter 5,6 and 7) of the study focuses on;

- Translation and cultural adaptation of the “Child Oral Health Impact Profile” (COHIP) (Broder & Genderson, 2007) into Sinhala, the principal language spoken in Sri Lanka.
- Translation and cultural adaptation of the “Intelligibility in Context Scale” (ICS) (McLeod et al., 2012) into Sinhala.

The questionnaires translated and culturally adapted as discussed in Chapter 5-7 were then used in the 2nd stage of the study (Chapter 8,9 and 10). Hence, results of stage one are necessary to complete before addressing research questions 1-7. There are no specific research questions associated with chapter 5-7 because translation and

adaptation assessments followed a standard procedure. Second stage of the study focused on exploring reliability and validity of the translated ICS and COHIP questionnaires and investigate QoL in adolescents with CLP. The research questions 1-7 will be answered in the second stage of this study.

5 TRANSCULTURAL

ADAPTATION PROCESS – Method

Introduction

The next three chapters of this thesis outline the procedure of translating selected English language assessments (COHIP & ICS) into Sinhala and applying appropriate cultural adaptations. Chapter 5 provides a description of the two English language assessments followed by a detailed description of the translation process undertaken. Chapter 6 presents the findings of this translation including any cultural adaptations applied to COHIP-S and ICS-SIN assessments. The final chapter (Chapter 7) discusses the findings of the translation cultural adaptation process followed by a conclusion and summary.

The first section of this chapter (5.1) describes the translation initiation process followed by the translation method (5.2) and details of the professionals involved in the translation process (5.3). Section 5.4 features information regarding assessment translation process. Finally, in section 5.5, process of piloting COHIP-S and ICS-SIN is described including the language and cultural adaptations applied after the process.

5.1 Initiation of the translation and cultural adaptation process

As discussed in the literature review, the lack of condition specific QoL and speech intelligibility assessments for the CLP population coupled with the challenges SLTs have been facing in order to conduct standardised assessments in clinical settings in Sri Lanka forms the underlying justification for translating and validating the English COHIP (Broder et al., 2007) and ICS (McLeod et al., 2012) into Sinhala. Subsequently, as shown in Figure 5.1, translation and cross-cultural adaptation processes were developed.

There have been measures developed in the English language intended for use in English speaking countries such as America, United Kingdom, Canada and Australia. Hence, questionnaires exist in a different language that measure both health related/oral health related impacts on individuals' QoL (COHIP, PedsQL, Cleft-Ado-QoL, OHP-14, SF-36) and speech intelligibility (ICS) were identified and the task of cross-cultural adaptation (translation, adaptation, and validation) into the new language was undertaken.

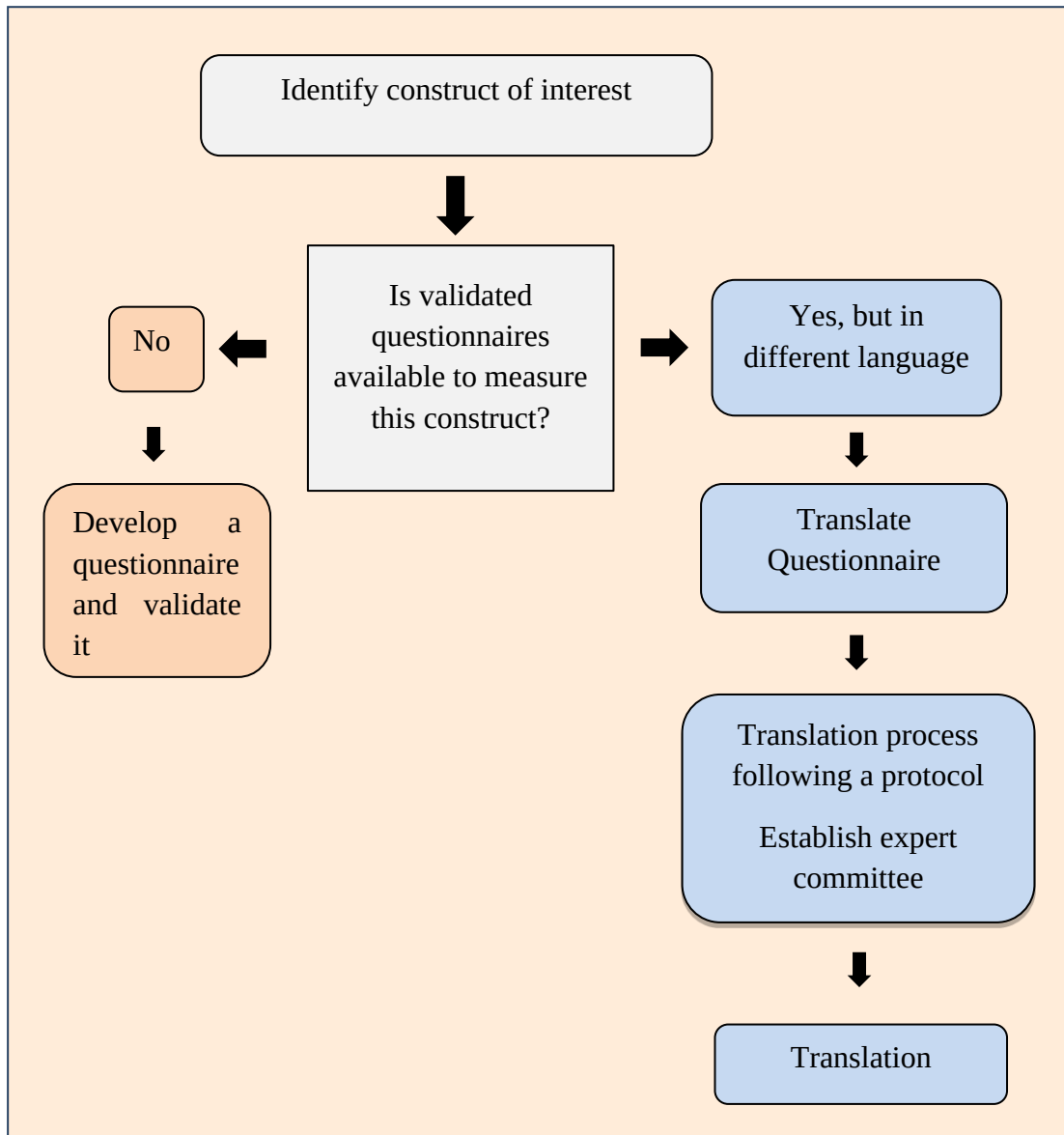


Figure 5.1 : Initiation and steps followed for the cross-cultural adaptation process

5.2 Translation Methodology

A cross cultural adaptation of any measure for use in a new country, language, or culture requires a distinctive and thorough methodology to reach an equivalence between the original source and the new language translation. Therefore, a simple translation process is unlikely to be successful because of linguistic and cultural differences (Guillemin et al., 1994). Hence, a systematic cross cultural adaptation

process as shown in Figure 5.2 is recommended by Guillemin et al. (1994) and WHO (2016). According to WHO (2016) guidelines (Appendix 7), the instrument should be equally natural and acceptable, and practical to perform in the same way to the original and the focus should be on cross-cultural and conceptual equivalence rather than simply linguistic. Hence, WHO (2016) state that use of forward translations and back-translations be employed by following these steps:

- Forward translation
- Back-translation
- Expert panel
- Pre-testing and cognitive interviews
- Final version

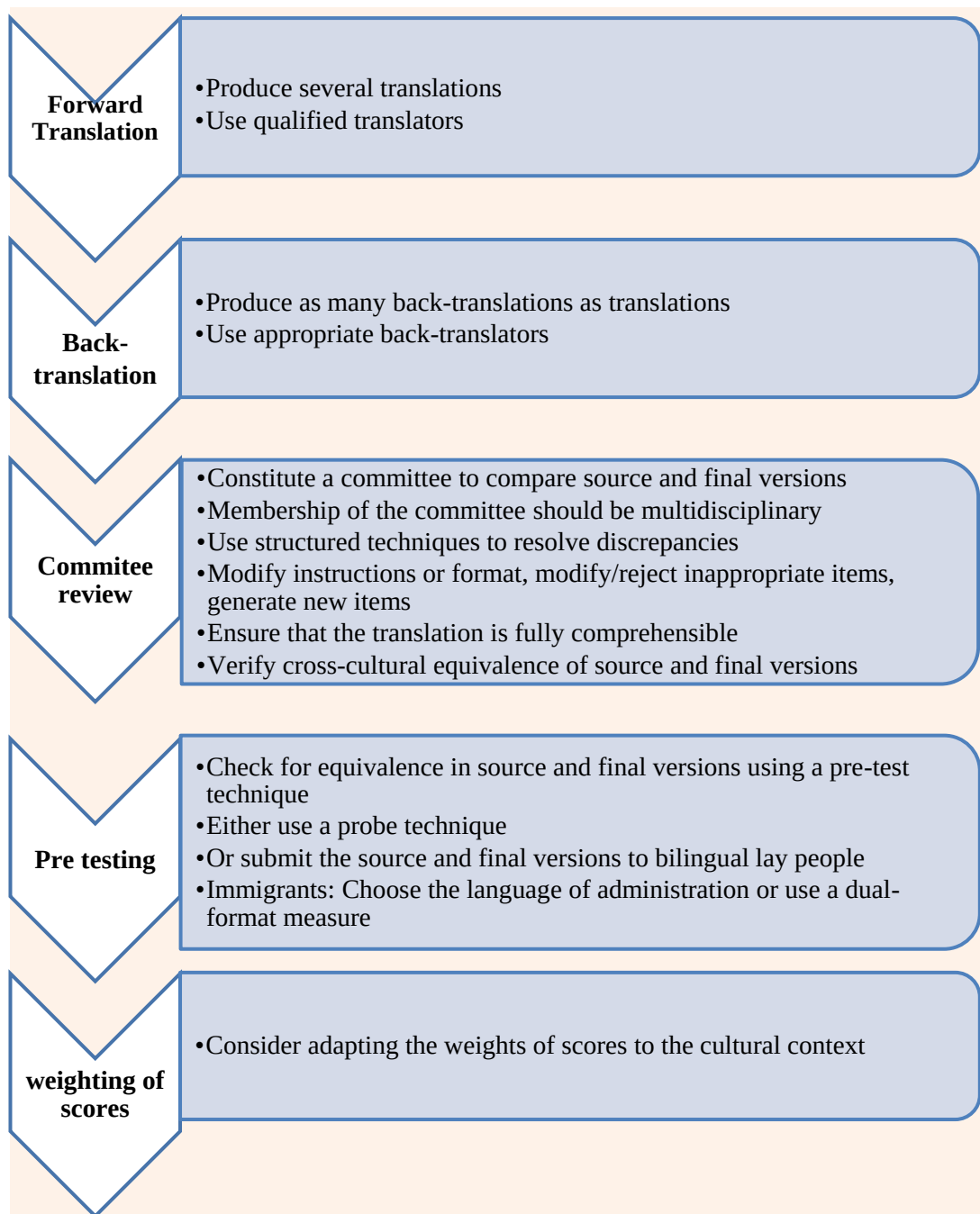


Figure 5.2 : Guidelines to preserve equivalence in cross-cultural adaptation of HRQOL measures Recommended by (Guillemin et al., 1994).

Firstly, the original COHIP and ICS questionnaires were translated into Sinhala following these cross-cultural translation and adaptation guidelines. Then, adaptations were applied to the questionnaire to meet cultural appropriateness. To ensure higher

quality translation, the initial translation should be undertaken by at least two independent translators (Guillemin et al., 1994; Tsang et al., 2017). In this study, three independent bilingual translators translated the questionnaire into Sinhala to better reflect the nuances of the target language (Tsang et al., 2017).

5.3 Translators

5.3.1 Forward Translators

The two forward translators (FT1 and FT2) were both speech and language therapists working in Sri Lanka. Both were fluent in Sinhala and English, with Sinhala their mother tongue. Both had been working in Sri Lanka as speech and language therapists for around twenty years. FT1 has experience working with young children and adolescents while FT2 with children and adults. FT1 was familiar with the concepts both questionnaires intend to measure, and discussion took place with investigator prior to the translation provided by FT1 to ensure that these concepts were clear. FT2 on the other hand was only somewhat aware of the concepts the questionnaires intend to measure but no discussion took place prior to their translation to allow for elicitation of unexpected meanings from the original tool.

5.3.2 Backward translator

A bilingual qualified speech and language therapist who has been working in the National Health Service, UK for 20 years was the backward translator. Their first language is English with fluency in Sinhala as a second language. The backward translator is a specialized therapist in neonatal feeding difficulties and was not familiar of the COHIP and ICS. To reduce bias, the investigator requested that they translate

the questionnaires item by item without reading the entire questionnaire before the translation. This step was to raise awareness of the intended concepts.

5.3.3 Expert committee

Expert committee consisted with two forward translators and a backward translator, who were involved in translation process, a medical consultant who has experience with working children and adolescents and their families with cleft lip and palate for more than 20 years in Sri Lankan hospital, and a teacher who has experience with working secondary school children and families for 10 years in a government school in Sri Lanka. The teacher and the medical consultant were not directly involved in the translation process of the questionnaire, but they were part of the expert committee to check the final translation version of the questionnaires for content validity and cultural appropriateness.

5.4 Assessment translation process

5.4.1 Obtaining permission for translation from original authors

Permissions are necessary prior to undertake any translation of published questionnaire tools. These were sought in relation to the COHIP (Appendix 8) and the ICS (**Error! Reference source not found.** The original authors of the COHIP, Hilary Broadner and the ICS, Sharynne McLeod were contacted to obtain permission to cross-culturally translate and validate the original English COHIP and ICS questionnaires into Sinhala. A collaboration account was set up with both original authors to check the backward English translation to ensure it matched the original measure and to then

make available the final COHIP and ICS Sinhala translations in the COHIP and ICS translation databases.

5.4.2 Translation process

A systematic approach was taken in translating the COHIP and ICS using the guidelines recommended by Gulimen et al. (1994) along with the protocol for translation and adaptation of instruments proposed by World Health Organization (2012). The questionnaires were translated according to *Forward-Backward- Forward* technique as illustrated in Figure 5.3.

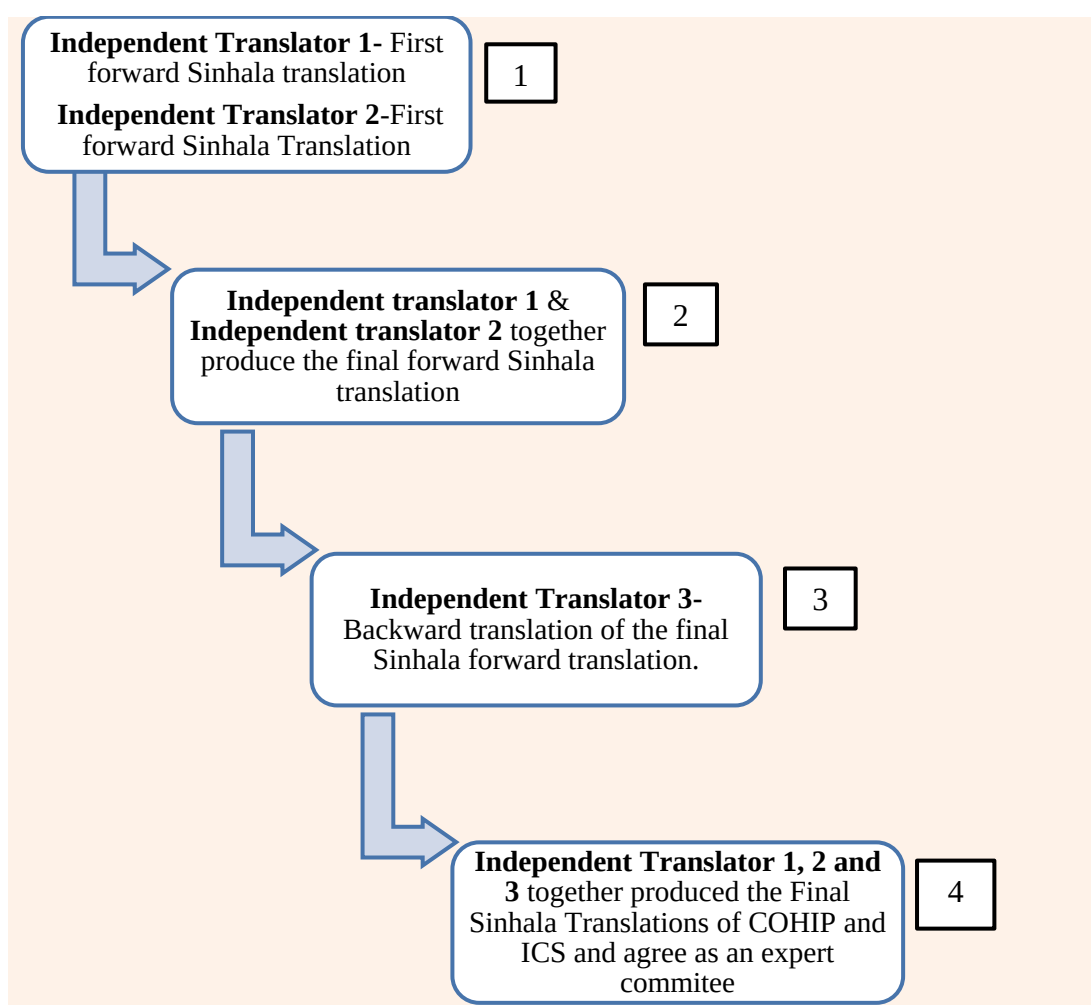


Figure 5.3: Translation process following forward – backward – forward method

5.4.2.1 Step 1- First forward Translations

The two forward translators translated the English COHIP and ICS questionnaires into Sinhala. These two translators produced independent forward translations which consisted of the entirety of the original; including, instructions and design as well as headers and footers. The translators followed the standard translation guidelines (WHO, 2012 & Gulimen et al., 1994) and considered linguistic and cultural factors throughout the translation process, using acceptable language for a broad audience, and ensuring that the meaning and concepts behind the original scale were preserved in the translated versions.

5.4.2.2 Step 2- Reconciliation step

The two forward translators together reviewed the two forward independent Sinhala translations. Discrepancies between the two translations were discussed and resolved. They then created a respective reconciled forward Sinhala translation, meeting all demands of linguistic and conceptual equivalence of the original English measures.

5.4.2.3 Step 3 – Backward Translation

The reconciled forward Sinhala translation was then independently back translated to English by the backward translator who was blind to the original English version to minimise bias and expectation. This was an important step to identify any discrepancies or inconsistencies that arose between the original English questionnaires and the forward final Sinhala translation.

5.4.2.4 Step 4 - Final Forward Translation

After the back translation was produced, all three translators reviewed the forward and respective backward translations and looked for any discrepancies between the original COHIP and ICS questionnaires. The discrepancies were then discussed, using structured techniques to overcome and agree on solutions leading to further refinements to generate the final forward Sinhala translation of the COHIP and ICS maintaining both conceptual equivalence (theoretical meaning and the idea or concept underlying the message) (Gulimen et al., 1994) while ensuring the questionnaires remained linguistically appropriate and fully comprehensible for a wide range of speakers.

Finally, a medical consultant and a teacher who were not involved in the translation process but recruited for the expert committee only were asked to check the final forward Sinhala translation for its cultural acceptability. As an expert committee all three translators, teacher and the medical consultant discussed and agreed on the final forward translation for its suitability and cultural appropriateness (Appendix 10 & Appendix 11).

The pre- testing step was applied to both COHIP and ICS Sinhala translations before applying it in the main study. Cognitive interviews (surveys to check whether the true meaning was conveyed to the respondent/ question is functioning as intended) were not conducted because of the time constraint issues, however, the expert committee decided on the cultural adaptations.

5.5 Piloting COHIP-S and ICS-SIN questionnaires

COHIP-S

The final forward Sinhala translation of the COHIP was piloted with 5 TD adolescents and 2 adolescents with CLP aged 12–15-year-olds. The TD participants were selected from the community, studied in local state schools and whose first language was Sinhala. The participants with CLP were selected from the Lady Ridgeway Hospital SLT clinic where the actual data sample was collected. The pilot study was used to check the equivalence in source and final versions of the COHIP-S questionnaires. The probe technique was used to check the face validity and confirm the questions were acceptable and understandable. Appropriate minor language and cultural adaptations were made to the COHIP-S before applying in the large study.

ICS-SIN

The final ICS-SIN questionnaire was piloted with parents of five TD Sinhala speaking adolescents aged 12-15 years old; parents of two Sinhala speaking adolescents with repaired CLP aged 12-15 years old; and five Sinhala speaking parents of younger children to check the equivalence in source and final versions. These participants were chosen as a representative match with the ICS study participant group and the general wider population. The probe technique was used to check face validity (by asking verbally) to confirm the questions were understandable. There were no changes made to the ICS-SIN questionnaire after piloting. The SLTs in the cleft clinic were consulted regarding the translation process and given the final ICS-SIN questionnaire. They were informed about the current evidence base for the use of the ICS in other languages with children with CLP and other speech sound disorders. The SLTs checked the

appropriateness of the language of the translated version, listened to parents' feedback on how easy the ICS was to use further confirm clinical feasibility of the ICS-SIN questionnaire.

5.5.1 Language adaptations applied after piloting

The sentence structure of the original questionnaire was changed to match with Sinhala syntax structure from question 15 to 30.

For Example:

- English – felt worried or anxious because of your teeth, mouth and face
- Sinhala - Because of your teeth, mouth and face, felt worried or anxious

5.5.2 Cultural adaptations applied after piloting

In the COHIP-S; the instruction 'Don't talk to anyone about the questions when you are answering them' (parents, other family members or friends as others/anyone) was modified. In Sri Lankan culture children and adolescents attend clinics with their parents or family members, so they may complete this questionnaire with the help of parents.

6 RESULTS

6.1 Applying cultural adaptations: COHIP-S Translation

In the COHIP-S final forward translation, no major changes were made in the questionnaire format or content of the thirty-four items. However, there were a small number of changes applied to wording as outlined below Table 6.1 to achieve cultural appropriateness. Some Sinhala dictionary version words were replaced with more user-friendly synonyms to make it easier for the adolescents to read and understand. Sentence structure was changed in the Sinhala questionnaire throughout as in Sinhala the verb comes after the noun/adjective, but not before the adjective as in English.

E.g. – In English – “I felt nervous”

In Sinhala - /matə (I) nosansun bavak (nervous) dænuna:/(felt)

Table 6.1 : Cultural adaptations applied to COHIP-S translation

Question number	English word	Translated word	Sinhala	Explanation of the changes proposed
Throughout the questionnaire	Mouth	/kaʈə/		The Sinhala dictionary version word for the mouth is /mukəjə/ However, this word is not used often in the spoken language and was replaced with the informal word /kaʈə/, a synonym for /mukəjə/.

3	discoloured teeth	/durvarnə/ & /avəpəhæ/ /dat/	The word “discoloured” is directly translated as /durvarnə/, but some children may not be familiar with this. Hence the synonym /avəpəhæ/ (off-colour) was used with /dat/ (teeth)
4	Crooked	/dat vələ hædɔjə venas veema/	It was challenging to apply direct Sinhala translation of “crooked” in relation to teeth. So, the question was translated into Sinhala as “changes to the shape of the tooth”
	Spaces	/hiɔæs/	The synonym /hiɔæs/ was used to make it more meaningful instead of the direct Sinhala translation /iɔə/. When speaking about tooth /hiɔæs/ is more appropriate and used more in spoken language.
6	Bad breath	/kaɔə duŋad̃ə / & /kaɔə gad̃ə /	In Sinhala this is more meaningful as “bad smell while exhaling”. This was then further simplified and explained using two similar terms (bad and rotten smell in mouth) together.
11	“Biting off” and “chewing.”	/hæpi:mə/	Two words were replaced with one Sinhala word /hæpi:mə/ (chewing) as both biting and chewing have similar meanings in Sinhala.
	trouble	/apəhasutavəjə/	The direct meaning of the word “trouble”

			/karədərəjə/ was replaced with a word meaning “difficulties”.
14	“confident” and “happy”	/satutak saha a:tməvɪʃvɑ:səjak/	These two words were translated to Sinhala as two words – similar in meaning to “self-confident” in English.
16	“worried” and “anxious”	/kanassallak/	These English words both translate into one similar meaning Sinhala word /kanassallak/
19	“smiling” and “laughing”	/sinaha/	In Sinhala, words used for “smiling” and “smiling loud” are similar.
24	“look different”	/penumen venas bavə/	In Sinhala, the direct translation of “look different” is not sufficient to convey meaning, so it was changed to “look different in appearance”
26	“attractive”	/sit ædə ganna: sulu bavak/	Direct translation into Sinhala using the dictionary word /a:karʃənəjə/ for “attractive” is a complex word for adolescents and not used frequently in spoken language. Therefore, a phrase giving the same meaning as “attractive” was used in COHIP-S.
31	“teeth”	/dat pelak/	In Sinhala “teeth” reads awkwardly in this sentence, so it was phrased into words similar to “teeth line” in English.
32	“teeth”		as above

36	“nervous”	/nosansun bavak/	The Sinhala dictionary translation word was not used for “nervous”, but a similar spoken language word was used to make the question more age-appropriate user friendly.

6.2 Applying cultural adaptations – ICS-SIN Translation

The ICS-SIN followed the same structure as the original questionnaire and the final ICS-SIN was designed using the ICS standard template following the guidance by the original author. There were a few changes made in the wordings in ICS-SIN to make it culturally appropriate. In the ICS-SIN reconciled version, the word “friends” was translated as /mituran/ by forward translator 1 and /jahaluwan/ by forward translator 2. Both these words are synonyms for “friends” in Sinhala. /mituran/ is the direct translation of friends in English, but /jahaluwan/ is more frequently used in day today communication. Therefore, the most culturally appropriate and familiar term /jahaluwan/ was used in the translation, with a footnote indicating that it can be changed to the synonym /mituran/.

Similarly, two forward translators gave different words for “acquaintances”: /amuttan/ & /nadunəṇə əjə/, also synonyms in Sinhala. On this occasion, the Sinhala word “ammuttan” (slightly known/ known recently) was used in the questionnaire. The alternative /nadunəṇə əjə/ can be confused with the term “strangers”. Thus, it was not used in this question to make it clear to the parent and avoid confusion with the previous question “Do strangers understands your child?”. Again, this was specified

in a footnote in the ICS-SIN questionnaire as an alternative word to use for question seven of the ICS-SIN. In Sinhala, the verb writes after the noun. Moreover, the question form of a sentence comes at the end on most occasions. Hence, the grammatical structure of the original questions was adapted according to the rules of the Sinhala language.

E.g. – In English - Can you understand your child?

In Sinhala - /obəʔə (you) obe (your) daruvavə (child) te:rum gæni:məʔə (understand) puluwandə/ (can)

The backward translation of the reconciled translation was equivalent to the original source; therefore, no amendments were applied. In the last step, all three translators (FT1, FT2 and Backward) agreed on the assessment content (instructions, questions, scales) and the appropriateness of administering the assessment as a parent rating scale in the Sri Lankan cultural context. Moreover, a teacher and a medical consultant also included into the expert committee together with translators to check the cultural appropriateness.

7 DISCUSSION

This chapter contains the discussion of the translation and cultural adaptation process of the COHIP-S and ICS-SIN. Section 7.1 discusses COHIP-S cross cultural adaptations followed by ICS-SIN cross cultural adaptations (7.2). Then a short summary (7.3) for the results chapter is included followed by an introduction to the next stage of the thesis (7.4)

7.1 Discussion of the COHIP-S cross cultural adaptation

The overarching aim of chapter 5-7 was to translate and culturally adapt the COHIP into Sinhala, the principal language spoken in Sri Lanka. The original English COHIP was successfully translated and adapted into the targeted language “Sinhala” following the forward-backward-forward method. The COHIP-S translation and cultural adaptation process was similar to previous studies (Ahn et al., 2012; Minamidate et al., 2020). The French translation for 12-year-olds in New Caledonia (Osta et al., 2015) reported that no major changes were applied to the questionnaire's format, the contents of the items or wording despite a modification of the *Self Image* domain response wording (“strongly disagree”, “somewhat disagree”, “don't agree or disagree”, “somewhat agree”, “strongly agree”) to make it more understandable to children. In the Korean version (Ahn et al., 2012) a rigorous translation procedure was carried out including the forward-backwards-forward translation process (Guillemin et al., 1994) as followed in this study. The Amharic (Ethiopia) translation (Abebe et al., 2018) emphasized that some of the questions such as “Felt you were attractive” needed to be expressed differently based on culture and language. In this Sinhala translation, this

question was modified using a synonym for “attractive” to make it easier for the adolescents to read and understand. The direct translation word in Sinhala for “attractive” - /ɑ:kɑrfənəjə/ was not used as this word is slightly complex for children and adolescents. Therefore, a similar meaning phrase /sit ædə ganna: sulu bavak/ (good look, having pleasing features/ appealing to look) was used in the final Sinhala version. Gees et al. (2008) also highlighted the importance of formulating these questions when administering the COHIP in children with craniofacial conditions. The COHIP-S was designed using the same original English questionnaire structure, format and rating system. An expert committee finally checked the face validity and agreed the cultural appropriateness and suitability of testing and using within the wider Sinhala speaking population.

7.2 Discussion of the ICS-SIN cross-cultural adaptation

The ICS has been translated into over 60 languages so far, and the present study translation process and adaptations are consistent with the published other language translation reports. The translation method in this study followed the same techniques previously used in translation and validation research on the ICS, including those translations prepared by SLTs, phoneticians, linguists and accredited translators, available in over 60 languages (McLeod, 2020). The South African translations of ICS into 11 languages were also undertaken by SLTs using forward and back translation and community checking. The ICS-SIN was also produced using the forward-backwards-forward method by SLTs. The expert committee checked the final translation before piloting to complete the community checking step. In cross-cultural translations, it is more acceptable to use user-friendly words in the questionnaire than

the formal dictionary translations to make it easier to complete. Hence, in this study, the most user-friendly Sinhala words were used for “friends” and “strangers” (which are synonyms of the dictionary versions) after discussing between translators to improve comprehensibility. An analogous situation was reported in the Vietnamese translation (Pham et al., 2017), the words for “parent” and “child” in original Vietnamese translations were changed to make it more user friendly, and a revised Vietnamese version was used for the validation study. The ICS-SIN translation was checked by the original author with its back translation and verified that ICS-SIN translation is acceptable to use with children and adolescents in Sri Lanka. The ICS-SIN translation was sent to the original author to upload on the Charles Sturts University -Multilingual Children’s Speech (n.d.) website.

7.3 Summary

Chapter 5-7 of the thesis focused on the translation and cultural adaptation process of the COHIP and ICS questionnaires, meeting the first two aims of the thesis: (1) to translate and culturally adapt COHIP questionnaire into Sinhala and (2) to translate and culturally adapt ICS into Sinhala. In Sri Lanka, where speech and language therapy is a young profession, there is a lack of validated questionnaires or standardised assessments to evaluate quality of life and speech in adolescents with repaired cleft lip and palate. Therefore, a cross-cultural adaptation of health-related, speech-related measurements into Sinhala is very advantageous in improving the quality of care. In this study, the COHIP and ICS questionnaires were successfully translated into Sinhala using the forward-backward-forward method and a committee review, following the

cultural adaptation framework suggested by Guillemín et al. (1994). The questionnaire was then piloted, and further necessary adaptations were applied.

Having completed the translation process, it is important that both questionnaires are examined in the Sri Lankan context to ensure their psychometric properties remain stable. This aspect of the thesis will be explored in next chapters, along with a comparison of TD and CLP adolescents' responses.

7.4 Introduction to the 2nd stage of the study

The next chapters (Chapter 8-10) of this thesis focuses on research questions 1-7 (4.6).

The next part of this thesis focuses on examination of the psychometric properties of the COHIP-S (Appendix 10 & Appendix 11) and a comparison of quality of life and speech intelligibility between adolescents with CLP and same-age TD peers by analysing responses to generic and condition-specific quality of life and speech intelligibility assessments. Moreover, based on the results analysis, suitability of the condition specific quality of life questionnaire for adolescents with CLP is highlighted. Chapter 8 outlines the method of the second stage of this study including study design, study participants, inclusion and exclusion criteria and the procedures used to test the psychometric properties of the two translated assessments. This chapter includes a description of how the QoL comparison was made. Chapter 9 outlines the results, consisting of the findings of the psychometric analysis of the COHIP-S and ICS-SIN, the findings of the QoL comparison between CLP and TD and the association of QoL results with parental report of the speech intelligibility using the ICS-SIN. Chapter 10 discusses the findings of the psychometric analysis of COHIP-S and ICS-SIN and the QoL findings between TD and CLP followed by limitations in this study, clinical and

research contributions of the study and future recommendations. Finally, Chapter 11 of the thesis provides a conclusion to the thesis.

8 METHOD

8.1 Overview

The first section is the overview for the chapter (8.1). The next section describes the study design (8.2) followed by the materials (8.3) and ethics approval for the study granted from UK and Sri Lanka (8.4). Section 8.5 features information regarding study participants. The section further explains the inclusion and exclusion criteria of the participants and recruitment process. In section 8.6, the procedure of the study is outlined. Following that the steps taken to ensure data security and storage are explained (8.7). Thereafter, in section 8.8, the questionnaire scoring details and the analysis of psychometric properties of the translated COHIP-S and ICS-SIN are outlined. Moreover, this section outlines the QoL comparison analysis process between TD and CLP adolescents and correlation analysis of QoL and speech intelligibility in CLP adolescents. Finally, the chapter will conclude with a short summary section (8.9).

8.2 Study design

This study was conducted using a mixed method design. The translated and piloted COHIP-S and ICS-SIN questionnaires at the first stage of the study were used within a cohort of TD and CLP adolescents aged 12-15 years to check the psychometric properties of these questionnaires. The validity and reliability of both questionnaires were tested. The PedsQL-Sinhala generic questionnaire was used with the same cohort of TD and CLP participants to gather generic QoL data. Then a comparative study was

conducted to compare the QoL findings between TD and adolescents with CLP. The PedsQL-Sinhala and COHIP-S responses were compared statistically between TD and CLP groups to examine any differences in QoL, with those findings reported in chapter 7. Quantitative data analysis was conducted to find out the validity and reliability of the COHIP-S and the ICS-SIN questionnaires and the QoL of adolescents with CLP population in Sri Lanka. Second stage of this mixed method design study was designed to answer research questions 1-7 (4.6 Research questions, research hypotheses and null hypotheses).

8.3 Materials

- COHIP-S

The translated and culturally adapted COHIP into Sinhala.

- PedsQL-Sinhala

4.2 Paediatric Quality of Life Inventory (PedsQL) -Sinhala
Paediatric Quality of Life Inventory (PedsQL) -Sinhala

- ICS-SIN

The translated and culturally adapted ICS into Sinhala.

8.4 Ethical Approval for the study

8.4.1 Ethical permissions

Ethical permission to conduct this study was obtained from the School of Psychological Sciences and Health ethics committee at the University of Strathclyde (**Error! Reference source not found.**). Following this, a further ethics application was submitted to the Lady Ridgeway Hospital, Colombo, Sri Lanka ethics panel, requesting permission to recruit adolescents with CLP through the SLT clinics (Appendix 13). In addition, permission was obtained from the relevant government educational authorities in Sri Lanka to recruit typically developing adolescents. The study proposal was submitted to the provincial education office and permission was obtained to conduct this study in the school settings. Provincial educational directors informed their consent to school principals nominated by the investigator. School principals in the area were contacted by the researcher and those willing to conduct the study within their school were included in the study leading to the two schools included in the investigation. Evidence of ethical permissions granted from Lady Ridgeway Hospital is provided in Appendix 14. Relevant procedures were followed throughout the study including informing participants and their parents about the conduct of the study and gaining written informed consent for participation, data storage and anonymous publication purposes. Procedure of obtaining consent from participants is outlined in detail under each participant group recruitment subsections.

8.4.2 Obtaining permission from original authors

PedsQL - The Mapi Research Trust and Dr. James W. Verne was contacted by the researcher and obtained permission to use PedsQL Sinhala questionnaire for this study. Mapi Research Trust provided a link to download necessary originals and translations. Evidence of obtaining permission is provided in Appendix 15 and Appendix 16.

COHIP – Original author Dr. Hilary Broder granted the permission. Evidence of obtaining permission is provided in Appendix 8

ICS – Original author Professor Sharynne McLeod granted permission via e-mail and provided the standard template to type the final ICS Sinhala translation. A collaboration account was set up with her to check the final versions and upload this on the ICS translations data base (Charles Sturt University – Multilingual Children’s Speech, n.d.). Evidence of obtaining permission is provided in Appendix 9.

8.5 Participants

The participants for this study were 400 TD adolescents aged 12-15 years old, their parents and 45 adolescents with CLP aged 12-15 years old and their parents. The TD participants were recruited through two mainstream schools in two districts in the Western Province of Sri Lanka. The CLP participants were recruited through the Lady Ridgeway Children’s Hospital, Sri Lanka.

8.5.1 Lady Ridgeway Hospital for Children Sri Lanka

Lady Ridgeway Hospital for children is the largest free of charge government paediatric hospital in Sri Lanka. It's in the capital of Sri Lanka known as Colombo, where all peripheral hospital referrals are accepted for special treatments. Hence, it serves as the national referral centre for paediatric care in Sri Lanka and was once deemed to be the largest paediatric hospital in the South Asian region. This hospital is equipped with one of the largest cleft treatment units out of three established in the country. The cleft unit is resourced with all professional expertise such as plastic surgeons, orthodontists, oro-maxillo facial surgeons, speech and language therapists, nutritionists, specialist cleft nurses, audiologists, occupational therapists, and physiotherapists (Lady Ridgeway Hospital for Children, 2020). Approximately, 350 new CLP patients are seen in this institution annually for surgeries, multidisciplinary care and other follow up treatments.

8.5.2 Rationale for participant numbers and age

For the questionnaire validation, the sample size was decided following the suggestions by Charter (1999) which states that the minimum sample size needs to be larger than 400 to evaluate validity and reliability. In previous COHIP validation studies by (Broder et al., 2012; Li et al., 2014; Osta et al., 2015) the sample sizes ranged from 100 to above 1000. Most of those studies used a TD participant sample for validation and found COHIP as a valid and reliable tool to assess OHRQoL in 8–16 year olds.

In Sri Lanka, the PedsQL, generic QoL questionnaire has been already translated and validated into Sinhala with good reliability and validity (Danansuriya & Rajapaksa, 2012). The PedsQL-Sinhala was validated using a sample size of 142 healthy

adolescents aged 12-14 years and 115 adolescents aged 12-14 years, who attended asthma clinics (Danansuriya et al., 2011). Karunasekera et al. (2009) documented the prevalence of asthma is one in every five children aged 5-11 years old. Mahara Hettiarachchige and Silva (2015) documented the prevalence of around 20.4% in aged 13-19 years old young children in the Western province of Sri Lanka where this study was also based. The CLP prevalence is estimated at 0.83 per 1000 live births by Amaratunga & Chandrasekara (1983). Compared to the recent worldwide statistics the prevalence of CLP in Sri Lanka has been relatively low and when compared to the prevalence of asthma in Sri Lanka it's considerably lower. Therefore, in accordance with all the prevalence figures and previous QoL questionnaire validation study sample sizes, a sample size of 400 TD adolescents and 45 adolescents with CLP was chosen for this study. Furthermore, Speech and Language Therapy services are not widely spread throughout all areas of the country. Therefore, the aim of recruiting forty-five CLP participants was considered to be a pragmatic sample size that could be possible to recruit. As this is the first study measuring QoL in the CLP adolescent population in Sri Lanka, there are no previous statistics available to compare participant numbers. ICS is validated into 60+ languages so far and there are 18 published/norming studies available. Sample sizes of those studies were ranged from 30-803 including the typical and atypical children and adolescents aged between 1.2 to 15 years (McLeod, 2020). There were 33 atypical children included in ICS – Traditional Chinese validation (Ng et al., 2014), 19 in Dutch validation (Van Doornik et al., 2018), 30 in German Validation (Neumann et al., 2017), 23 in Korean validation (Lee, 2018). Typically developing samples ranged from 33 to 642 (McLeod, 2020). Even though, most validation studies included young children, the English-Fijian and

Fiji-Hindi validation study (Sprunt and Marella, 2018) included 257 typical children and adolescents and 71 atypical children and adolescents aged 5-15 years old. Though, the study targeted a bigger parents' sample of TD adolescents only 50 parents responded. The ICS was distributed among 45 parents of CLP adolescents and 40 parents returned the questionnaire. After applying exclusion criteria, only 38 were qualified for the analysis from anticipated 45. Thus, in this thesis, questionnaires completed by parents of 50 typical and 38 atypical (CLP) adolescents are included. These sample sizes are within the range of other published validation studies and considered to be an acceptable sample when consider the total population in Sri Lanka (22.16 million) and the low prevalence of CLP (0.83 per 1000).

8.5.3 Inclusion and Exclusion criteria

The inclusion and exclusion criteria applied for TD and CLP participant recruitment process is displayed in Table 8.1 and Table 8.2.

Table 8.1: Description of participant's inclusion criteria

Inclusion criteria	Justification	How determined
TD		
Speaking Sinhala as first language	The selected two mainstream state schools for data collection conducting all studies in the country's principal language, Sinhala. Hence, pupils who speak Sinhala as their first language will be studying in these schools	This was confirmed using the demographic information section about language spoken in questionnaires. The investigator verbally asked this from the participants and received confirmation before distributing the questionnaires.
Aged between 12-15 years	Adolescents who were younger than 12 or older than 15 because of their	looking at the date of birth and age details at the class register

	date of birth were not included.	
Healthy adolescents (no long-lasting medical conditions)	Healthy TD adolescents who did not report any medical conditions (eg-severe asthma, arthritis) that need any long-term medication and clinic follow-ups were included in the study.	This information was gathered by the investigator by asking verbally from adolescents and teachers. Also, parents were asked to inform this with consent forms.
Studying in a school, have sufficient language and literacy skills.	Adolescents who have enough language levels to read, understand and answer the questionnaire were chosen for the study.	This information was gathered from the class teacher.
CLP		
Speaking Sinhala as first language	Only Sinhalese speaking adolescents were included in the study as the questionnaire is printed in Sinhala.	This was confirmed looking at medical notes and further confirmed verbally before completing the questionnaire.
Aged between 12-15 years	Only between 12 years and 15 years were selected.	This information was gathered by checking the date of birth from medical notes.
Had surgical interventions at acceptable time periods	CLP adolescents who completed surgical procedures to repair their cleft in an acceptable time period were chosen for the study	This information was extracted from the participants' medical notes with the help of the speech and language therapist.
Studying in a school, have sufficient language and literacy skills.	CLP adolescents who attend school and have sufficient language and literacy skills to complete questionnaires by themselves were only included in the study.	This was confirmed by checking with the participants before completing the questionnaire.
Parents of TD and CLP participants	Only Sinhalese speaking as their first language	This was confirmed by verbally asking and looking at the

parents were recruited into the study.	questionnaire language spoken details.

Table 8.2 : Description of participants' exclusion criteria

Exclusion criteria	Justification	How it's determined
TD		
Having long lasting medical, dental, or syndromic conditions	TD adolescents with long term medical and dental conditions that require frequent hospital admissions and treatments were not considered for the study as those can be contributing factors to the quality of life.	This information was asked from the class teacher and adolescents. In some cases, clarification was provided by parents
Cognitive impairments or having read or writing difficulties (Dyslexia/ Dyspraxia).	TD adolescents identified as having cognitive impairments, dyslexia or dyspraxia and motor speech impairments such as dysarthria were not included either since reading and understanding the content of the question made up a substantial part of the study.	This information was requested from the class teacher.
Depression or other psychiatric conditions	Any participants who suffer from depression, or any other psychiatric condition/ or taking treatments were not included as these can directly impact their quality of life.	This information was requested from the class teacher.
CLP		
Presence of genetic syndromes with CLP	CLP adolescents who have associated syndromes were not considered for the study as their cognitive level may not be sufficient to understand the content of the questionnaires. Also, syndromes that can impact the appearance will result in extreme recordings in	This information was extracted from the participants medical notes with the help of the SLT.

	appearance related questions as this is not common to all participants.	
Had late primary repairs of cleft lip and palate	CLP adolescents who completed surgical procedures in their late childhood (such as primary lip and palate repair after five years) were not considered for this study as this can significantly affect their speech development that can directly cause problems with their quality of life and speech intelligibility.	These details were extracted from medical notes and speech therapy clinic records with the help of the SLT
Presence of cognitive impairments or reading and writing difficulties (Dyslexia, Dyspraxia)	CLP adolescents who do not have syndromic conditions but have cognitive impairments, dyslexia and dyspraxia are excluded as adolescents need reading and understanding skills to complete questionnaires.	These details were extracted from medical notes and speech therapy clinic records with the help of the SLT.
Depression or other psychiatric conditions	Any participants who suffer from depression, or any other psychiatric condition/ or taking treatments were not included as these can directly impact their quality of life.	These details were extracted from medical notes and speech therapy clinic records with the help of the SLT.
Parents	Sinhala is not their first language	This was confirmed by verbally asking and looking at the questionnaire language spoken details.

8.5.4 Details of TD participants and recruitment process

Four hundred TD adolescents aged between 12-15 years old and their parents were invited to take part in the study from two schools representing two districts in the western province of Sri Lanka. The two schools were recruited according to convenience sampling, based on the ability to recruit above 100 adolescents from a combination of urban and non-urban schools. This participant sample was chosen using the convenience sampling method. Three hundred participants from school A and hundred participants from school B were randomly selected. Participants were chosen from four grades in school within the study age range. These participants belonged to four age categories (12, 13, 14, and 15). Parents and adolescents were sent a participant information letter (Appendix 17 and Appendix 18) and parent consent forms (permitting the child opt in or out for the study) (Appendix 19) a week before the targeted data collection date. The consenting process is outlined in Figure 8.1. Parents of the recruited TD adolescents for the study were asked to complete and return the ICS-SIN questionnaire if they were willing to participate in that part of the study. The investigator travelled to Sri Lanka, attended all data sites and was available throughout.

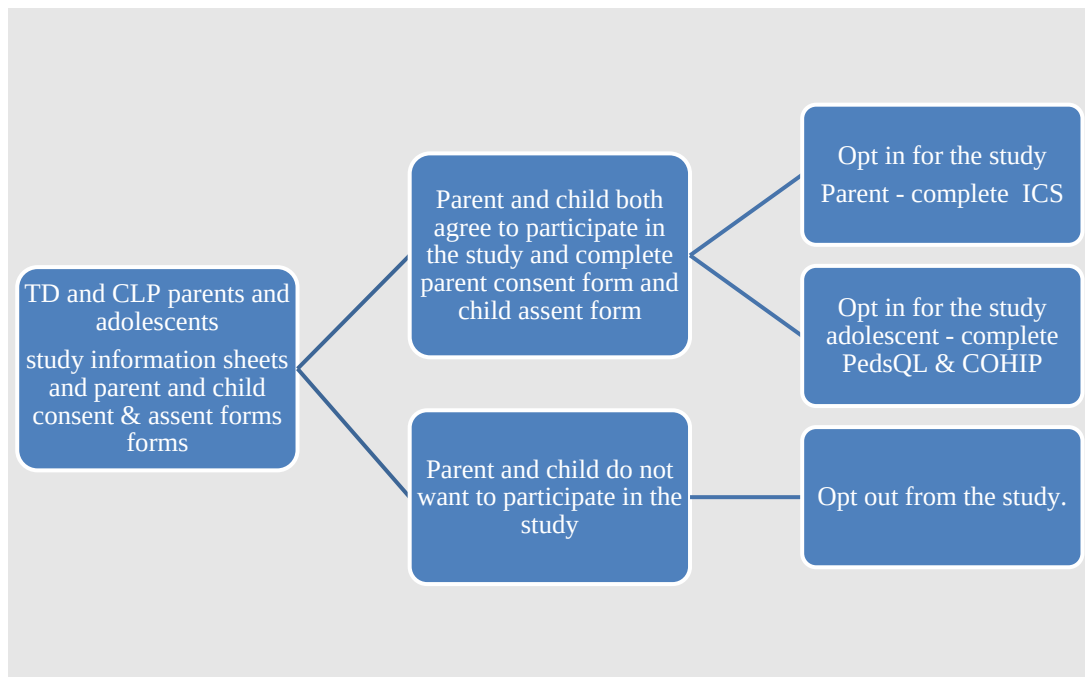


Figure 8.1: Participants opt-in and opt-out procedure

From this original invitation, 340 adolescents responded with parental consent forms opting into the study. These participants subsequently completed their assent forms (Appendix 20) and the COHIP-S and PedsQL-Sinhala questionnaires. Detailed descriptions of the participants in each of the four age groups (12 years, 13 years, 14 years, and 15 years) from each school are listed in Table 8.3. Two hundred ICS-SIN questionnaires were sent to randomly chosen parents of TD adolescents. Only 54 parents/ immediate family members completed the ICS-SIN questionnaire and returned these. Detailed description of respondents and the ages of their children are displayed in Table 8.4 and Table 8.5.

Table 8.3 : Age details of the TD participants

Age of the participant	School A		School B	
	Female	Male	Female	Male
12 years old	29	26	14	16

13 years old	40	47	16	16
14 years old	27	31	13	13
15 years old	14	22	7	9
Total	110	126	50	54

Table 8.4 : Details of Parents responding to ICS-SIN– TD group

Respondent	Mother	Father	Other carer (brother, sister, grandparents)
Number of respondents	39	10	5

Table 8.5 : ICS-SIN respondents; adolescents age details

Age	12	13	14	15
Number of adolescents	11	26	11	6

8.5.5 Details of CLP participants and recruitment process

Forty-five adolescents with repaired CLP aged 12-15 who were patients at the Lady Ridgeway Hospital for children, Colombo, Western Province, Sri Lanka and their parents/ carers were invited to participate to the study. The hospital’s multidisciplinary cleft clinic provides intervention for one third of the country’s children and adolescents with CLP from birth up to 18 years from a range of provinces across Sri Lanka. The

investigator worked closely with the SLT during this process and SLT was in touch with the adolescents and parents to explain the study (**Error! Reference source not found.**) and deliver the participant information sheets and consent forms (Appendix 22, Appendix 23, Appendix 24, Appendix 25). These adolescents were continuing to attend speech and language therapy and orthodontic clinics for regular follow ups. Speech and language therapists considered the inclusion and exclusion criteria of the study and identified 45 CLP adolescents randomly for the study and delivered the questionnaires to complete while they are waiting for the clinic appointments. Parents of the recruited CLP adolescents for the study were asked to complete the ICS-SIN questionnaire if they were willing to participate while their child was completing their questionnaires.

Among 45 invited, only 40 parents returned the completed ICS-SIN questionnaire and 38 qualified for the final analysis. The age and gender details of the 38 CLP adolescents are listed below in Table 8.6. There were 28 mothers completed the questionnaire while the remainder were completed by fathers or immediate family members. Descriptions of the respondents are detailed in Table 8.7.

Table 8.6 : Age and sex description of CLP adolescents qualified for the final analysis.

Age	Total number of participants	Participants Gender	
		Male	Female
12 years old	4	2	2
13 years old	6	2	4
14 years old	8	4	4
15 years old	20	6	14
Total	38	14	24

Table 8.7 : Details of parents responding to ICS-SIN; CLP group

Respondent	Mother	Father	Other (brother, sister, grandparents)

Number of respondents	28	6	4

8.6 Procedure

8.6.1 Gathering data – TD participants

Following the school principals' permission, teachers were informed about the study. Participants were selected randomly from each grade including some classes from each grade as some grades have more than five classes. The investigator together with the teacher explained the study and what adolescents were expected to do. The study information leaflets for parents (Appendix 17), adolescents (Appendix 18) and parents' consent forms (Appendix 19) were distributed to potential participants who were asked to bring the parents' consent forms in the following week. Adolescents who returned their parents' consent forms were asked to complete their ascent forms (Appendix 20) on the day of data collection at school to participate in the study if they still wish to participate in the study. In Sri Lanka, it is vital to ask parents' consent to recruit children and adolescents until the age of 18 years for research purposes as parents are legal guardians of children and adolescents until the age of 18.

Participants were advised to declare if their adolescent had an ongoing medical condition or dental condition which requires daily medication or any physical disability that affects everyday life on their consent forms. This information was verified with class teachers against the students' personal records. Any questionnaires completed by an adolescent who would then be excluded due to any of the stated exclusion criteria were destroyed at the data analysis stage of the study. While there were three hundred participants from school A and one hundred from school B,

recruitment was random and not therefore possible to ensure equal distribution across each of the age bands.

Participants who successfully provided the parental consent process were given a verbal explanation along with an information sheet about the purpose of the study and the data anonymity. Following this explanation participants were asked to provide the signed assent form. The participating adolescents' assent was considered important, even though parental permission had already been given. Hence, they were advised about their right to withdraw at any stage. Furthermore, the ethical considerations were discussed, and participants informed of their right to opt out from the study if they feel distressed or upset while completing the questionnaires.

The COHIP-S and PedsQL – Sinhala self-administered questionnaires were distributed to participating adolescents who completed assent forms. All questionnaires were completed in class time. Participants were asked to fill out both questionnaires on their own without discussing answers with friends in order to minimise response bias. The investigator was present at the site while participants were completing the questionnaires to help with further clarifications when necessary. Some participants were not very sure about replying to all the questions negatively saying that they haven't experienced any issues raised by the COHIP-S questionnaire. The investigator reassured them explaining the purpose of the study was to check whether the questions were understandable and appropriate to use and compare the data with another same age group of people. Some participants asked for further explanations for some questions in both questionnaires. Participants were expected to complete the questionnaires within 30 minutes. However, this timescale was not strictly followed and allocated extra 5-10 minutes to complete when necessary. No participant requested

to opt out while completing the questionnaires. The participant adolescents who answered the questionnaires received a piece of stationery in gratitude for participating in the study.

8.6.2 Gathering data – CLP participants

The speech and language therapists identified 45 adolescents with CLP within the age range who had been receiving SLT treatments during that time. SLTs checked the suitability of these participants with the investigator and invited them to participate in the study. During their next routine appointment, the clinic SLT explained the nature of the study and provided study information leaflets for parents (Appendix 22) and adolescents (Appendix 23) to review. They were encouraged to ask any questions from the SLT or contact the investigator if they need any further clarifications. The parents and adolescents with CLP were asked to sign the consent and assent forms (Appendix 24 & Appendix 25). While they were waiting for their SLT and orthodontics appointments or at the end of therapy sessions (as CLP children and adolescents visit for multidisciplinary team services on the same day), participants were requested to complete COHIP-S and PedsQL- Sinhala. Their parent or immediate family member who accompanied them were requested to complete the ICS-SIN. All these steps were done on the same day as these adolescents were attending the clinic. As this was done in the clinic, parents and adolescents were reassured that this is not part of the treatment process, and they have the right to opt out from the study or not participate in the study without affecting their future treatments or services. Five parents declined to participate in the study because they wanted to leave early due to work, travel and family commitments. The clinic SLT was available while parents and adolescents were

completing the questionnaires to provide any further clarifications about questions, resolve any queries or help them if necessary. Participants were requested to complete questionnaires within 30 minutes; however, extra time was provided when necessary. SLTs reported that no issues were raised while completing the questionnaires. As the participants' own responses were highly valued in this study, parents and immediate family members were politely asked to not interfere with their adolescent's completion of the COHIP-S and PedsQL-Sinhala questionnaires. Meanwhile, parents were asked to complete the ICS-SIN considering the child's speech intelligibility. The CLP data collection was completed within three months.

8.7 Data security and storage

Data was pseudo anonymized by allocating a code for each child's name (Appendix 26 & Appendix 27). Key codes for the names were separately stored in a locked filing cabinet in a different location in Sri Lanka and Scotland, and not together with completed questionnaires. Data was pseudo-anonymized in this way in order to identify any child who may present with previously unknown QoL concerns, so these could be reported either to their class teacher via the school principal (for TD adolescents) or the SLT (for adolescents with CLP). This was to ensure that if a young person may require additional support as identified through the study participation they could be appropriately followed up and referred to necessary professionals for appropriate interventions.

The investigator collected all the completed questionnaires from schools and SLT clinics and ensured that all questionnaires were returned. The raw data was stored separately, with individual scans of all original questionnaires made and stored in a university remote server before bringing the original copies to the UK for analysis. This served as a backup copy of the data. The original paper copies were safely transported to the UK in locked hand luggage when the investigator travelled back to the UK after the data collection. Original questionnaires were stored in the University of Strathclyde SLT department in a locked filing cabinet with the authorisation of the supervisors of the study. Paper and electronic data were stored in the university secure servers and with the investigator for ten years. Data will be destroyed after ten years by shredding paper files and deleting electronic files.

8.8 Data analysis

Each questionnaire was scored according to the scoring guidelines for that questionnaire. Datasets were then created on Microsoft Excel where individual question responses and scores for each question in each questionnaire was captured for each individual. This was then subject to a further reliability check to ensure the integrity of the information.

8.8.1 COHIP-S questionnaire scoring

The COHIP questionnaire consisted of 34 questions inquiring how frequently the child had experienced oral impacts during the past three months under five subscales. Four of these five conceptually distinct subscales are negatively worded:

- Oral Health well-being (10 items)
- Functional well-being (6 items)
- Social emotional well-being (8 items)
- School environment (4 items)

with the fifth positively worded;

- self- image (6 items)

Responses for those negatively worded subscale questions were recorded as “never” = 0, “almost never” = 1, “sometimes” = 2, “fairly often” = 3 and “almost all of the time” = 4. According to the COHIP scoring guidelines, (Broder & Wilson Genderson, 2007). The scoring of the twenty-eight negatively worded items was reversed so that higher COHIP scores reflect more positive OHRQoL while lower scores reflect lower OHRQoL (Broder & Wilson Genderson, 2007). Responses for items in the self-image subscale were scored as “strongly disagree” = 0, “somewhat disagree” = 1, “don’t agree or disagree” = 2, “somewhat agree” = 3, “strongly agree” = 4. Overall COHIP score is the sum of the scores of all thirty-four items from all five subscales with a possible range of 0 -136. Prevalence of the COHIP impacts was defined as the frequency of responses of “fairly often” or “almost all the time” for the negatively worded twenty-eight questions (the negative COHIP score - ranged from 0-112) and responses of “strongly disagree” or “somewhat disagree” for the six positively worded self-image items. The five subscale scores were calculated as the sum of the scores of the items included in the domains. Furthermore, there were two items regarding treatment expectations and one global health perception item included in the COHIP questionnaire. Participants recorded how best they describe themselves as “excellent”

to “very bad” for the global health perception item and “strongly disagree” to “strongly agree” for the treatment expectation items. Responses for those three questions were not included in the overall COHIP scores and those are recommended for use in clinical studies (Broder & Wilson Genderson, 2007). Participants’ who did not answer at least 75% of the items of five subscales were excluded as an incomplete dataset. As instructed in the COHIP scoring system, this percentage was checked across all subscales and if more than 25% were missing in each subscale the scores were not computed. If fewer than 25% of the items in a subscale were missing, the average of available items was calculated and used to replace the missing item and the total scores.

8.8.2 PedsQL-Sinhala questionnaire scoring

The PedsQL™ 4.0 Generic Core Scales (Varni et al., 2001) consists of twenty-three items grouped into four domains:

- physical function,
- emotional functioning
- social functioning
- school functioning.

The adolescent version (13-18 years) of this questionnaire was used for this study. The PedsQL Sinhala validation (Danansuriya & Rajapaksa, 2012) was conducted using the adolescent version suitable for children from 12 years old. The PedsQL questionnaire

assessed how much of a problem each item has been during the past month and responses are made on a five-point scale ranging from 0 = “Never” to 4 = “Almost always” (Table 8.8). Items were reverse scored and linearly transformed to a 0-100 scale as follows; 0 = 100, 1 =75, 2 =50, 3 = 25, 4 = 0 (Varni et al., 2001).

Table 8.8 : Details of the PedsQL five-point Likert scale and scoring

Response choices	Never	Almost never	Sometimes	Often	Almost Always
Raw scores	0	1	2	3	4
0-100 Scale scores	100	75	50	25	0

This scoring system was used to indicate that higher scores report better HRQoL. Following the scaling and scoring procedures of PedsQL TM (Varni, 1998 - 2024) scale scores were computed as the sum of the items divided by the number of items answered. The total PedsQL score was the sum of all the items over the number of items answered on all the scales. The Physical Health Summary Score (8 items) is the same as the Physical Functioning Scale. The Psychosocial Health Summary Score was computed as the sum of the items divided by the number of items answered in the Emotional, Social and School Functioning Scales. Following the guidelines of PedsQL TM scoring (Varni, 1998 -2024) if more than 50% of the items in the scale were missing the scale scores were not computed. When 50% or more were completed, the mean of the completed items on a scale was used to replace the missing scores and the total scores. The Mean score calculation = sum of the items over the number of items answered.

8.8.3 ICS-SIN questionnaire scoring

The seven questions on ICS –SIN questionnaire was answered on a 5-point scale: 5 = “always”, 4 = “usually”, 3 = “sometimes”, 2 = “rarely”, 1 = “never” and summed order to create a score out of thirty-five. The total score was then divided by 7 to calculate the total average score out of 5. This scoring is applied as described by the original author (McLeod, 2020).

8.8.4 Selecting a statistical software

The research study focuses on determining the validity and reliability of COHIP-S and ICS-SIN, and then compares the QoL findings between TD and CLP adolescents and identifies any correlation between QoL and speech intelligibility data in CLP adolescents as stated in research questions 1-7 (4.6). Therefore, quantitative data analysis was necessary. Hence the Microsoft Excel data files were converted into SPSS files and data analysis was completed using IBM SPSS Statistics 25 software.

8.8.5 Psychometric testing of the translated instruments

The importance of measuring the accuracy and consistency of research instruments, especially questionnaires after translation and cross-culturally adaption is well documented (Guillemin et al., 1994, Bannigan & Watson, 2009; Jain et al., 2016). Reliability (consistency) refers to the stability and the reproducibility of the instrument (Jain et al., 2016). Reliability can be assessed in several ways; stability, internal consistency and equivalence. Validity is the degree to which a scale measures what it intends to measure (Bannigan and Watson, 2009). Validity can be assessed in several ways, however, the most commonly used methods in questionnaire testing studies include content validity, discriminant validity, construct validity, and criterion validity. Therefore, using some of these suggestions, the reliability (internal

consistency and retest reliability) and validity (discriminant and construct) were tested for COHIP-S and ICS-SIN questionnaires.

8.8.6 Reliability and validity of the COHIP-S

As a first step, all participant responses were described in both item and subscale levels. According to this description, the feasibility of the COHIP-S was assessed using the percentage of missing values and the rate of completion of scales. The range of measurement was assessed based on ceiling and floor effects. The test of normality (Kolmogorov- Smirnov with Lilliefors) was conducted for each data set to measure the distribution of the data. As the data was not normally distributed, non-parametric tests were used for the statistical analysis. Following the analysis steps described by Field (2018) an item level analysis was performed. A correlation matrix was produced for each subscale and inter-item correlations were inspected. These correlations provide evidence of the strength and direction of the relationship between items within the subscale. For both TD and CLP samples, correlations and reliability statistics were calculated for each subscale. The values below 0.3 ($r < 0.3$) were considered as weak correlations and values above 0.7 ($r > 0.7$) were considered as good correlations.

Internal consistency was measured using Cronbach's alpha. Items total statistics tables were inspected for "Cronbach's alpha if item deleted" to check the items which could decrease the reliability of the subscale. This was checked in both TD and CLP groups. Cronbach's alpha value above 0.7 was considered good (Field, 2018) and below 0.5 was considered as low reliable.

Convergent validity, a subtype of construct validity was evaluated by using inter scale correlations, inter scale and total scale correlations and total scale and global health

score correlations. The non-parametric Spearman correlation test was used and analysed for both TD and CLP group responses. It was hypothesized that conceptually related scales (e.g. – social emotional wellbeing, school environment) would correlate significantly with one another in both groups and those scales with less in common (e.g.- oral health wellbeing and self-image) would have lower correlations according to previous validations (Broder et al., 2007, (Ahn et al., 2012). Furthermore, it was expected that when the total score is higher (ie OHRQoL is higher) the perceived global health score was also higher and therefore there would be a strong correlation.

Discriminant validity was assessed by comparing the total and subscale COHIP-S scores of the CLP and TD groups within different age groups of each sample. The Kruskal-Wallis non-parametric test was used to compare the groups. It was expected that COHIP-S scores would be higher in the TD group when compared to the CLP group.

Test re-test reliability was originally planned at the beginning of the study, however, due to COVID-19 travel restrictions where both UK and Sri Lanka went into several lockdowns, it was not possible to organise a return to Sri Lanka to complete this step or carry this out via the local clinic SLT's due to clinic closures in Sri Lanka in the pandemic times.

8.8.7 Psychometric testing of the validity of ICS-SIN version

The same procedure described above (8.8.6) applied in here to test the reliability and validity of the ICS-SIN. All parents' responses were analysed at the item level. As the data was not normally distributed, non-parametric tests were used for the statistical analysis. A correlation matrix was produced for each of the seven items and average

mean scores. The inter-item correlations were inspected. For both TD and CLP samples, correlations and reliability statistics were calculated. Values below 0.3 ($r < 0.3$) were considered as weak correlations, above 0.7 ($r > 0.7$) were considered good and in between values were considered as acceptable.

Internal consistency was measured using Cronbach's alpha and a Cronbach's alpha value above 0.7 was considered good and below 0.5 was considered as low. Cronbach's alpha values between 0.5 and 0.7 were considered as acceptable (Field, 2018). Convergent validity was evaluated by using seven item scores and ICS total score correlations between the total participant group, TD and CLP groups. The nonparametric Spearman correlation test was used. Discriminant validity was assessed by comparing ICS mean scores between TD and CLP groups. The nonparametric Mann-Whitney U test was used for this comparison. Diagnostic specificity of the ICS-SIN discussed based on the validity results.

8.8.8 Quality of life comparison analysis

The QoL comparison between TD and CLP groups was conducted using both the PedsQL-Sinhala and COHIP-S responses. Firstly, the PedsQL-Sinhala responses were analysed in item and subscale levels in both TD and CLP groups. The test of normality (Kolmogorov- Smirnov with Lilliefors) was conducted for each sample data set to measure the distribution of the data. As the data was not normally distributed, non-parametric tests were used for the statistical analysis. The total PedsQL-Sinhala scores and subscale scores were compared between TD and CLP groups using the Mann-Whitney U test. It was hypothesized that there would be a significant difference (at $p < 0.05$) between those two groups and CLP would score lower than the TD group.

The average mean distribution of total PedsQL-Sinhala score and subscale scores between different age groups and sex groups of both samples were analysed.

8.8.9 Correlation between PedsQL-Sinhala & COHIP-S responses

The correlation between the participants' total PedsQL-Sinhala score and COHIP-S score was checked using the non-parametric Spearman correlation test. This step was used to further highlight the strength of the COHIP-S version. Moreover, a descriptive item level analysis was carried out in the CLP group to highlight the QoL impacts identified by each assessment (PedsQL-Sinhala and COHIP-S) to highlight if a condition specific OHRQoL measure can identify more impact than a generic HRQoL measure in adolescents with CLP.

8.8.10 Correlation between PedsQL-Sinhala and ICS-SIN responses in CLP group

The correlation between PedsQL-Sinhala total scores and the ICS-SIN total scores was analysed using the non-parametric Spearman correlation test to find the association between QoL and speech intelligibility in the CLP group.

8.9 Summary

This chapter presented the methodologies employed in this study, which detailed the psychometric testing of the translated and culturally adapted questionnaires and the QoL comparison study. As part of this chapter, the study design (8.2) was introduced and the materials (8.3), ethical approval process (8.4), participants and inclusion and

exclusion criteria (8.5) of the study were explained. This was followed by the details of participant recruitment and the procedures for gathering data (8.6) and storing data (8.7). In a further section, the data analysis process (8.8) was described in detail including questionnaire scoring systems followed by methods of testing validity and reliability. The comparison study of QoL between CLP and TD groups was outlined and finally, the two questionnaire responses were evaluated to highlight the value of using a condition specific QoL instrument to identify CLP impact in adolescents.

9 RESULTS

This chapter reports the results of this study. Results are categorised into four sections followed by an overall summary. First section (9.1) presents, and analyses data gathered from the COHIP-S from both participant groups, including the validity and reliability data of the COHIP-S from the TD and CLP adolescents' groups. This section concludes with a comparison of COHIP-S findings between the TD and CLP groups. The latter part of this section (9.1.13) presents, and analyses data gathered from PedsQL-Sinhala from both participant groups along with a comparison of the COHIP-S and PedsQL-Sinhala findings between participant groups. The next section (9.2) presents the correlation analysis between COHIP-S and PedsQL-Sinhala scores. Section (9.3) presents and analyses data from the ICS-SIN from both participant groups, including findings relating to reliability and validity and compares responses between participant groups. Finally, section 4 (9.4) summarises all findings in relation to research questions outlined in Chapter 2.

9.1 COHIP-S Analysis

This section is presenting the results of the psychometric properties; reliability (evidenced by Cronbach's alpha) and validity (face, discriminant and convergent) of the COHIP-S for TD and CLP adolescents. Moreover, the COHIP-S results between two groups (TD and CLP) are compared using statistical analysis to determine whether there's any difference of quality of life between groups. Section 1 results will answer research questions 1 and 2; "What are the psychometric properties (reliability and face, convergent, discriminant validity) in the COHIP-S in TD and CLP 12–15-year-old

adolescents” and “Does quality of life investigated using a condition specific oral health related quality of life assessment (defined by COHIP-S) differ between TD and CLP adolescents”. This first half of the section 1 starts with response rate of TD adolescents (9.1.1) followed by an item (9.1.2) and scale level analysis (9.1.3) of the of the TD adolescents. Thereafter, section 9.1.4 lays out the TD responses for treatment expectation questions and overall health scale. Section 9.1.5 describes the analysis of psychometric properties of the COHIP-S for TD adolescents.

The second half of the section 1 presents CLP participants’ response rate (9.1.6) followed by the item (0) and scale level (9.1.8) analysis responses for the COHIP-S. Section 9.1.9 presents the statistical analysis to investigate the psychometric properties of the COHIP-S for adolescents with CLP. Finally, the responses for the COHIP-S by TD and adolescents with CLP are compared (9.1.10) to determine whether there are any statistically significant differences in quality of life exists between two groups followed by overall health score comparison (9.1.11) and a short summary (9.1.12).

9.1.1 Descriptive analysis of COHIP-S (TD group)

This section includes a descriptive analysis of the TD adolescents’ responses for the COHIP-S questionnaire.

Out of 400 TD adolescents, 340 returned the signed parents' consent forms (representing a return rate of 85%). Subsequently, those 340 completed the COHIP-S. Twenty-three (6.76%) were excluded from the analysis due to being incomplete (i.e., not completed at least 75% as per the scoring guidelines (8.8.1) or for one or more other exclusion criteria (8.5.3). Therefore, 317 questionnaires (93.23% of those returned) were included in the final analysis. The questionnaires were reasonably well

distributed across the four age groups (Figure 9.1) ranging from 51 - 110 participants in each age group. The greatest proportion aged 13 ($n=110$) and the lowest proportion aged 15 ($n=51$). However, it was difficult to include equal participant numbers for each age group due to excluded questionnaires and provision of parental consent. The participants' mean age was 13.33 years ($SD=1.02$). The number of participants in each age category of these 317 participants' is shown in Figure 9.1.

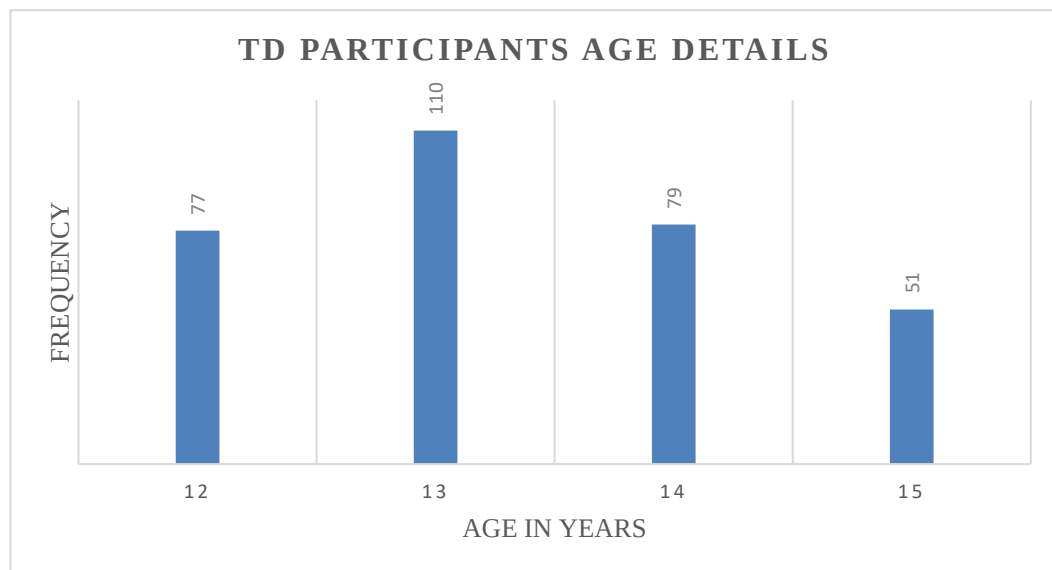


Figure 9.1: Distribution of TD participants by age ($N=317$)

9.1.2 Item level analysis of COHIP-S responses - TD

adolescents' group

Firstly, as described in section 9.1.1, participants' responses were analysed at item level. As presented in

Table 9.1, frequency and percentage of the impacts experienced by the TD adolescents were calculated. The most frequent response for each question has been shaded and underlined in the

Table 9.1.

Table 9.1 : Frequency distribution (n & %) of the TD participants responses for COHIP-S items (*n*= 317)

In the past three months, how often have you?	Never	Almost Never	Some times	Fairly often	All the time
Q1. Had pain in your teeth/toothache.	<u>167</u> 52.7%	91 28.7%	55 17.4%	3 0.9%	1 0.3%
Q2. Been breathing through your mouth or snoring.	213 67.2%	49 15.5%	45 14.2%	7 2.2%	3 0.9%
Q3. Had discoloured teeth or spots on your teeth.	217 68.5%	53 16.7%	31 9.8%	10 3.2%	6 1.9%
Q4. Had crooked teeth or spaces between your teeth.	217 68.5%	53 16.7%	22 6.9%	9 2.8%	16 5.0%
Q5. Had sores or sore spots in or around your mouth.	206 65%	65 20.5%	38 12%	7 2.2%	1 0.3%
Q6. Had bad breath.	237 74.8%	42 13.2%	29 9.1%	5 1.6	4 1.3%
Q7. Had bleeding gums.	246 77.6%	35 11%	25 7.9%	8 2.5%	3 0.9%

Q8. Had food sticking in or between your teeth.	116 36.6%	85 26.8%	90 28.4%	15 4.7%	11 3.5%
Q9. Had pain or sensitivity in your teeth with hot or cold things.	167 52.7%	71 22.4%	54 17%	11 3.5%	14 4.4%
Q10. Had dry mouth or lips.	156 49.2%	99 31.2%	40 12.6%	13 4.1%	9 2.8%
Q11. Had trouble biting off or chewing foods such as apple, carrot or firm meat.	270 85.2%	25 7.9%	16 5.0%	3 0.9%	3 0.9%
Q12. Been unhappy or sad because of your teeth, mouth, or face.	242 76.3%	37 11.7%	24 7.6%	6 1.9%	8 2.5%
Q13. Missed school for any reason because of your teeth, mouth, or face.	288 90.9%	18 5.7%	9 2.8%	2 0.6%	0 0%
Q14. Been confident because of your teeth, mouth, or face.	38 12%	15 4.7%	35 11%	71 22.4%	158 49.8%
Q15. Had difficulty eating foods you would like to eat because of your teeth, mouth, or face	265 83.6%	31 9.8%	21 6.6%	0 0%	0 0%
Q16. Felt worried or anxious because of your teeth, mouth, or face.	233 73.5%	48 15.1%	26 8.2%	3 0.9	7 2.2%
Q17. Felt shy or withdrawn because of your teeth, mouth, or face.	269 84.9%	29 9.1%	13 4.1%	4 1.3%	2 0.6%
Q18. Had difficulty paying attention in school because of your teeth, mouth, or face.	280 88.3%	35 11%	1 0.3%	1 0.3%	0 0%
Q19. Avoided smiling or laughing with other children because of your teeth, mouth, or face.	278 87.7%	26 8.2%	8 2.5%	4 1.3%	1 0.3%
Q20. Had trouble sleeping because of your teeth, mouth, or face.	286 90.2%	22 6.9%	7 2.2%	2 0.6%	0 0%

Q21. Not wanted to speak/read out loud in class because of your teeth, mouth, or face.	279 88%	28 8.8%	6 1.9%	2 0.6%	2 0.6%
Q22. Been teased, bullied, or called names by other children because of your teeth, mouth, or nose.	276 87.1%	26 8.2%	10 3.2%	4 1.3%	1 0.3%
Q23. Had difficulty saying certain words because of your teeth, mouth, or face.	260 82%	37 11.7%	16 5%	3 0.9%	1 0.3%
Q24. Felt that you look different because of your teeth, mouth, or face.	239 75.4%	43 13.6%	22 6.9%	8 2.5%	5 1.6%
Q25. Have people had difficulty understanding what you were saying because of your teeth, mouth, or face.	272 85.8%	31 9.8%	11 3.5%	3 0.9%	0 0%
Q26. Felt that you were attractive because of your teeth, mouth, or face.	68 21.5%	49 15.5%	69 21.8%	62 19.6%	69 21.8%
Q27. Had difficulty keeping your teeth clean because of your teeth, mouth, or face.	266 83.9%	27 8.5%	12 3.8%	7 2.2%	5 1.6%
Q28. Been worried about what other people think about your teeth, mouth, or face.	273 86.1%	28 8.8%	11 3.5%	3 0.9%	2 0.6%
Q29. Been upset or uncomfortable with being asked questions about your teeth, mouth, or face.	260 82.0%	28 8.8%	18 5.7%	5 1.6%	6 1.9%
Q30. Not wanted to go to school because of your teeth, mouth, or face.	288 90.9%	16 5.0%	10 3.2%	2 0.6%	1 0.3%
Q30C. Been sensitive to or cared more about other people's feelings because of your teeth, mouth, or face.	271 85.5%	35 11%	7 2.2%	3 0.9%	1 0.3%

	Strongly disagree	Somewhat Disagree	Do not agree or disagree	Somewhat agree	Strongly agree
Q31. I have good teeth	25 7.9%	14 4.4%	27 8.5%	49 15.5%	202 63.7%
Q32. When I am older, I believe that I will have good teeth.	40 12.6%	21 6.6%	30 9.5%	61 19.2%	165 52.1%
Q33. When I am older, I believe that I will have good health.	31 9.8%	21 6.6%	24 7.6%	64 20.2%	177 55.8%
Q34. I feel good about myself.	5 1.6%	26 8.2%	26 8.2%	60 18.9%	200 63.1%
Q35. I will feel better about myself when treatment for my teeth, mouth or face is completed.	41 12.9%	16 5.0%	47 14.8%	48 15.1%	165 52.1%
Q36. I am nervous (anxious) about the treatment that I need for my teeth, mouth, or face.	193 60.9%	53 16.7%	35 11%	19 6%	17 5.4%
	poor	Fair	Average	Good	Excellent
Q37. Overall, I feel my health is;	0 0%	1 0.3%	69 21.8%	126 39.7%	121 38.2%

Most of the TD participants did not experience oral health issues. As shown in Table 9.1, >50% of participants responded that they had not experienced (said “never” or positively answered) oral health-related issues during the past three months. However, participants’ answers were distributed across all ratings, indicating that there were some TD participants who experienced at least one or more oral health-related problems such as “had pain in your teeth”, “had spaces between your teeth” and “had bad breath” as displayed in

Table 9.1.

Out of the 34 oral health impacts in the COHIP-S, 18 were not experienced by most TD adolescents. The oral health-related problems that were not experienced by 75% or more of the study population are presented in Figure 9.2. These can be considered as non-common oral health impact issues in TD adolescents.

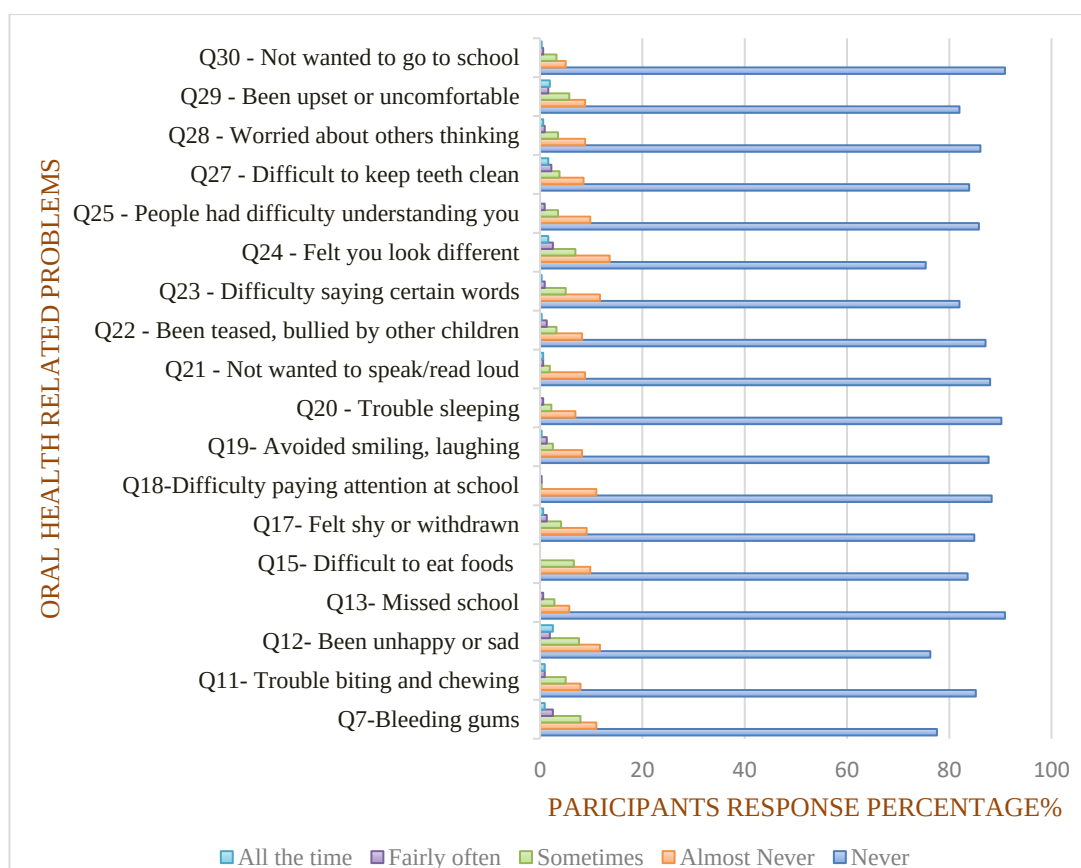


Figure 9.2 : Percentages (%) of least experienced oral health problems in the TD group

Conversely, oral health-related problems shown in Figure 9.3 were the most common oral health impacts experienced “fairly often” or “all of the time” by more than 5% of the TD study population. No participant recorded their overall health as "poor" for the global health statement; “Overall, I feel my health is” (Q37) at the end of the questionnaire, while the majority rated it as "good" (39.7%) or "excellent" (38.2%). Therefore, this item-level summary showed that the participants utilised the full range

of response choices and item distributions skewed toward a higher OHRQoL in TD adolescents.

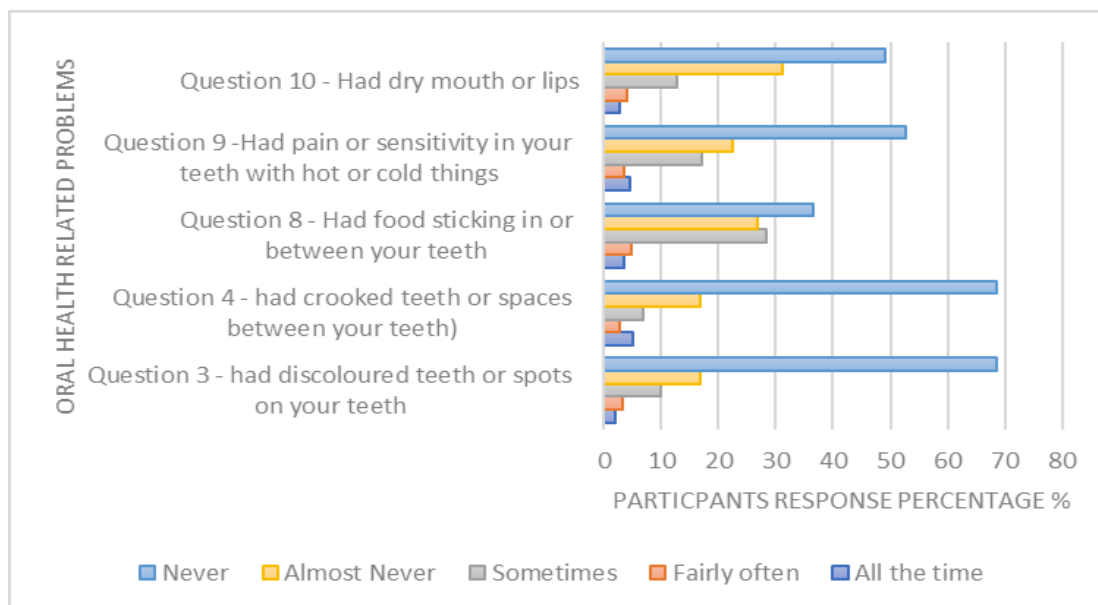


Figure 9.3 : Percentages (%) of mostly (“fairly often” or “all the time”) experienced oral health problems in the TD group

9.1.3 Scale level analysis of TD adolescents' group COHIP-S responses

Out of COHIP-S thirty-seven items, thirty-four items are divided in to five subscales (8.8.1). The items listed under each subscale are presented in Table 9.2. Each subscale has a maximum potential score. Moreover, the COHIP-S questionnaire consists of two items related to treatment expectations; “I will feel better about myself when treatment for my teeth, mouth or face is completed (Q35) and “I am nervous (anxious) about the treatment that I need for my teeth, mouth, or face” (Q36) and one item which is an overall health rating (also called “global health scale”); “Overall, I feel my health is” (Q37).

Table 9.2 : A detailed explanation of the COHIP-S five subscales

Subscale	Question Type	Questions	Maximum potential score
Oral Health	Ten negatively worded questions evaluating specific oral health symptoms	Q1. Had pain in your teeth/toothache.	40
		Q2. Been breathing through your mouth or snoring.	
		Q3. Had discoloured teeth or spots on your teeth.	
		Q4. Had crooked teeth or spaces between your teeth.	
		Q5. Had sores or sore spots in or around your mouth.	
		Q6. Had bad breath.	
		Q7. Had bleeding gums.	
		Q8. Had food sticking in or between your teeth.	
		Q9. Had pain or sensitivity in your teeth with hot or cold things.	
		Q10. Had dry mouth or lips.	
Functional Wellbeing	Six negatively worded items related to the child's ability to carry out specific daily activities	Q11. Had trouble biting off or chewing foods such as apple, carrot or firm meat.	24
		Q15. Had difficulty eating foods you would like to eat because of your teeth, mouth, or face.	
		Q20. Had trouble sleeping because of your teeth, mouth, or face.	

Social and Emotional wellbeing"	Eight negatively worded items pertaining to peer interactions and mood states of the child.	Q23. Had difficulty saying certain words because of your teeth, mouth, or face.	32
		Q25. Have people had difficulty understanding what you were saying because of your teeth, mouth, or face.	
		Q27. Had difficulty keeping your teeth clean because of your teeth, mouth, or face.	
		Q12. Been unhappy or sad because of your teeth, mouth, or face.	
		Q16. Felt worried or anxious because of your teeth, mouth, or face.	
		Q17. Felt shy or withdrawn because of your teeth, mouth, or face.	
		Q19. Avoided smiling or laughing with other children because of your teeth, mouth, or face.	
		Q22. Been teased, bullied, or called names by other children because of your teeth, mouth, or nose.	
		Q24. Felt that you look different because of your teeth, mouth, or face.	
		Q28. Been worried about what other people think about your teeth, mouth, or face.	
		Q29. Been upset or uncomfortable with being asked questions about your teeth, mouth, or face.	
School Environment	Four negatively worded items		16

	relating to tasks associated with the school environment.	Q13. Missed school for any reason because of your teeth, mouth, or face. Q18. Had difficulty paying attention in school because of your teeth, mouth, or face. Q21. Not wanted to speak/read out loud in class because of your teeth, mouth, or face. Q30. Not wanted to go to school because of your teeth, mouth, or face.	
Self-Image	Six positively worded items addressing positive feelings about self.	Q14. Been confident because of your teeth, mouth, or face. Q26. Felt that you were attractive because of your teeth, mouth, or face. Q31. I have good teeth. Q32. When I am older, I believe that I will have good teeth. Q33. When I am older, I believe that I will have good health. Q34. I feel good about myself.	24

Participants' responses were analysed according to these five different subscales. Overall COHIP-S and each subscale findings are presented in Table 9.3 and **Error! Reference source not found.** The maximum score that can be achieved in each subscale is presented in the first row of Table 9.3. The total COHIP-S score could range from 0 to 136. In the TD group, COHIP-S total mean score was 118.68

(SD=12.93). The mean scores of each subscale were analysed and recorded in Table 9.3. All subscales mean scores skewed toward a positive oral health-related quality of life. The subscale mean scores were not compared with each other as each subscale consists of a different number of questions. The *school environment* subscale total mean was closest to the maximum potential score and *oral health* and *self-image* subscales showed a considerable difference when compared with the maximum potential score indicating even in a TD population there are some people who experienced oral health impacts identified under those subscales. The participants' response range for each scale was varied as shown in Table 9.3.

Table 9.3 : The Descriptive statistics of five subscales and COHIP-S total score.

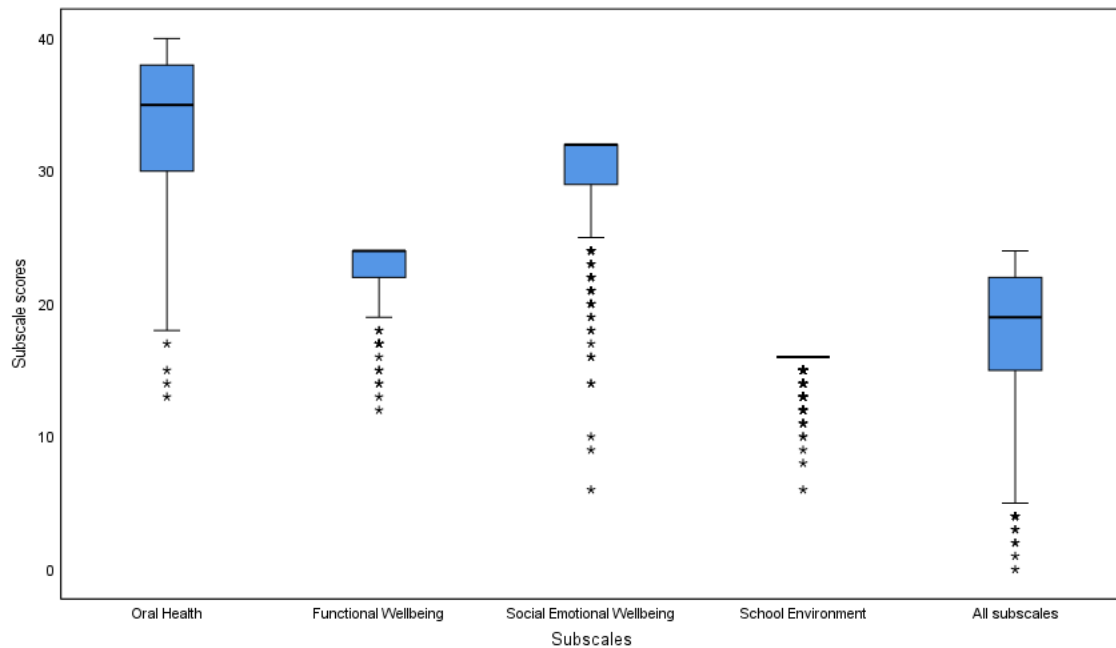
Subscale	Oral health Total	Functional Well-being Total	Social- Emotional Well-being Total	School Environment Total	Self-Image Total	COHIP- S Total (34)
Maximum potential score	40	24	32	16	24	136
Mean	33.54	22.65	29.57	15.42	17.49	118.68
Std. Deviation	5.26	2.12	4.21	1.38	5.63	12.93
Median	35.00	24.00	32.00	16.00	19.00	121.00
Minimum	13.00	12.00	6.00	6.00	.00	62.00
Maximum	40.00	24.00	32.00	16.00	24.00	136.00

Figure 9.4 : The distribution of the COHIP-S subscale and total scores

As shown in **Error! Reference source not found.**, *oral health* and *social-emotional well-being* subscales show a wider range when compared to other subscales.

9.1.4 Treatment expectations and global health score analysis – TD adolescents' group

Apart from the subscales, the COHIP-S questionnaire has two treatment expectation questions (question 35 and 36) and one last statement to record how the child feels about their overall health (global health score). More than half of the participants



responded positively to the questions related to treatment expectations:

- Q35 (I feel better about myself when treatment for my teeth, mouth or face is completed)

- Q36 (I am nervous (anxious) about the treatment that I need for my teeth, mouth or face).

The remaining participants' views were varied as displayed in **Error! Reference source not found.** This may be due to the relevance of this question within a typically developing population.

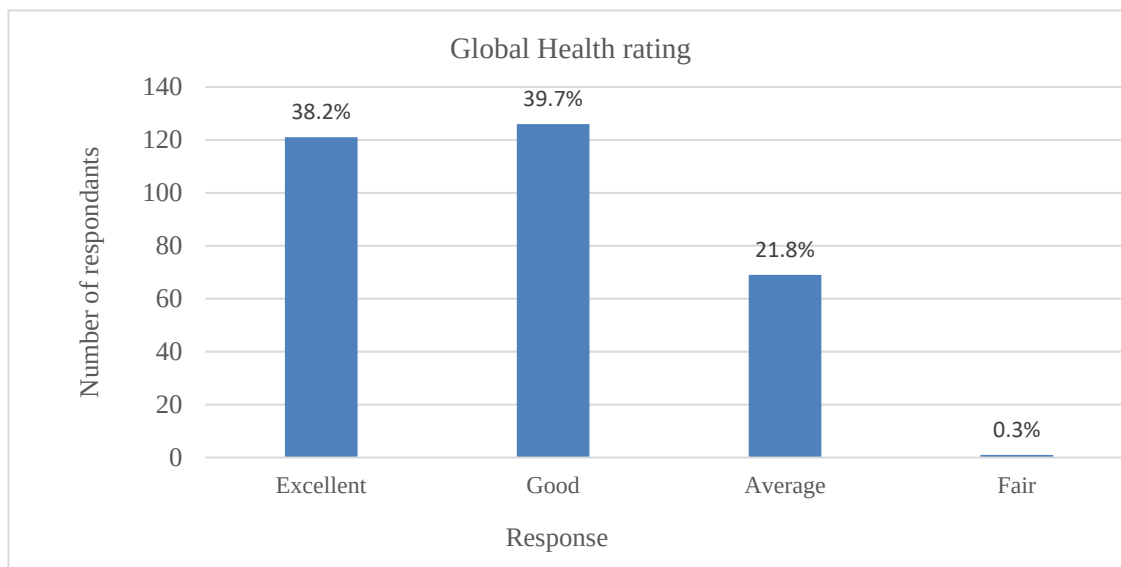
Table 9.4 :Participants' responses for the treatment expectation questions (n=317)

	Minimum	Maximum	Mean	Std. Deviation	Skewness	Std.Error
Q 35 - I feel better about myself when treatment for my teeth, mouth or face is completed	0	4	2.88	1.424	.984	.137
Q36 - I am nervous (anxious) about the treatment that I need for my teeth, mouth or face	0	4	.78	1.183	1.434	.137

More than 75% of adolescents recorded as "excellent" or "good" for item thirty-seven in COHIP-S related to how the child feels about their overall health, which indicated

Figure 9.5 : Global Health Rating - study participants' ratings on how they feel about their overall health

overall positive health and a good oral health-related quality of life. The actual percentages of the responses are displayed in Figure 9.5.



9.1.5 Analysis of psychometric properties of COHIP-S (TD participants)

9.1.5.1 Reliability (internal consistency) analysis of COHIP-S

Reliability was assessed within each subscale in the questionnaire. Results revealed excellent internal consistency, as shown in Table 9.5 for the *oral health* subscale with a Cronbach's alpha of 0.75. The inter-item correlation matrix below shows a weak correlation between some items. However, when analysed together, the Cronbach's alpha value was > 0.7 , which indicates good internal consistency.

Table 9.5 : Inter-item correlation for oral health subscale

	question 01	question 02	question 03	question 04	question 05	question 06	question 07	question 08	question 09	question 10
Question 01		.101	.200	.401	.277	.121	.298	.319	.209	.208
Question 02	.101		.121	.110	.132	.152	.094	.107	.090	.140

Question 03	.200	.121		.309	.182	.428	.400	.329	.271	.325
Question 04	.401	.110	.309		.168	.116	.326	.311	.225	.171
Question 05	.277	.132	.182	.168		.282	.271	.363	.164	.183
Question 06	.121	.152	.428	.116	.282		.270	.288	.188	.281
Question 07	.298	.094	.400	.326	.271	.270		.358	.130	.358
Question 08	.319	.107	.329	.311	.363	.288	.358		.287	.352
Question 09	.209	.090	.271	.225	.164	.188	.130	.287		.297
Question 10	.208	.140	.325	.171	.183	.281	.358	.352	.297	

The corrected item-total correlations were all positive and ranged from 0.19 to 0.51 for the *oral health* subscale. The Cronbach's alpha score ranged from 0.715 to 0.763, a slight increase when question 2 (been breathing through your mouse or snoring) was deleted, as highlighted in Table 9.6.

Table 9.6 : Cronbach s alpha variation statistics if item deleted – oral health subscale

	Scale Mean if Item Deleted	Scale Variance if Item Deleted	Corrected Item-Total Correlation	Squared Multiple Correlation	Cronbach's Alpha if Item Deleted
Question 1	30.22	23.664	.423	.244	.735
Question 2	30.09	25.173	.195	.046	.763
Question 3	30.08	22.336	.510	.335	.721
Question 4	30.14	22.289	.416	.260	.736
Question 5	30.07	23.929	.388	.207	.739
Question 6	29.96	23.713	.412	.258	.736
Question 7	29.92	23.152	.494	.307	.726
Question 8	30.67	21.217	.541	.316	.715
Question 9	30.41	22.484	.367	.172	.744
Question 10	30.34	22.353	.457	.252	.729

The *functional wellbeing* subscale showed a moderate internal consistency, as shown in Table 9.7 with a Cronbach's alpha of 0.61. The coefficients displayed in the inter-item correlation matrix below are variable and show a weak co-relation between some items. However, when these items were analysed together, the Cronbach's alpha value was above 0.61, which indicate an acceptable internal consistency as the *functional wellbeing* subscale only consists of six items.

Table 9.7 : Inter-item correlation for functional wellbeing subscale

	Question 11	Question 15	Question 20	Question 25	Question 27	Question 23
Question 11		.160	.175	.075	.158	.141
Question 15	.160		.413	.246	.203	.229
Question 20	.175	.413		.293	.190	.287
Question 25	.075	.246	.293		.227	.392
Question 27	.158	.203	.190	.227		.204
Question 23	.141	.229	.287	.392	.204	

The corrected item-total correlations were all positive and ranged from 0.22 to 0.43 within the *functional wellbeing* subscale. Although the corrected item-total correlation was slightly lower (0.22), it could be still acceptable because the questionnaire had been tested with a large participant group in this study. The Cronbach's alpha score ranged from 0.544 to 0.619. The Cronbach's alpha value did not increase above 0.61 if any items were deleted, as presented in Table 9.8.

Table 9.8 : Cronbach's alpha variation statistics if item deleted – functional wellbeing subscale

	Scale Mean if Item Deleted	Scale Variance if Item Deleted	Corrected Item-Total Correlation	Squared Multiple Correlation	Cronbach's Alpha if Item Deleted
Question 11	18.90	3.496	.223	.059	.619
Question 15	18.88	3.407	.389	.207	.549
Question 20	18.79	3.587	.436	.239	.544
Question 25	18.84	3.500	.395	.213	.550
Question 27	18.94	3.060	.313	.100	.590
Question 23	18.91	3.245	.394	.204	.544

There was an excellent Cronbach's alpha value of 0.861 for the *social-emotional wellbeing* subscale, which contained eight items. The coefficients displayed in the inter-item correlation matrix below (Table 9.9) are variable, resulting from participants' varied answers. However, when these items were analysed together, the Cronbach's alpha value was above 0.8, which proved an excellent internal consistency for the *social-emotional wellbeing* subscale.

Table 9.9 : Inter-item correlation for social-emotional wellbeing subscale

	Question 12	Question 16	Question 17	Question 19	Question 22	Question 24	Question 28	Question 29
Question 12		.580	.544	.321	.391	.404	.527	.567
Question 16	.580		.559	.461	.423	.366	.517	.549
Question 17	.544	.559		.545	.410	.384	.526	.628
Question 19	.321	.461	.545		.367	.174	.341	.502
Question 22	.391	.423	.410	.367		.152	.512	.336
Question 24	.404	.366	.384	.174	.152		.385	.429

Question 28	.527	.517	.526	.341	.512	.385		.644
Question 29	.567	.549	.628	.502	.336	.429	.644	

The corrected item-total correlations were all positive and ranged from 0.45 to 0.73 within the *social-emotional wellbeing* subscale. The Cronbach's alpha score ranged from 0.828 to 0.865. The Cronbach's alpha value did not increase above 0.86 if any of the items were deleted, as presented in Table 9.10.

Table 9.10 : Cronbach's alpha variation statistics if item deleted – social-emotional wellbeing subscale

	Scale Mean if Item Deleted	Scale Variance if Item Deleted	Corrected Item-Total Correlation	Squared Multiple Correlation	Cronbach's Alpha if Item Deleted
Question 12	26.00	12.649	.670	.479	.837
Question 16	26.00	12.813	.688	.487	.834
Question 17	25.81	13.903	.717	.542	.834
Question 19	25.75	15.192	.516	.396	.854
Question 22	25.77	15.230	.487	.351	.856
Question 24	25.99	14.098	.451	.260	.865
Question 28	25.78	14.234	.689	.546	.838
Question 29	25.90	12.853	.732	.602	.828

The *school environment* subscale showed a significant internal consistency, as shown in Table 9.11 with a Cronbach's alpha of 0.70. The coefficients displayed in the inter-item correlation matrix below are relatively variable and do not show a significant correlation between some items. When these items were analysed together, the Cronbach's alpha value was above 0.70, which indicates a good internal consistency in the *school environment* subscale.

Table 9.11 : Inter-item correlation for school environment subscale

	Question 13	Question 18	Question 21	Question 30
Question 13		.444	.240	.385
Question 18	.444		.383	.351
Question 21	.240	.383		.487
Question 30	.385	.351	.487	

The analysis shows that the corrected item-total correlations were positive and ranged from 0.44 to 0.55 within the *school environment* subscale. The Cronbach's alpha score ranged from 0.59 to 0.66 and did not increase if any items were deleted. Detailed statistics are presented in Table 9.12.

Table 9.12 : Cronbach's alpha variation statistics if item deleted – school environment subscale

	Scale Mean if Item Deleted	Scale Variance if Item Deleted	Corrected Item- Total Correlation	Squared Multiple Correlation	Cronbach's Alpha if Item Deleted
Question 13	11.56	1.254	.440	.258	.668
Question 18	11.55	1.343	.511	.284	.640
Question 21	11.59	1.078	.484	.289	.648
Question 30	11.57	1.062	.553	.319	.596

The Cronbach's alpha value for the *self-image* subscale was excellent at 0.80. This value showed a highly significant internal consistency for the *self-image* subscale, as shown in Table 9.13. The coefficients displayed in the inter-item correlation matrix

below are variable, and the correlation between some items are relatively low. But, when these items were analysed together, the Cronbach's alpha value was above 0.80, which shows an excellent internal consistency within the *self-image* subscale.

Table 9.13 : Inter-item correlation for self-image subscale

	Question 34	Question 33	Question 32	Question 31	Question 26	Question 14
Question 34		.636	.503	.582	.251	.357
Question 33	.636		.695	.582	.260	.326
Question 32	.503	.695		.576	.191	.285
Question 31	.582	.582	.576		.308	.375
Question 26	.251	.260	.191	.308		.374
Question 14	.357	.326	.285	.375	.374	

According to further analysis, the corrected item-total correlations were all positive and ranged from 0.36 to 0.69 within the *self-image* subscale. The Cronbach's alpha score ranged from 0.74 to 0.82 and increased slightly when question 26 (Had difficulty keeping your teeth clean because of your teeth, mouth or face) was deleted, as highlighted in Table 9.14.

Table 9.14 : Cronbach's alpha variation statistics if item deleted - self-image subscale

	Scale Mean if Item Deleted	Scale Variance if Item Deleted	Corrected Item-Total Correlation	Squared Multiple Correlation	Cronbach's Alpha if Item Deleted
Question 34	14.18	23.943	.642	.482	.763
Question 33	14.44	21.374	.695	.604	.742
Question 32	14.59	21.585	.613	.529	.762
Question 31	14.27	22.236	.673	.485	.750

Question 26	15.45	24.502	.360	.179	.823
Question 14	14.56	23.747	.457	.238	.798

Table 9.15 : Inter-item correlation for subscales and total COHIP-S

	Oral Health Total	Functional Wellbeing Total	Social-Emotional Wellbeing Total	School Environment Total	Self-Image Total	COHIP-S Total (34)
Oral Health Total		.507	.555	.475	.119	.774
Functional –Well-being Total	.507		.611	.577	.061	.658
Social-Emotional Well-being Total	.555	.611		.635	.177	.797
School Environment Total	.475	.577	.635		.140	.663
Self-Image Total	.119	.061	.177	.140		.567
COHIP –S Total (34)	.774	.658	.797	.663	.567	

The detailed analysis proved high levels of internal consistency for the overall COHIP-S questionnaire. Cronbach's alpha for the overall COHIP-S in the TD sample was 0.75, as shown in Table 9.15. The correlation of each subscale total and total COHIP-S score was varied. Internal consistency was acceptable within and between scales with a good Cronbach's alpha value when all subscales were combined and did not change when items were deleted. The corrected total item correlations were all positive (Table 9.16) and showed a moderate correlation (above 0.3) as values between 0 - 0.3 indicate a weak correlation.

Table 9.16 : Cronbach's alpha variation statistics if item deleted – COHIP-S

	Scale Mean if Item Deleted	Scale Variance if Item Deleted	Corrected Item-Total Correlation	Squared Multiple Correlation	Cronbach's Alpha if Item Deleted
Oral Health Total	203.8328	486.583	.669	1.000	.676

Functional Wellbeing Total	214.7224	601.651	.608	1.000	.738
Social Emotional Wellbeing Total	207.8044	513.430	.724	1.000	.682
School Environment Total	221.9527	623.982	.631	1.000	.751
Self-Image Total	219.8770	536.045	.390	1.000	.739
COHIP –S Total (34)	118.6877	167.380	1.000	1.000	.626

9.1.5.2 Summary of the COHIP –S reliability analysis

Results evidenced high level of internal consistency for the overall COHIP-S questionnaire. Cronbach's alpha for the overall COHIP-S in the TD sample was high ($\alpha=0.75$). When the COHIP-S subscales were examined separately, the alpha coefficients for *school environment*, *oral health* were satisfactory (>0.70) and excellent for *social-emotional wellbeing* and *self-image* (>0.80). The *functional wellbeing* score was 0.6, which is still acceptable as it was above 0.5, and the scale contains only six questions (Field, 2018). Therefore, removing any items from the questionnaire was unnecessary to achieve an acceptable Cronbach's alpha value as all subscales recorded a value between 0.6 and 1, as shown in Table 9.17. Hence, the subscales of COHIP-S had acceptable internal consistency evidenced by Cronbach's alpha values above 0.7 except the functional wellbeing subscale which had a slightly low value. In conclusion, the COHIP-S questionnaire had good internal consistency across items and reported an acceptable reliability measured by the Cronbach's alpha value (between 0.6 - 1).

Table 9.17 : Summary of Cronbach s alpha values for COHIP-S and subscales

Scale (number of items)	Cronbach's alpha
Oral Health (10)	.75
Functional well-being (6)	.61
Social-emotional wellbeing (8)	.86
School environment (4)	.70
Self-image (6)	.80
Overall scale (34)	.75

9.1.5.3 Validity Analysis – COHIP-S – TD group

In this section, results from the analysis of face validity, convergent validity and discriminant validity results analysis of the COHIP-S for the TD adolescents' group is outlined.

9.1.5.3.1 Face Validity

Face validity is the extent to which a test is subjectively viewed as covering the concept it claims to measure. Three bilingual qualified and experienced speech and language therapists were involved in the translation process. They together with a teacher and a medical consultant as the expert committee checked all the questions (5.4.2.4) to ensure the COHIP-S questionnaire had face validity. Furthermore, no significant changes were applied to the questionnaire after piloting. All TD participants completed the given questionnaires without any difficulty or the need for clarification of any questions or statements. When asked for verbal feedback from the TD adolescents after completing the questionnaire, almost all of them reported it was easy to answer and obvious what it measures. The response rate was 100% and 93.63% were valid for the analysis. Therefore, it can be suggested that the COHIP-S has good face validity.

9.1.5.3.2 Convergent validity

Convergent validity, a fundamental aspect of construct validity, refers to how closely the new scale is related to other variables and other measures of the same construct (Krabbe, 2016). The construct's positive correlation with related variables considered as good convergent validity. The convergent validity of the COHIP-S was assessed in two ways.

1. Determining the correlations between COHIP-S total score (total of five subscale scores- question 1 to question 34) and self-perceived overall health ratings score from question 37 (How participant feel about their overall health). The total COHIP score is calculating adding scores of questions 1-34 and the self -perceived overall health score is a single last question to ask about how they feel about their overall health that will not include in the total COHIP-S score. This will show how closely the scale is related to other variables that measures similar constructs.
2. Determining the correlation between two QoL measures; COHIP-S and PedsQL-Sinhala (9.2.1). This will analyse how closely the scale is related to another instrument that measures the same QoL construct.

The Kolmogorov-Smirnov test showed that the distribution of overall COHIP-S (34) scores was positively skewed and significantly different from a normal distribution (skewness = -1.29; kurtosis =2.04; $p < 0.001$). Similarly, the self-perceived overall health ratings were also positively skewed and significantly different from a normal distribution (skewness =-0.32; kurtosis =-1.09; $p < 0.001$). Therefore, a non-parametric correlation test: Spearman's rank-order correlation was run to determine the relationship between the COHIP-S total score and perceived overall health rating score. The Spearman's correlations between the overall COHIP-S score and self-

perceived overall health ratings were statistically significant for the TD participant group ($r = .33, p < 0.001$). Furthermore, there were strong, positive correlations between all five subscale scores and perceived overall health rating score, which was statistically significant, as displayed in Table 9.18 below. The association between functional wellbeing, social-emotional wellbeing, and self-perceived overall health ratings was the strongest and statistically significant in this participant group.

Table 9.18 : Convergent validity - Spearman correlations of the COHIP-S scores with the global health score (perceived overall health) rating.

	Global Health Score	
	rs (p)	P - value
Total COHIP - S	0.330	0.001
Oral Health	0.293	0.001
Functional Well-being	0.312	0.001
Social-Emotional well-being	0.311	0.001
School environment	0.259	0.001
Self-image	0.189	0.001

Findings confirmed the participants who scored higher COHIP-S scores had higher subscale scores indicating a better oral health-related quality of life and rated positively on the self-perceived overall health scale. The positive relationship between these variables that measures constructs of QoL within this questionnaire shows excellent convergent validity of the COHIP-S.

9.1.5.3.3 Discriminant validity

Discriminant validity, another subtype of construct validity refers to whether concepts or measurements that are not supposed to be related are actually unrelated. The total COHIP-S score was analysed according to each age group. The age range of the participants was 12-15 years of age. As previously discussed, the COHIP-S total score

was positively skewed and significantly different from a normal distribution (Convergent validity); the non-parametric Kruskal –Wallis test was used to compare the scores among four age groups (Table 9.19).

Table 9.19 : Kruskal – Wallis Test - Total COHIP-S (TD) Scores in different age groups

Age (years)	N	Mean Rank
12	77	145.01
13	110	148.73
14	79	173.49
15	51	179.82

There was a statistically significant difference in the COHIP-S total scores between different age groups ($H(4) = 7.788, p = 0.05$), with a mean rank of 145.01 for 12-year-olds, 148.73 for 13-year-olds, 173.49 for 14-year-olds and 179.82 for 15-year-olds. Chi-square value was 9.015 and statistically significant ($p = 0.029$). According to the results, the COHIP-S total score (total of all five subscales) showed a trend of increasing with age, indicating that the oral health-related quality of life may improve when they grow old. Furthermore, the total COHIP-S (TD) mean scores were different in males and females, where males ($n=123$) scored slightly higher ($M= 121.68, SD = 12.14$) than females ($n=96$) ($M=119.33, SD = 13.60$). To further find the discriminant validity of the COHIP-S, the TD participants' responses were compared with the CLP participant group responses. This analysis is presented in detail in the latter part of this chapter (Discriminant Validity). The results were statistically significant, and COHIP-S total score is higher in TD than CLP young people.

The above results evidenced that the COHIP-S has a good discriminant validity as it can effectively discriminate data according to age and biological sex. In conclusion, the COHIP-S has shown excellent face validity, convergent validity and discriminant validity together with high internal consistency results discussed at the beginning of this chapter. The proven reliability and validity results of the COHIP-S confirm that this translation can be considered a valid oral health-related quality of life tool to use with the TD adolescent's population.

9.1.6 Participants response rate – CLP adolescents

Forty-five adolescents aged 12-15 years old with repaired CLP were recruited to the study (8.5.5). The response rate was 100%. Two questionnaires were incomplete with more than ten questions unanswered and was therefore excluded leaving 43 (97.72%) for the final analysis. The questionnaires were reasonably distributed across the four age groups (Figure 9.6) ranging from 7-20 participants in each age group. The greatest proportion aged 15 ($n=20$) and the lowest proportion aged 12 ($n=7$). However, it was difficult to include equal participant numbers for each age group due to different age groups has been seen at SLT clinics during the data collection period, excluded questionnaires and provision of parental consent. The participants' mean age was 13.95 years ($SD=1.15$). The number of participants in each age category of these 43 participants' is shown in Figure 9.6. All participants (100%) reported Sinhala as their first language.

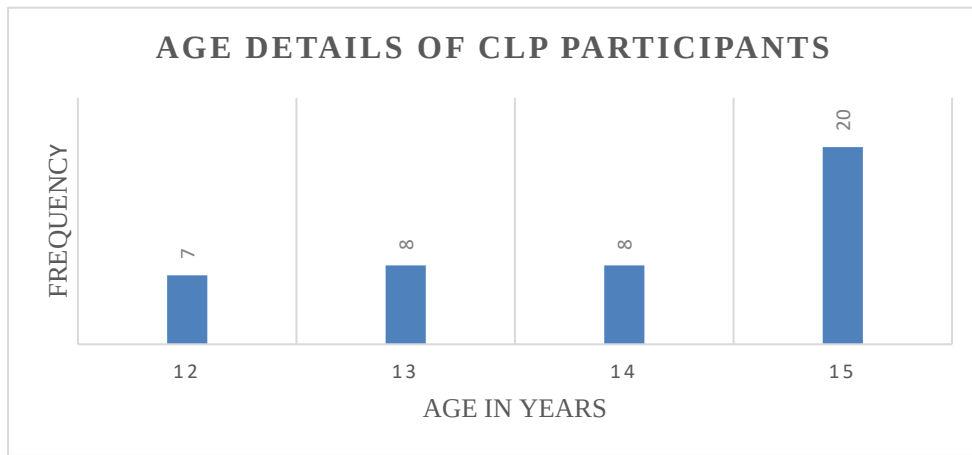


Figure 9.6 : Distribution of CLP participants by age ($n=43$)

9.1.7 Item level analysis – COHIP-S (CLP adolescents' group)

Item level analysis of the COHIP-S – CLP group is presented in Table 9.20.

Table 9.20 : Frequency distribution (n%) of the responses for COHIP items (n = 43)
(CLP adolescents)

In the past three months, how often have you?	Never	Almost Never	Some times	Fairly often	Almost All the time
Q1. Had pain in your teeth/toothache.	13 30.2%	21 48.8%	8 18.6%	1 2.3%	0 0.0%
Q2. Been breathing through your mouth or snoring.	20 46.5%	12 27.9%	6 14.0%	4 9.3%	1 2.3%
Q3. Had discoloured teeth or spots on your teeth.	16 37.2%	16 37.2%	7 16.3%	4 9.3%	0 0.0%
Q4. Had crooked teeth or spaces between your teeth.	21 48.8%	10 23.3%	6 14.0%	3 7.0%	3 7.0%
Q5. Had sores or sore spots in or around your mouth.	22 51.2%	12 27.9%	7 16.3%	2 4.7%	0 0.0%
Q6. Had bad breath.	25 74.8%	10 23.3%	6 14.0%	2 4.7%	0 0.0%
Q7. Had bleeding gums.	29 67.4%	8 18.6%	6 14.0%	0 0.0%	0 0.0%
Q8. Had food sticking in or between your teeth.	8 18.6%	17 39.5%	14 32.6%	4 9.3%	0 0.0%
Q9. Had pain or sensitivity in your teeth with hot or cold things.	20 46.5%	17 39.5%	5 11.6%	1 2.3%	0 0.0%

Q10. Had dry mouth or lips.	19 44.2%	20 46.5%	1 2.3%	1 2.3%	0 0.0%
Q11. Had trouble biting off or chewing foods such as apple, carrot or firm meet.	27 62.8%	9 20.9%	7 16.3%	0 0.0%	0 0.0%
Q12. Been unhappy or sad because of your teeth, mouth, or face.	25 58.1%	7 16.3%	6 14.0%	5 11.6%	0 0.0%
Q13. Missed school for any reason because of your teeth, mouth, or face.	34 79.1%	5 11.6%	1 2.3%	2 4.7%	1 2.3%
Q14. Been confident because of your teeth, mouth, or face.	7 16.3%	2 4.7%	2 4.7%	12 27.9%	20 46.5%
Q15. Had difficulty eating foods you would like to eat because of your teeth, mouth, or face	18 41.9%	13 30.2%	9 20.9%	3 7.0%	0 0.0%
Q16. Felt worried or anxious because of your teeth, mouth, or face.	22 51.2%	9 20.9%	6 14.0%	3 7.0%	3 7.0%
Q17. Felt shy or withdrawn because of your teeth, mouth, or face.	26 60.5%	9 20.9%	5 11.6%	3 7.0%	0 0.0%
Q18. Had difficulty paying attention in school because of your teeth, mouth, or face.	30 69.8%	9 20.9%	2 4.7%	2 4.7%	0 0%
Q19. Avoided smiling or laughing with other children	28 65.1%	7 16.3%	5 11.6%	1 2.3%	2 4.7%

because of your teeth, mouth, or face.					
Q20. Had trouble sleeping because of your teeth, mouth, or face.	38 88.4%	3 7.0%	1 2.3%	1 2.3%	0 0%
Q21. Not wanted to speak/read out loud in class because of your teeth, mouth, or face.	24 55.8%	4 9.3%	7 16.3%	3 7.0%	5 11.6%
Q22. Been teased, bullied, or called names by other children because of your teeth, mouth, or nose.	26 60.5%	9 20.9%	3 7.0%	3 7.0%	2 4.7%
Q23. Had difficulty saying certain words because of your teeth, mouth, or face.	13 30.2%	19 44.2%	5 11.6%	2 4.7%	4 9.3%
Q24. Felt that you look different because of your teeth, mouth, or face.	12 27.9%	13 30.2%	8 18.6%	5 11.6%	5 11.6%
Q25. Have people had difficulty understanding what you were saying because of your teeth, mouth, or face.	21 48.8%	9 20.9%	6 14.0%	4 9.3%	3 7.0%
Q26. Felt that you were attractive because of your teeth, mouth, or face.	16 37.2%	12 27.9%	9 20.9%	6 14.0%	0 0.0%
Q27. Had difficulty keeping your teeth clean because of your teeth, mouth, or face.	25 58.1%	6 14.0%	8 18.6%	2 4.7%	2 4.7%

Q28. Been worried about what other people think about your teeth, mouth, or face.	24 55.8%	9 20.9%	8 18.6%	2 4.7%	0 0.0%
Q29. Been upset or uncomfortable with being asked questions about your teeth, mouth, or face.	17 39.5%	10 23.3%	9 20.9%	5 11.6%	2 4.7%
Q30. Not wanted to go to school because of your teeth, mouth, or face.	38 88.4%	3 7.0%	2 4.7%	0 0.0%	0 0.0%
	Strongly disagree	Somewhat Disagree	Do not agree or disagree	Somewhat agree	Strongly agree
Q31. I have good teeth	9 20.9%	5 11.6%	8 18.6%	7 16.3%	14 32.6%
Q32. When I am older, I believe that I will have good teeth.	5 11.6%	1 2.3%	8 18.6%	10 23.3%	19 44.2%
Q33. When I am older, I believe that I will have good health.	5 11.6%	1 2.3%	5 11.6%	10 23.3%	22 51.2%
Q34. I feel good about myself.	4 9.3%	2 4.7%	4 9.3%	9 20.9%	24 55.8%
Q35. I will feel better about myself when treatment for my teeth, mouth or face is completed.	4 9.3%	1 2.3%	2 4.7%	9 20.9%	27 62.8%
Q36. I am nervous (anxious) about the treatment that I need for my teeth, mouth, or face.	24 55.8%	4 9.3%	9 20.9%	2 4.7%	4 9.3%

	poor	Fair	Average	Good	Excellent
Q37. Overall, I feel my health is	0 0%	0 0.0%	7 16.3%	25 58.1%	11 25.6%

The shaded responses are the most frequent response among participants and the percentage (%) is also included in the table. More than half of participants (above 50%) responded that they had not experienced or rarely experienced (almost never) oral health-related issues. Only 48.9% agreed or somewhat agreed that they have good teeth (question 31). However, almost all of them experienced at least one or more oral health-related problems in their lifetime. According to the findings adolescents with CLP had higher scorings (above 50%) on question 01, 05, 06, 07, 09, 10, 11, 13, 17, 18, 19, 20, 22, 30 and 35 to confirm that most of them did not experience those oral health-related qualities of life issues during the last three months (Figure 9.7).

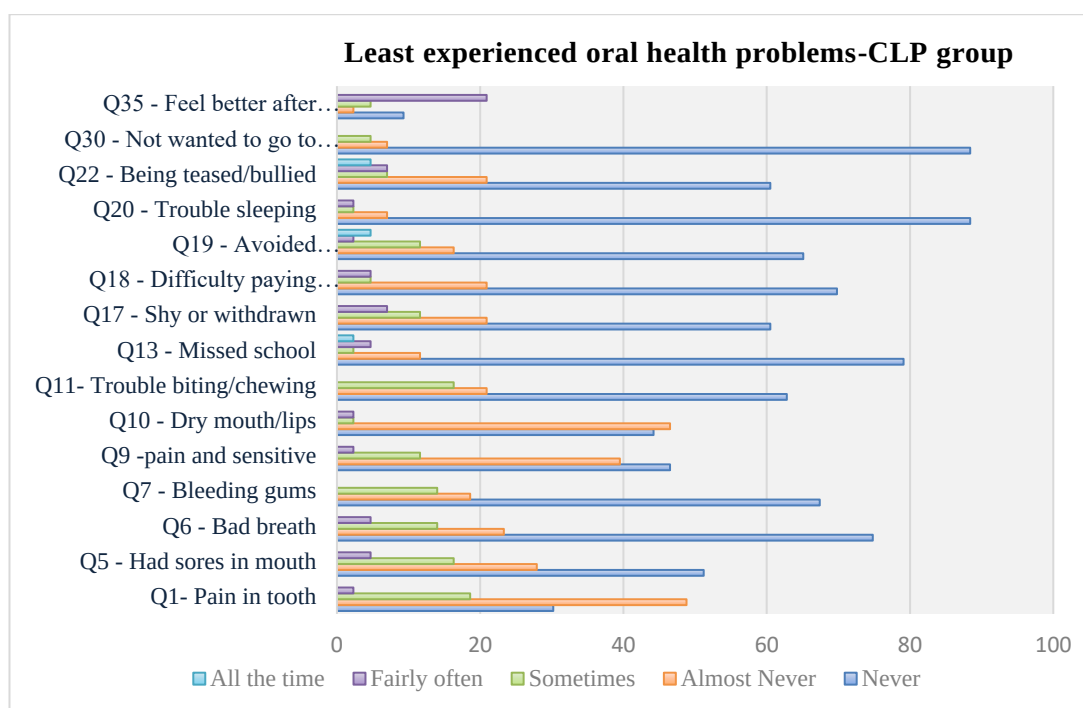


Figure 9.7 : Percentages (%) of least experienced oral health problems – CLP group

On the other hand, "fairly often" or "almost all the time" experienced (more than 10%) oral health related problems were displayed in Figure 9.8. Nearly a quarter (23.20%) of the total CLP participant group “fairly often” or “almost all the time” felt that “they look different.”

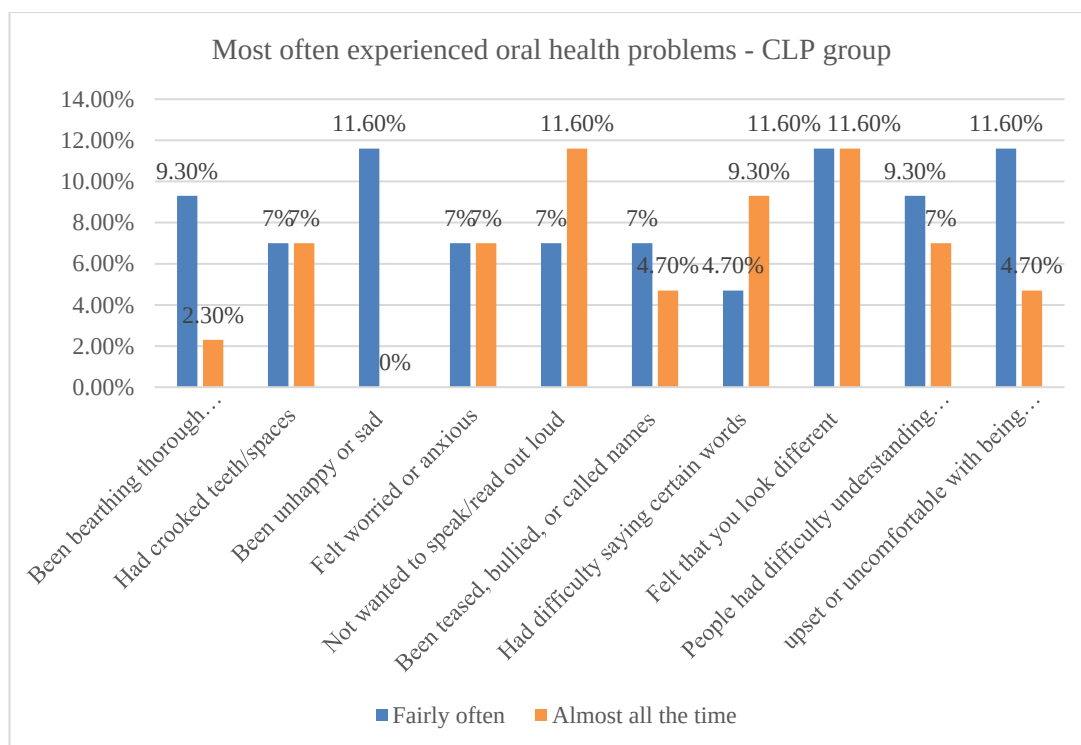


Figure 9.8 : “Fairly often” or “almost all the time” oral health issues experienced by the CLP group

Moreover, 13.9% of participants strongly disagreed or somewhat disagreed with the statement, "I believe that I will have good teeth". Furthermore, 21% rated that they "never" or "almost never" felt confident because of their teeth, mouth, or face and 32.5% of participants "disagreed" or "somewhat disagreed" that they have good teeth. No participant recorded their global health score as "poor" while the majority rated it as "good" (58.1%) or "excellent" (25.6%). Therefore, this item-level summary showed

that the participants utilised the full range of response choices and item distributions inclined toward a moderate to good oral health-related quality of life.

9.1.8 Scale level analysis – COHIP-S (CLP adolescents' group)

The COHIP-S questionnaire consists of thirty-seven items representing five subscales, as explained above in the TD scale level analysis (8.8.1). Similarly, the CLP participants' responses were analysed under each of the five subscales. Overall COHIP-S score and each subscale score descriptive statistics are presented in Table 9.21 and Figure 9.9.

Table 9.21: Descriptive statistics for overall COHIP-S and five subscales

Subscale	Oral health Total	Functional Wellbeing Total	Social- Emotional Well-being Total	School Environment Total	Self- Image Total	Total COHIP
Maximum Potential Score	40	24	32	16	24	136
Mean	31.46	19.27	24.79	13.74	15.18	104.46
Median	31.00	20.00	27.00	15.00	17.00	107.00
Std. Deviation	4.98	3.88	6.67	3.10	5.83	16.59
Minimum	16.00	10.00	10.00	2.00	00	65.00
Maximum	40.00	24.00	32.00	16.00	23.00	130.00

The maximum score that can be scored for each subscale is displayed in the top row of Table 9.21. The mean scores for each subscale calculated for the CLP group and the scores were different to the maximum potential score; *oral health*=31.46, *functional wellbeing* = 19.27, *social-emotional wellbeing* = 24.79, *school environment* = 13.74, *self-image* = 15.18 and skewed toward a positive side of oral health-related quality of life. The participants' response range for each scale varied; oral health ranged from 16-40, *functional wellbeing* ranged from 10-24, *social-emotional wellbeing* ranged from 10-32, *school environment* ranged from 2-16 and *self-image* ranged from 0-23,

indicating that adolescents experienced oral health issues listed in these subscales during the past three months.

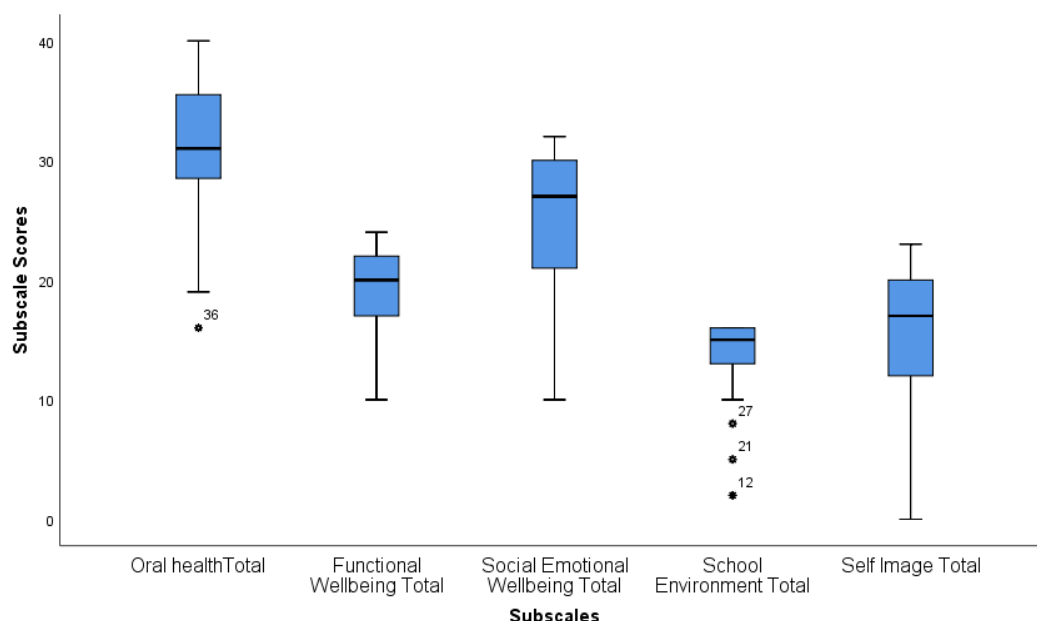


Figure 9.9 : Box plots representing COHIP-S Subscale distribution results - CLP

As shown in Figure 9.9 *social emotional well-being* and *self-image* subscales showed a wider range of responses when compared to other subscales. All five subscales showed long lower whisker in the sample means that the adolescents' responses were varied amongst the lower quartile of the group.

9.1.9 Treatment Expectation and Global Health Rating score analysis – CLP

More than half of the study population responded positively to treatment expectation questions (Q35 & Q36). 62.8% strongly agreed with the Q35 statement (M = 3.26, SD 1.25) "I feel better about myself when treatment for my teeth, mouth or face is completed". 55.8% rated "never" (M = 2.98, SD 1.35) to question 36 (I am nervous

(anxious) about the treatment that I need for my teeth, mouth or face). The rest of the participants' views were varied and displayed in Table 9.22.

Table 9.22 : CLP Participant's response percentages for treatment expectation questions

Question 35			Question 36		
	Frequency	Valid Percent%		Frequency	Valid Percent%
Strongly disagree	4	9.3	Always	4	9.3
Somewhat disagree	1	2.3	Fairly often	2	4.7
Do not agree or disagree	2	4.7	Sometimes	9	20.9
Somewhat agree	9	20.9	Almost never	4	9.3
Strongly agree	27	62.8	Never	24	55.8

Over half of the adolescents (58.1%) chose "good" for item 37 (global health score) in COHIP-S, related to how the child feels about their overall health, where 25.6% rated as "very good" and 16.3% rated as "average", which indicated overall positive health, also a good oral health-related quality of life. None of them rated their overall health as "poor" or "very poor". The results are displayed in Figure 9.10.

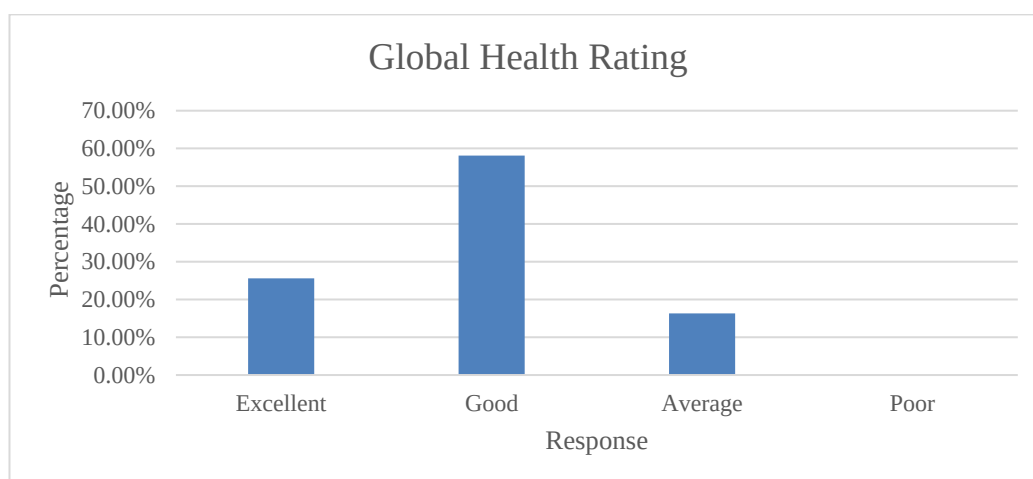


Figure 9.10 : Global Health Score ratings of the CLP study participants

The subscale analysis of the COHIP-S highlighted that CLP participants' responses were varied in their responses with the most affected subscales *oral health*, *social-emotional well-being* and *self-image*. *Functional well-being* and *school environment* subscale average mean scores did not deviate much from the maximum potential score. However, the subscales were not compared with each other hence there were no equal number of items listed under each subscale.

9.1.10 Analysis of psychometric properties of COHIP-S - CLP participants

9.1.10.1 Reliability (Internal consistency) of the COHIP-S

Reliability was assessed between items within each subscale of the questionnaire. Results revealed a good internal consistency as shown in Table 9.23 for the *oral health* subscale, which consisted of ten items. This was measured with Cronbach's alpha. The inter-item correlation matrix below shows a weak, negative correlation between some items. However, when all items analysed together, the Cronbach's alpha value was above 0.72, which indicate a good internal consistency (Table 9.23).

Table 9.23 : Inter-item correlation matrix for oral health subscale- COHIP-S (CLP adolescents)

	Question 1	Question 2	Question 3	Question 4	Question 5	Question 6	Question 7	Question 8	Question 9	Question 10
Question 1		.349	.099	.205	.169	.275	.152	.336	.071	.092
Question 2	.349		.156	.207	.222	.168	.071	.315	.171	.074
Question 3	.099	.156		.394	.157	.349	.150	.369	.086	.274
Question 4	.205	.207	.394		.442	.127	.388	.170	.123	.117

Question 5	.169	.222	.157	.442		-.084	.507	.283	.365	.175
Question 6	.275	.168	.349	.127	-.084		-.109	.205	-.018	.205
Question 7	.152	.071	.150	.388	.507	-.109		.272	.295	.222
Question 8	.336	.315	.369	.170	.283	.205	.272		.250	.172
Question 9	.071	.171	.086	.123	.365	-.018	.295	.250		.380
Question 10	.092	.074	.274	.117	.175	.205	.222	.172	.380	

The corrected item-total correlations were all positive and ranged from 0.23 to 0.48 for the subscale. The Cronbach's alpha score ranged from 0.68 to 0.72. A slight increase was shown if question 6 was deleted, as highlighted in Table 9.24. However, this question was not removed from the COHIP-S questionnaire as the Cronbach's value was generally within an acceptable range for the subscale (0.68) which is close to 0.7 without removing this question and this assists in maintaining the same the number of questions in this subscale equal to the original COHIP.

Table 9.24 : Cronbach's alpha variation statistics if item deleted - oral health subscale

	Scale Mean if Item Deleted	Scale Variance if Item Deleted	Corrected Item-Total Correlation	Squared Multiple Correlation	Cronbach's Alpha if Item Deleted
Question 1	28.44	21.824	.362	.248	.702
Question 2	28.40	20.245	.346	.208	.706
Question 3	28.44	20.157	.438	.357	.688
Question 4	28.47	18.493	.446	.371	.688
Question 5	28.21	20.312	.461	.407	.685

Question 6	28.12	22.105	.233	.259	<u>.721</u>
Question 7	27.93	21.590	.402	.359	.697
Question 8	28.79	20.217	.481	.329	.682
Question 9	28.16	21.806	.342	.275	.704
Question 10	28.23	20.992	.330	.241	.707

The *functional wellbeing* subscale showed an acceptable internal consistency, shown in Table 9.25 with a Cronbach's alpha value of 0.69. The coefficients display in the inter-item correlation matrix below are somewhat variable and shows a weak, negative correlation between some items. Nevertheless, when these items were analysed together, the Cronbach's alpha value was above 0.695, that was very close to 0.7. Hence, it can be concluded that the *functional well-being* subscale that only has six items has an acceptable internal consistency.

Table 9.25 : Inter-item correlation for functional well-being subscale

	Question 11	Question 15	Question 20	Question 23	Question 25	Question 27
Question 11		.246	.249	.045	-.026	.152
Question 15	.246		.150	.197	.291	.370
Question 20	.249	.150		.119	.083	.287
Question 23	.045	.197	.119		.640	.563
Question 25	-.026	.291	.083	.640		.461
Question 27	.152	.370	.287	.563	.461	

The corrected item-total correlations were all positive and ranged from 0.15 to 0.63 within the subscale. Hence, the questionnaire was tested with a reasonable number of

participants; a lower corrected item-total correlation of 0.158 was still considered acceptable. The Cronbach's alpha score ranged from 0.576 to 0.721. The Cronbach's alpha value showed an increase if question 11 (had trouble biting off or chewing foods such as apple, carrot or firm meat) was deleted, as presented in Table 9.26. However, the items were not deleted as the subscale overall value (0.69) was within an acceptable level.

Table 9.26 : Cronbach's alpha variation statistics if item deleted – functional wellbeing subscale

	Scale Mean if Item Deleted	Scale Variance if Item Deleted	Corrected Item-Total Correlation	Squared Multiple Correlation	Cronbach's Alpha if Item Deleted
Question 11	15.81	13.584	.158	.124	<u>.721</u>
Question 15	16.21	11.598	.388	.208	.666
Question 20	15.47	13.636	.249	.127	.700
Question 23	16.47	9.350	.582	.507	.595
Question 25	16.33	9.225	.533	.454	.616
Question 27	16.12	9.200	.630	.429	.576

The Cronbach's alpha value for the *social-emotional wellbeing* subscale contained eight items was 0.878. Hence, the internal consistency of the *social-emotional wellbeing* subscale was excellent within the CLP participant group. The coefficients displayed in the inter-item correlation matrix below (Table 9.27) were variable. However, when these items were analysed together, the Cronbach's alpha value was above 0.8, which evidenced an excellent internal consistency for the *social-emotional wellbeing* subscale.

Table 9.27 : Inter-item correlation for social-emotional wellbeing subscale

	Question 12	Question 16	Question 17	Question 19	Question 22	Question 24	Question 28	Question 29
Question 12		.676	.415	.199	.337	.700	.624	.608
Question 16	.676		.570	.531	.403	.601	.560	.559
Question 17	.415	.570		.387	.438	.458	.344	.222
Question 19	.199	.531	.387		.400	.251	.206	.480
Question 22	.337	.403	.438	.400		.330	.549	.524
Question 24	.700	.601	.458	.251	.330		.647	.645
Question 28	.624	.560	.344	.206	.549	.647		.632
Question 29	.608	.559	.222	.480	.524	.645	.632	

Within the subscale, the corrected item-total correlations (as shown in Table 9.28) were all positive and ranged from 0.46 to 0.76. The Cronbach's alpha score ranged from 0.849 to 0.880. The Cronbach's alpha value slightly increased from 0.878 to 0.880 if question 19 was deleted, but this was not necessary as the overall alpha value of the *social-emotional well-being* subscale was excellent ($\alpha=0.878$).

Table 9.28 : Cronbach's alpha variation statistics if item deleted – social-emotional wellbeing subscale

	Scale Mean if Item Deleted	Scale Variance if Item Deleted	Corrected Item-Total Correlation	Squared Multiple Correlation	Cronbach's Alpha if Item Deleted
Question 12	21.58	34.535	.700	.658	.857
Question 16	21.77	32.087	.763	.676	.849
Question 17	21.44	37.443	.539	.520	.873
Question 19	21.44	37.252	.464	.512	<u>.880</u>
Question 22	21.53	35.588	.556	.502	.872
Question 24	22.28	32.158	.705	.656	.857
Question 28	21.51	35.875	.702	.619	.859
Question 29	21.98	32.976	.723	.699	.854

The *school environment* subscale contains four items. It has a good internal consistency, as shown in Table 9.29 with a Cronbach's alpha of 0.710. The coefficients displayed in the inter-item correlation matrix below are relatively variable and do not show a significant correlation between some items. However, when these items were analysed together, the Cronbach's alpha value was above 0.70, which verified an acceptable internal consistency in the subscale.

Table 9.29 : Inter-item correlation for school environment subscale

	Question 13	Question 18	Question 21	Question 30
Question 13		.563	.149	.541
Question 18	.563		.564	.365
Question 21	.149	.564		.386
Question 30	.541	.365	.386	

Within the *school environment* subscale, the corrected item-total correlations were positive and ranged from 0.43 to 0.67. The Cronbach's alpha score ranged from 0.58 to 0.74 and slightly increased if question 21 was deleted, as displayed in Table 9.30. However, it was only a small increase, and overall, this subscale alpha value is acceptable. Moreover, this *school environment* subscale contains only four questions, none of the items were removed.

Table 9.30 : Cronbach s alpha variation statistics if item deleted –School environment subscale

	Scale Mean if Item Deleted	Scale Variance if Item Deleted	Corrected Item- Total Correlation	Squared Multiple Correlation	Cronbach's Alpha if Item Deleted
Question 13	10.14	6.599	.462	.535	.668
Question 18	10.19	6.346	.671	.566	.581
Question 21	10.84	4.806	.439	.458	<u>.740</u>
Question 30	10.07	6.114	.546	.406	.621

The Cronbach's alpha value was excellent for the *self-image* subscale, which includes six items and was calculated as 0.81. This value verified a highly significant internal consistency within the subscale, as shown in Table 9.31. The coefficients displayed in the inter-item correlation matrix below are somewhat variable, and the correlation between some items are negative. When these items were analysed together, the Cronbach's alpha value was above 0.80, which evidenced internal consistency within the *self-image* subscale.

The corrected item-total correlations were all positive within the *self-image* subscale and ranged from 0.32 to 0.86. The Cronbach's alpha score ranged from 0.71 to 0.86 and increased only slightly if questions 14 (Been confident because of your teeth, mouth, or face) & 26 (Had difficulty keeping your teeth clean because of your teeth, mouth or face) were deleted, as highlighted in Table 9.32, hence none of the items were deleted.

Table 9.31 : Inter-item correlation for Self-Image subscale

	Question 14	Question 26	Question 31	Question 32	Question 33	Question 34
Question 14		-.078	.260	.361	.371	.304
Question 26	-.078		-.006	.161	.099	.077
Question 31	.260	-.006		.629	.583	.611
Question 32	.361	.161	.629		.913	.853
Question 33	.371	.099	.583	.913		.935
Question 34	.304	.077	.611	.853	.935	

Table 9.32 : Cronbach's alpha variation statistics if item deleted –Self Image

Subscale

	Scale Mean if Item Deleted	Scale Variance if Item Deleted	Corrected Item- Total Correlation	Squared Multiple Correlation	Cronbach's Alpha if Item Deleted
Question 14	12.35	26.852	.328	.176	<u>.838</u>
Question 26	14.07	32.209	.057	.075	<u>.866</u>
Question 31	12.91	22.991	.584	.442	.780
Question 32	12.33	21.511	.867	.855	.712
Question 33	12.19	21.488	.863	.928	.713
Question 34	12.09	22.229	.822	.884	.725

The above-described detailed analysis of all five subscales indicates high levels of internal consistency for each subscale and subsequently, the overall COHIP-S questionnaire. Cronbach's alpha value was 0.76 for the overall COHIP-S score in the CLP participant sample. The correlation of each subscale total and total COHIP-S total score was analysed (Table 9.33). The correlations were varied, and some were negative because participants had a range of responses for each subscale. Internal consistency was acceptable within and between scales with a good Cronbach's alpha value when all subscales were combined which did not change significantly if items were deleted. The corrected total item correlations were all positive (Table 9.34). Therefore, no item was removed from the questionnaire as internal consistency was within a good range as the overall COHIP-S score Cronbach's alpha value is above 0.7. Since no items were removed, the translated COHIP remained similar to the original questionnaire format.

Table 9.33 : Inter-item correlation for subscales and the total COHIP-S score

	Oral health Total	Functional Well-being Total	Social Emotional Well-being Total	School Environme nt Total	Self-Image Total	Total COHIP-S
Oral health Total		.693	.388	.327	-.219	.603
Functional Well-being Total	.693		.682	.702	-.040	.834
Social Emotional Well-being Total	.388	.682		.740	.096	.851
School Environment Total	.327	.702	.740		.234	.830
Self-Image Total	-.219	-.040	.096	.234		.359
Total COHIP-S	.603	.834	.851	.830	.359	

Table 9.34 : Cronbach s alpha variation statistics if item deleted – COHIP-S

	Scale Mean if Item Deleted	Scale Variance if Item Deleted	Corrected Item- Total Correlation	Cronbach's Alpha if Item Deleted
Oral health Total	177.4651	927.350	.494	.739
Functional Wellbeing Total	189.6512	902.328	.792	.711
Social Emotional Wellbeing Total	184.1395	769.504	.777	.666
School Environment Total	195.1860	940.488	.797	.726
Self-Image Total	193.7442	997.243	.192	.787
Total COHIP-S	104.4651	275.540	1.000	.668

When the subscales were analysed separately (Table 9.35Table 9.35), the alpha coefficients (Cronbach's alpha) for overall COHIP-S, *school environment*, *oral health* were good (>0.70) and excellent for *social-emotional wellbeing* and *self-image* (>0.80). The *functional wellbeing* score was 0.69, which is still acceptable as it is above the low value (0.5) and very close to the good level (0.7).

Hence, removing any items or subscales from the questionnaire was unnecessary to achieve an acceptable Cronbach's alpha value as all subscales recorded a value between 0.69 and 1. In conclusion, the COHIP-S questionnaire had high reliability, Cronbach's alpha = 0.76 for the CLP participant group. The reliability statistics of the COHIP-S for the CLP group ($\alpha = 0.76$) are very similar to the COHIP-S TD ($\alpha = 0.75$) group. However, the Cronbach's alpha value is slightly high for the CLP group indicating the questionnaires' increased reliability of using this with adolescents with CLP. Therefore, the COHIP-S questionnaire has high reliability within CLP and TD adolescents' participant groups in Sri Lanka. The slightly higher Cronbach's alpha value for the CLP group is suggesting that COHIP-S, which has a high reliability for the CLP group is a suitable questionnaire to use to find out oral health related quality of life.

Table 9.35 : Summary of Cronbach s alpha values for COHIP-S and subscales

Scale (number of items)	Cronbach's alpha
Oral Health (10)	.72
Functional well-being (6)	.69
Social-emotional wellbeing (8)	.87
School environment (4)	.71
Self-image (6)	.81
Overall scale (34)	.76

9.1.10.2 Validity of the COHIP-S (CLP participants)

9.1.10.2.1 Face validity

The face validity of the COHIP-S was discussed previously (Face Validity). Additionally, all the CLP participants completed the questionnaire without any difficulty, and the SLT or the investigator did not have to clarify any questions further. Hence, the response rate was 100% in CLP adolescents. The SLT verbally asked for feedback from participants about the questionnaire, and the majority reported it was easy to complete and the questions asked were understandable. Only one questionnaire had to be excluded from the analysis because it was incomplete. Therefore, it can be concluded that COHIP-S has good face validity.

9.1.10.2.2 Convergent validity

The convergent validity of the COHIP-S for the CLP group was assessed by analysing the correlations between COHIP-S total score and global health rating score (Table 9.36). Again, as described in 9.1.5.3.2 the total COHIP-S score was calculated adding responses to questions 1-34 and the self-perceived global health rating is a one single question about how participants feel about their overall health. The average global health rating was 3.09 (SD=0.64). The Kolmogorov-Smirnov test showed that the distribution of the total COHIP-S scores was normal and positively skewed (skewness = -0.51; kurtosis = -0.46; $p < 0.146$), as were the subscales. However, according to the Kolmogorov-Smirnov test, the global health score ratings was significantly different from a normal distribution and positively skewed (skewness=-0.08, kurtosis = -0.50, $p < 0.001$). Hence, a non-parametric correlation test of statistical significance, Spearman's rank-order correlation was conducted to determine the relationship of the COHIP-S score and subscale scores with the global health score.

Spearman correlations (Table 9.36) between the overall COHIP-S score and global health ratings were statistically significant in the CLP study population ($r=0.34$, $p<0.05$). The correlation between the global health rating and subscales were not always statistically significant. The *oral health*, *functional wellbeing*, and *social-emotional wellbeing* subscales were also strongly correlated with the global health score while the *school environment* and *self-image* subscales were not. All coefficients were positive values ranged from 0.28 to 0.43. The global health score and the *functional wellbeing* subscale showed the highest partial correlation coefficient. However, a negative non-significant correlation was observed between the global health score and the *self-image* subscale score.

Table 9.36 : Spearman correlations between global health score and the COHIP-S subscales & total scores

	rs (p)	P value
Total COHIP - S	0.341	0.02
Oral Health	0.377	0.01
Functional Well-being	0.437	0.00
Social-Emotional well-being	0.354	0.02
School environment	0.218	0.16
Self-image	-0.005	0.97

Findings confirmed the participants who had higher COHIP-S scores and higher subscale scores (indicating a better oral health-related quality of life) also rated positively on the global health score to indicate good overall health status. The positive relationship between these variables that measures the constructs of QoL within this questionnaire shows an excellent convergent validity of the COHIP-S questionnaire within the CLP population. Moreover, the convergent validity of the COHIP-S was assessed finding the correlation between COHIP-S total score and PedsQL-Sinhala

total score in CLP group (9.2.1). The correlation between the COHIP-S and PedsQL-Sinhala questionnaires, that measure the same construct (QoL) were positive indicating a good convergent validity of COHIP-S.

9.1.10.2.3 Discriminant Validity (age)

The total COHIP-S score (total of five subscales) of the CLP participants was compared among the different age groups. According to the test of normality (Shapiro Wilk – $n < 50$), $p > 0.05$, the total COHIP-S score data showed a normal distribution. However, when split into age categories, some group sizes are small ($n < 10$). Hence, the non-parametric Kruskal -Wallis test was used to compare the scores among different age groups (Table 9.37).

Table 9.37 : Kruskal – Wallis Test statistics - Total COHIP-S (CLP) scores in different age groups

Child's age in years	Participant numbers (n)	Mean Rank
12	7	24.21
13	8	16.69
14	8	25.38
15	20	22.00

There was no statistically significant difference in the COHIP-S total scores between different age groups ($H(4) = 2.230$, $P = 0.526$). The mean ranks were 24.21 for 12 year olds, 16.69 for 13 year olds, 25.38 for 14 year olds and 22 for 15 year olds. According to the results, the COHIP-S total score did not change with age, suggesting that the oral health-related quality of life did not improve or decline with age in adolescents with CLP.

9.1.10.2.4 Discriminant validity (Participant groups) – Mean score comparison (TD and CLP)

As the COHIP-S total scores were not normally distributed (evidenced by Kolmogorov - Smirnov test of normality, $p < 0.05$), the Mann-Whitney non-parametric test was conducted to compare the two groups overall COHIP-S mean scores. The results were statistically significant with the TD group's overall COHIP-S score (representing the oral health-related quality of life) statistically significantly higher than the overall COHIP-S scores of the CLP group ($U = 3240.5$, $p < 0.001$).

TD and CLP participant groups' responses for five subscales of the questionnaire were also compared. The two groups descriptive mean statistics are displayed in Table 9.38 and Figure 9.11.

Table 9.38 : Mean and Standard Deviation (SD) statistics in TD and CLP groups.

Group	Oral Health	Functional wellbeing	Social and Emotional wellbeing	School Environment	Self-Image
CLP	31.46 (4.98)	19.27 (3.88)	24.79 (6.67)	13.74 (3.10)	15.18 (5.8)
TD	33.54 (5.26)	22.65 (2.12)	29.57 (4.21)	15.42 (1.38)	17.49 (5.63)

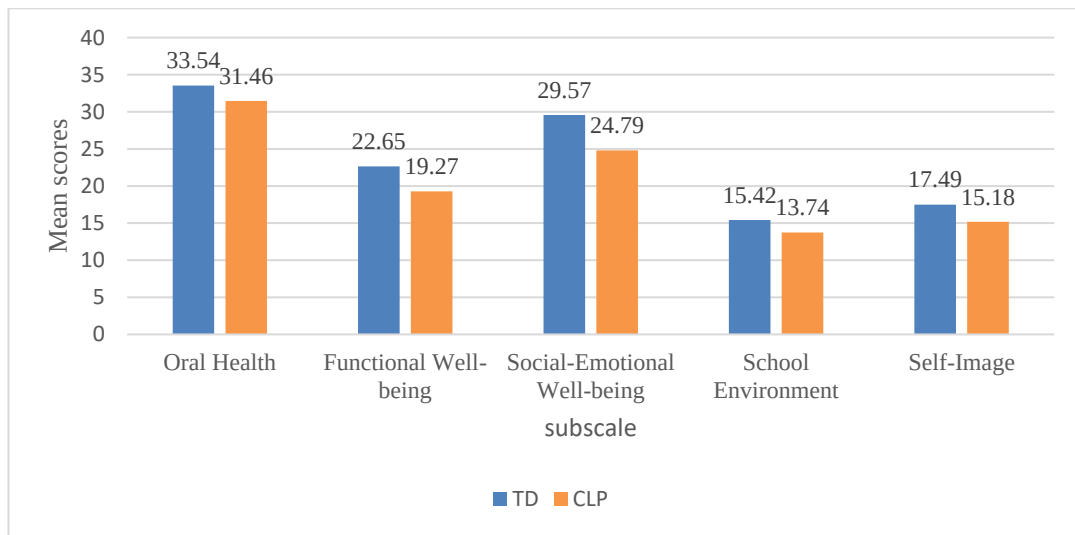


Figure 9.11 : COHIP-S subscale mean score comparison between TD and CLP groups

The five subscale totals were not normally distributed, as evidenced by the Kolmogorov-Smirnov test of normality ($p < 0.05$). Therefore, the Mann-Whitney non-parametric test was used to compare the two groups subscale responses. Results (Table 9.39) showed that all five subscales, *oral health*, *functional wellbeing*, *social-emotional wellbeing*, *school environment* and *self-image* response totals, were statistically significantly higher ($p < 0.05$) in the TD participant group when compared to the CLP group.

Table 9.39 : Comparison of mean scores of each subscale between TD and CLP groups

Mann-Whitney U Test results					
	Oral Health	Functional wellbeing	Social & Emotional wellbeing	School Environment	Self-Image
Mann-Whitney U	4988.500	2755.000	3586.000	4154.500	5026.500
Significance (2-tailed)	.004	.000	.000	.000	.005

9.1.10.2.5 Discriminant Validity (male Vs female)

The total COHIP-S (CLP) mean scores were different in males and females, where females ($n=27$) scored slightly higher ($M= 104.92$, $SD =17.42$) than males ($n=16$) ($M=103.68$, $SD = 15.97$).

To further find the discriminant validity of the COHIP-S, the CLP participant group's COHIP-S subscale and overall scores were compared with the TD participants' subscale and overall scores. Mean statistics and SD statistics according to sex groups in TD and CLP participants are displayed in Figure 9.10. The overall COHIP-S mean score of the TD group males was higher than females. In the CLP group, the overall COHIP-S mean score of the females was higher than males.

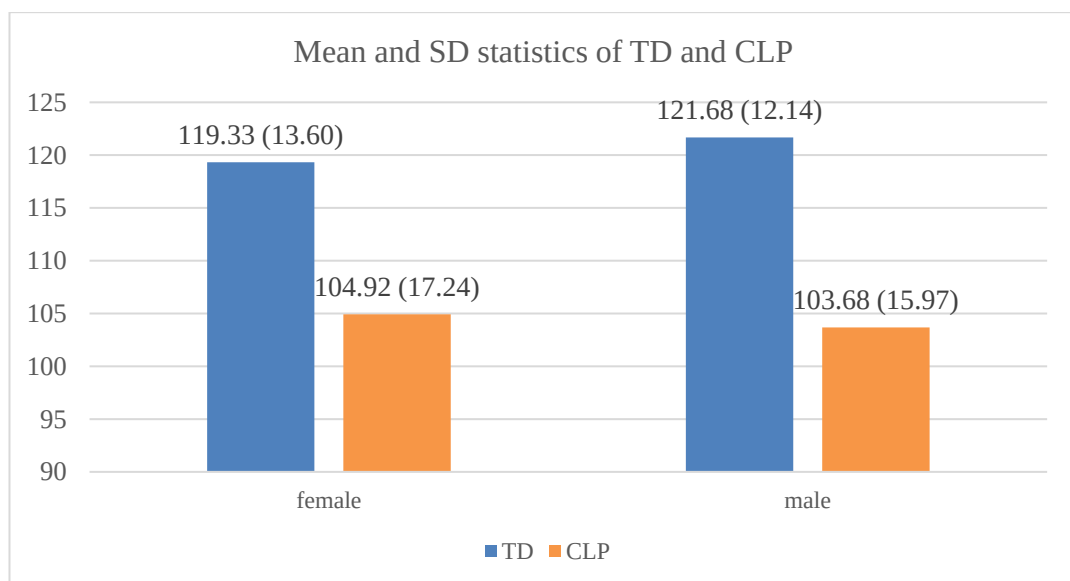


Figure 9.12 : Mean and standard deviation statistics (female Vs male)

The above results suggest that the COHIP-S has a good discriminant validity as it can effectively discriminate data according to age, sex and furthermore by participant group. Therefore, it can be concluded that the COHIP-S has shown excellent face

validity, convergent validity and discriminant validity together with high internal consistency within the CLP study population group.

9.1.11 Global health score comparison between TD and CLP groups

The last question of the COHIP-S questionnaire: the global health score (one question to rate how patients perceive their overall health) is not included into the total COHIP-S score. But it is recommended to assess this (COHIP-S questionnaire scoring) as it gives the participant the opportunity to rate feelings on overall health. As shown in Figure 9.13, most of TD and adolescents with CLP rated their overall health as good (TD-40.10%, CLP-58.10%) and more than quarter of both groups rated their overall health as excellent. The overall health score differences in the two groups were small [TD-3.16 (SD=.765), CLP – 3.09 (SD=.648)] indicating both groups' ratings for the overall health scoring question is similar despite COHIP-S total scores.

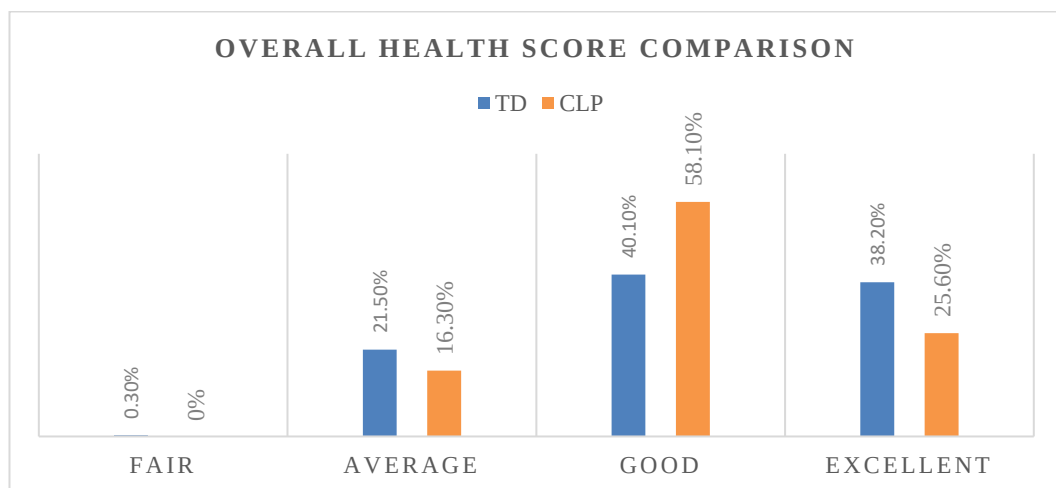


Figure 9.13 : Question 37 – Overall health score rating percentages comparison between TD and CLP groups

9.1.12 COHIP-S analysis results summary

Section 1 aimed to answer research questions 1 and 2; “*What are the psychometric properties of the Sinhala version of COHIP for TD (12-15 years old) adolescents and adolescents with CLP (12-15 years old)*”? and “*Does the quality of life investigated using a condition specific oral health related quality of life assessment (defined by COHIP-S) differ between TD and adolescents with CLP*”? Item and scale analysis revealed that adolescents with CLP are experiencing issues stated in COHIP-S “always” and “sometimes” higher than their TD developing peers. Subscale analysis showed that emotional wellbeing and social well-being subscales are affected more than the other subscales, and this is also greater than TD peers. The psychometric analysis of the COHIP-S provided evidence that this tool has an excellent internal consistency (reliability) along with acceptable face, convergent and discriminant validity. Hence, the section 1 results supported hypothesis 1; “COHIP-S translations will demonstrate acceptable psychometric properties; good reliability (defined by Cronbach’s alpha above 0.7) and validity (face, convergent and discriminant validity) to consider as appropriate tools to use with TD and adolescents with CLP in Sri Lanka” and hypothesis 2; “There will be a statistically significant ($p < 0.05$) difference between TD and CLP COHIP-S scores indicating that the COHIP-S provides condition-specific information for CLP in Sri Lanka”. (Research questions, research hypotheses and null hypotheses) Therefore, the null hypothesis will be rejected. The proven reliability and validity results of the COHIP-S confirm that this translation can be considered as a potential tool to assess OHRQoL in CLP adolescents in Sri Lanka and identify the impacts of CLP on QoL in adolescents' population. The analysis confirmed the extent that a condition specific QoL assessment identifies impacts associated with CLP.

Hence, these results will be compared with generic assessment QoL findings in the next results section.

9.1.13 PedsQL-Sinhala analysis

This section will present the analysis of the PedsQL-Sinhala responses gathered from TD and adolescents with CLP. The results were analysed to determine whether quality of life measured using a generic measure (defined by PedsQL) differed between TD and adolescents with CLP and to determine the most suitable measure for assessing quality of life in adolescents with CLP (generic or condition specific). Section 2 results will answer research questions 3 and 4: “Does the quality of life investigated using a generic measure (defined by PedsQL-Sinhala) differ between CLP and TD adolescents?” and What is the most suitable measure for assessing quality of life in adolescents with CLP; generic or condition specific?”. This section starts with item and scale level analysis of the responses of the TD and adolescents with CLP (9.1.14-9.1.19) followed by a statistical comparison of the PedsQL-Sinhala responses between TD and CLP groups (9.1.23). A short summary of the section 2 will be outlined at the end of the section (9.1.24).

9.1.14 Participants response rate – TD group

Three hundred and eighteen 12-15 years old TD adolescents completed the PedsQL-Sinhala generic questionnaire. This is one more than the COHIP-S, because one student only completed PedsQL and did not complete the COHIP-S due to his personal choice. Out of these, 16 (5.03%) questionnaires were incomplete (each more than 50% incomplete) and were therefore excluded (8.8.2) leaving 302 (94.97%) questionnaires in the final analysis. TD participants belonged to four age groups, as displayed in Table 9.40. As with the COHIP-S (9.1) it was not possible to distribute the questionnaires equally amongst the four age groups due to the excluded questionnaires and

convenience sampling method. The TD participants' mean age was 13.34 (SD =1.01) years.

Table 9.40 : Age distribution of TD participants completed PedsQL-Sinhala ($n=302$)

Age in years	Number of participants	Percentage
12	71	23.5%
13	109	36.1%
14	71	23.5%
15	51	16.9%

9.1.15 Participants' response rate - CLP group

There were 43 adolescents with CLP completed the PedsQL-Sinhala generic questionnaire. Six questionnaires were incomplete (50% incomplete) and excluded from the analysis (13.95%), leaving 37 questionnaires included in the analysis. Participants belonged to four age groups, as displayed in Table 9.41. The participant number in each age group is not equal due to the excluded questionnaires and convenient sampling method. The participants' mean age was 13.91 (SD=1.21) years.

Table 9.41: Age distribution of CLP participants completed PedsQL-Sinhala ($N=37$)

Age in years	Number of participants	Percentage
12	7	18.9%
13	7	18.9%
14	5	13.5%
15	18	48.6%

9.1.16 Item level analysis of PedsQL-Sinhala - TD adolescents

Item level analysis was carried out to determine participants' most frequent responses for each item of PedsQL-Sinhala. For all twenty-three questions, more than half of the TD adolescents responded that they had not experienced problems explained in the questionnaire. The most frequent (mode) individual response was "0"- "Never" for all questions except question 11 (I feel angry) and question 20 (I forgot things). For Question 11 and question 20, the most frequent answer was "1" – Almost never". The detailed item-level analysis of twenty-three questions included in PedsQL is displayed in Table 9.42.

Table 9.42 : Frequency distribution (*n* & %) of the responses for PedsQL-Sinhala items in TD group (*n* = 302)

In the past one month, how much of a problem has this been	Never	Almost Never	Some times	Often	Almost always	Mode
Q1. It is hard for me to walk more than 100m	248 82.1	25 8.3	19 6.3	7 2.3	3 1.0	0
Q2. It is hard for me to run	206 68.2	49 16.2	35 11.6	7 2.3	5 1.7	0
Q3. It is hard for me to do sports activity or exercise	241 79.8	31 10.3	19 6.3	8 2.6	3 1.0	0
Q4. It is hard for me to lift something heavy	190 62.9	52 17.2	47 15.6	7 2.3	6 2.0	0
Q5. It is hard for me to take a bath or shower by myself	283 93.7	10 3.3	2 0.7	2 0.7	5 1.7	0
Q6. It is hard for me to do chores around the house	245 81.1	29 9.6	22 7.3	4 1.3	2 0.7	0
Q7. I hurt or ache	131 43.4	86 28.5	66 21.9	15 5.0	4 1.3	0

Q8. I have low energy	114 37.7	91 30.1	75 24.8	16 5.3	6 2.0	0
Q9. I feel afraid or scared	163 54.0	62 20.5	67 22.2	7 2.3	3 1.0	0
Q10. I feel sad or blue	111 36.8	84 27.8	71 23.5	26 8.6	10 3.3	0
Q11. I feel angry	76 25.2	86 28.5	83 27.5	39 12.9	18 6.0	1
Q12. I have trouble sleeping	200 66.2	54 17.9	27 8.9	16 5.3	5 1.7	0
Q13. I worry about what will happen to me	164 54.3	58 19.2	48 15.9	18 6.0	14 4.6	0
Q14. I have trouble getting along with other kids	238 78.8	34 11.3	19 6.3	9 3.0	2 0.7	0
Q15. Other kids do not want to be my friends	262 86.8	25 8.3	7 2.3	7 2.3	1 0.3	0
Q16. Other kids tease me	192 63.6	55 18.2	37 12.3	8 2.6	10 3.3	0
Q17. I cannot do things that other kids on my age can do	174 57.6	61 20.2	49 16.2	12 4.0	6 2.0	0
Q18. It is hard to keep up when I play with other kids	198 65.6	62 20.5	25 8.3	10 3.3	7 2.3	0
Q19. It is hard to pay attention in class	156 51.7	67 22.2	56 18.5	13 4.3	10 3.3	0
Q20. I forget things	89 29.5	103 34.1	79 26.2	20 6.6	11 3.6	1
Q21. I have trouble keeping up with my school work	152 50.3	82 27.2	44 14.6	17 5.6	7 2.3	0
Q22. I miss school because of not feeling well	112 37.1	96 31.8	72 23.8	17 5.6	5 1.7	0
Q23. I miss school to go to the doctor or hospital	144 47.7	91 30.1	50 16.6	13 4.3	4 1.3	0

According to the item level analysis, more than 10% of the TD participants reported that they experienced the following difficulties “often” or “almost always” during the past three months (Figure 9.14)

- Question 10 – I feel sad or blue
- Question 11 – I feel angry
- Question 13 – I worry about what will happen to me
- Question 20 – I forget things

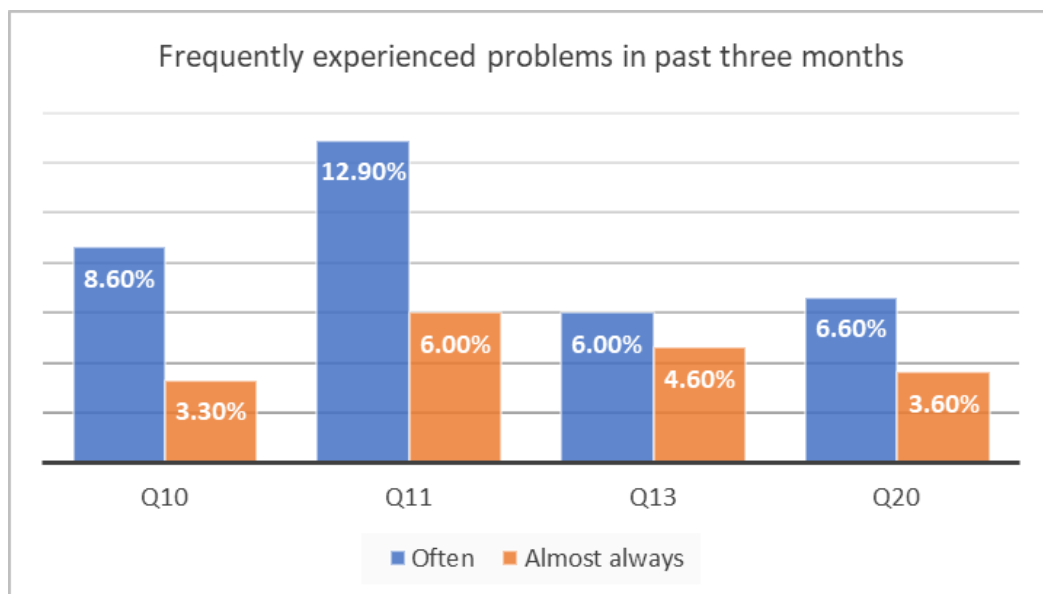


Figure 9.14 : Frequently experienced issues during past three months - TD group

Moreover, a considerable percentage of TD adolescents (above 20%) experienced the following “sometimes” within last three months (Figure 9.15)

- Question 7 – I hurt or ache
- Question 8 - I have low energy
- Question 9 – I feel afraid or scared

- Question 10 – I feel sad or blue
- Question 11- I feel angry
- Question 20 – I forget things
- Question 22 – I miss school because of not feeling well

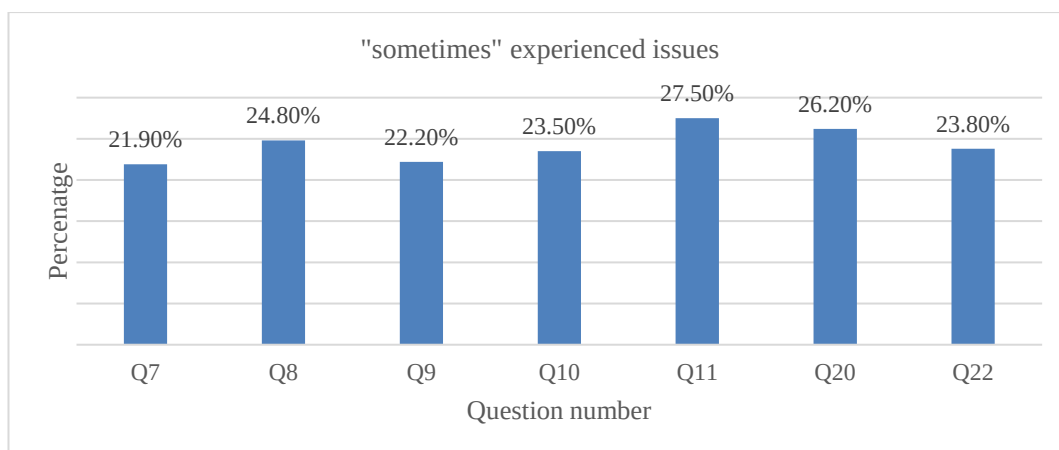


Figure 9.15 : “sometimes” experienced issues during past three months – TD group

9.1.17 Item level analysis of PedsQL-Sinhala – CLP group

Item level analysis was carried out to determine CLP participants’ most frequent responses for each item of PedsQL-Sinhala. Except for question 23 “*I miss school to go to the doctor or hospital*” for all other questions, more than half of adolescents with CLP responded that they had “never” or “almost never” experienced the problems in the questionnaire. The most frequent individual response (mode) was “0”-“Never” for all questions except question 7 “*I hurt or ache*”, question 8 “*I have low energy*”, question 22 “*I miss school because of not feeling well*” and question 23 “*I miss school to go to the doctor or hospital*”. The detailed item-level analysis of 23 questions is displayed in Table 9.43.

Table 9.43 : Frequency distribution (*n* & %) of the responses for PedsQL-Sinhala items in CLP group (*n* = 37)

In the past one month, How much of a problem has this been	Never	Almost Never	Some times	Often	Almost always	Mode
Q1. It is hard for me to walk more than 100m	23 62.2	12 32.4	2 5.4	0	0	0
Q2. It is hard for me to run	21 56.8	12 32.4	2 5.4	1 2.7	1 2.7	0
Q3. It is hard for me to do sports activity or exercise	22 59.5	6 16.2	9 24.3	0	0	0
Q4. It is hard for me to lift something heavy	16 43.2	14 37.8	6 16.2	1 2.7	0	0
Q5. It is hard for me to take a bath or shower by myself	32 86.5	4 10.8	1 2.7	0	0	0
Q6. It is hard for me to do chores around the house	17 45.9	8 21.6	11 29.7	1 2.7	0	0
Q7. I hurt or ache	8 21.6	15 40.5	14 37.8	0 0	0 0	1
Q8. I have low energy	12 32.4	10 27.0	14 37.8	1 2.7	0	2
Q9. I feel afraid or scared	23 62.2	10 27.0	4 10.8	0 0	0 0	0
Q10. I feel sad or blue	15 40.5	14 37.8	8 21.6	0 0	0 0	0
Q11. I feel angry	12 32.4	11 29.7	10 27.0	3 8.1	1 2.7	0
Q12. I have trouble sleeping	24 64.9	9 24.3	2 5.4	1 2.7	1 2.7	0
Q13. I worry about what will happen to me	22 59.5	10 27.0	4 10.8	1 2.7	0 0	0

Q14. I have trouble getting along with other kids	14 37.8	11 29.7	11 29.7	0 0	1 2.7	0
Q15. Other kids do not want to be my friends	16 43.2	9 24.3	12 32.4	0 0	0 0	0
Q16. Other kids tease me	16 43.2	13 35.1	7 18.9	1 2.7	0 0	0
Q17. I cannot do things that other kids on my age can do	14 37.8	11 29.7	9 24.3	2 5.4	1 2.7	0
Q18. It is hard to keep up when I play with other kids	15 40.5	11 29.7	8 21.6	1 2.7	2 5.4	0
Q19. It is hard to pay attention in class	19 51.4	10 27.0	6 16.2	1 2.7	1 2.7	0
Q20. I forget things	18 48.6	14 37.8	3 8.1	0 0	2 5.4	0
Q21. I have trouble keeping up with my school work	16 43.2	13 35.1	6 16.2	0 0	2 5.4	0
Q22. I miss school because of not feeling well	14 37.8	15 40.5	3 8.1	5 13.5	0 0	1
Q23. I miss school to go to the doctor or hospital	11 29.7	6 16.2	18 48.6	2 5.4	0 0	2

According to the item level analysis, more than 10% of the CLP participants reported that they experienced following difficulties “often” or “almost always” during the past three months (Figure 9.16)

- Question 10 – I feel sad or blue
- Question 11 – I feel angry
- Question 13 – I worry about what will happen to me
- Question 20 – I forget things

According to the item level analysis, more than 10% of participants reported that they experienced the following "often" or "almost always".

- Question 11 – I feel angry
- Question 22 – I miss school because of not feeling well

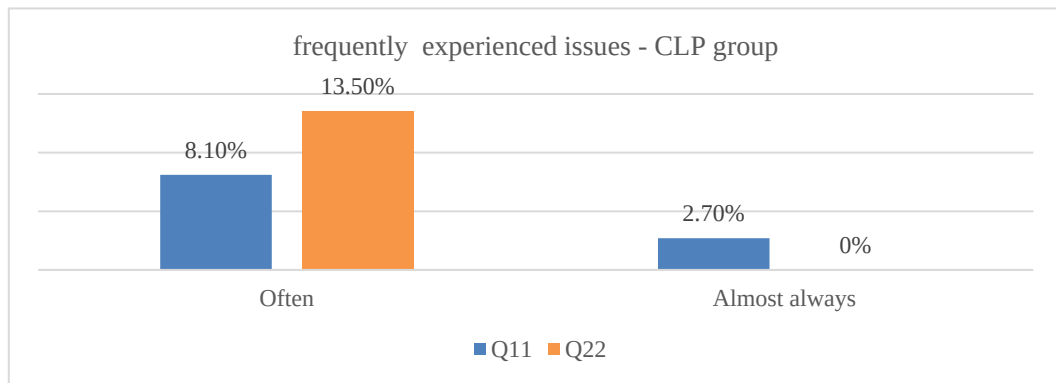


Figure 9.16 : “often” and “almost always” experienced issues during past three months – CLP group

A proportion of adolescents with CLP (above 20%) experienced the following "sometimes", and the percentages are displayed in (Figure 9.17).

- Question 3 - It is hard for me to do sports activity or exercise
- Question 6 - It is hard for me to do chores around the house
- Question 8 - I have low energy
- Question 10 - I feel sad or blue
- Question 11 - I feel angry
- Question 14 - I have trouble getting along with other kids
- Question 15 - Other kids do not want to be my friends
- Question 17 - I cannot do things that other kids on my age can do
- Question 18 - It is hard to keep up when I play with other kids
- Question 23 - I miss school to go to the doctor or hospital

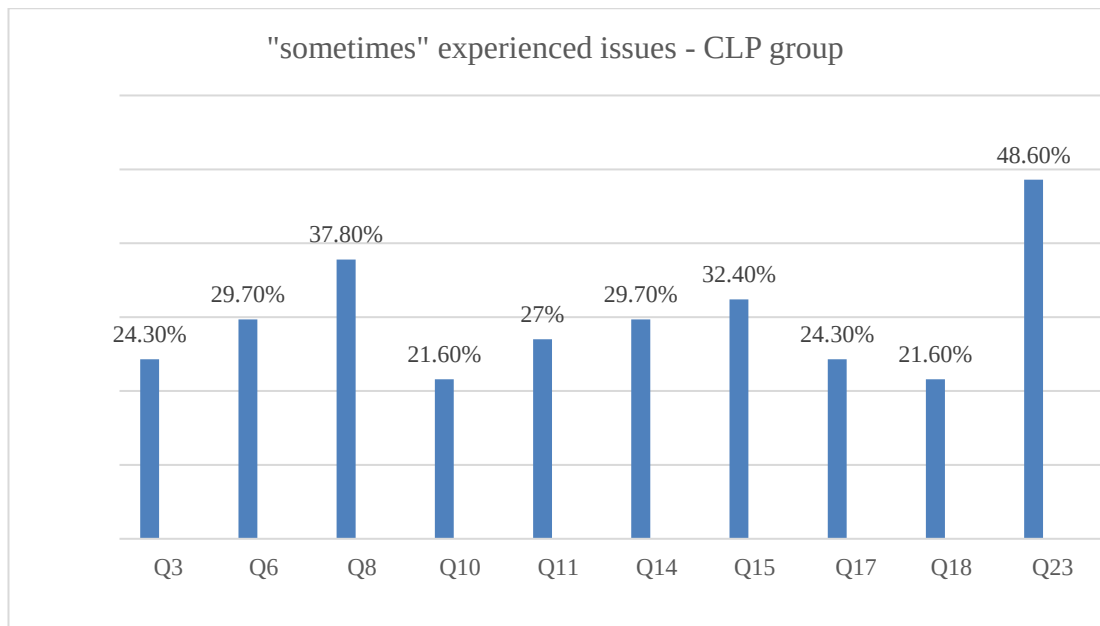


Figure 9.17 Percentages (%) of "sometimes "experienced oral health problems – CLP group

Table 9.44 : Comparison of “sometimes” experienced health related quality of life impacts stated in PedsQL-Sinhala

	TD	CLP
“sometimes” experienced health issues <u>common</u> for both groups	Q 8. I have low energy Q 10. I feel sad or blue Q 11. I feel angry	Q 8. I have low energy Q 10. I feel sad or blue Q 11. I feel angry
“sometimes” experienced health issues <u>not common</u> in both groups	Q 7. I hurt or ache Q 9. I feel afraid or scared Q 20. I forget things Q 22. I miss school because of not feeling well	Q 3. It is hard for me to do sports activity or exercise Q 6. It is hard for me to do chores around the house Q 14. I have trouble getting along with other kids

Q 15. Other kids do not want to be my friends

Q 17 I cannot do things that other kids on my age can do

Q 18. It is hard to keep up when I play with other kids

Q 23. I miss school to go to the doctor or hospital

3

9.1.18 Item level distribution comparison summary - TD & CLP groups

Ten percent of adolescents with CLP reported that they “always” or “almost always” miss school. This could be directly related to their CLP. As evidenced by the item level analysis, more than 10% of TD adolescents experienced four health issues while adolescents with CLP only experienced two oral health issues “often” or “almost always”. The possible explanation for this may be the sample size. The TD adolescents sample size was approximately eight times larger than the CLP size. However, a significant percentage of adolescents with CLP “sometimes” experienced ten health issues listed in the PedsQL-Sinhala questionnaire during previous three months while TD group only experienced seven oral health issues. Moreover, the percentages of the “sometimes” experienced issues were higher in the CLP group than the TD group. When considered alongside the sample size this is a remarkable difference: in the 37

³ Social functioning issues are highlighted in blue colour and school functioning issues are highlighted in orange colour

CLP participants, there were reports of ten issues experienced during the previous three months while the 302 TD adolescents only experienced eleven issues during the previous three months. It can thus be suggested that the majority of CLP adolescents experienced health issues “sometimes” in the previous three months when compared with the TD same age peers who experienced these less often. As shown in Table 9.44, both groups only experience three issues “sometimes” in common. Adolescents with CLP experienced social functioning related issues (highlighted in blue), issues related to friendships and a reasonably high percentage of CLP participants (highlighted in orange) “sometimes” missed school to go to the doctor or hospital. Hence, item level analysis highlights that adolescents with CLP showed health related quality of life impacts “sometimes” during the past three months that may be as a result of their craniofacial abnormality.

9.1.19 PedsQL-Sinhala Scale level analysis

The PedsQL generic original English assessment consists of 23 questions and is divided into four scales. The PedsQL Sinhala assessment also follows the same format and comprises 23 items comprising the following four dimensions.

- Physical functioning
- Emotional functioning
- Social functioning
- school functioning

The detailed description of each subscale is presented in Table 9.45. The higher the score in each dimension indicates a higher quality of life score.

Table 9.45 : A detailed explanation of the PedsQL- Sinhala four dimensions

Dimension	Number of items and position in the questionnaire	Items
Physical functioning	8	Q1. It is hard for me to walk more than 100m Q2. It is hard for me to run Q3. It is hard for me to do sports activity or exercise Q4. It is hard for me to lift something heavy Q5. It is hard for me to take a bath or shower by myself Q6. It is hard for me to do chores around the house Q7. I hurt or ache Q8. I have low energy
Emotional functioning	5	Q9. I feel afraid or scared Q10. I feel sad or blue Q11. I feel angry Q12. I have trouble sleeping Q13. I worry about what will happen to me
Social functioning	5	Q14. I have trouble getting along with other kids Q15. Other kids do not want to be my friends Q16. Other kids tease me Q17. I cannot do things that other kids on my age can do Q18. It is hard to keep up when I play with other kids
School functioning	5	Q19. It is hard to pay attention in class. Q20. I forget things. Q21. I have trouble keeping up with my schoolwork. Q22. I miss school because of not feeling well. Q23. I miss school to go to the doctor or hospital

9.1.20 Scale level analysis of PedsQL-Sinhala responses – TD & CLP

TD and CLP participants' responses to the PedsQL-Sinhala questionnaire were analysed according to the four physical, emotional, social, and school functioning subscales. The number of questions and the maximum achievable total PedsQL scores for each subscale are explained under each subscale descriptions. Different scores achieved by adolescents in both groups and percentages are presented in below tables followed by a subscale level PedsQL –Sinhala responses analysis summary. PedsQLTM standard scoring information is presented in detail in Chapter 8 (8.8.2) and the subscale analysis was conducted following the standard scoring system.

PedsQL-Sinhala item scores were transformed on a scale from 0-100. PedsQL scores are calculated following a reverse scoring procedure so that higher scores indicate better HRQOL. Firstly, all items are reversed so that 0 (never) = 100, 1 =75, 2=50, 3=24 and 4 (almost always) =0. Then scale scores are determined from the sum of the items over the number of items answered (which allows missing data to be accounted for). A total scale score is the sum of all the items over the number of items answered (PedsQLTM, 1998-2004).

Total mean score is the sum of the items over the number of items answered on all the scales. Subscale total scores were calculated by summing all of the items over the number of items answered on each subscale. The total mean score and individual mean

score were computed by dividing the total score by number of items in the questionnaire. Hence, the total mean score of the PedsQoL-Sinhala could vary from 0-100. The same procedure was applied to calculate subscale mean scores. Higher mean scores indicated good quality of life.

9.1.20.1 Physical functioning subscale – TD group (n=302)

The physical subscale consists of 8 questions; total scores can be ranged from 0 – 800, where high scores show a higher quality of life. The physical subscale total mean score was 89.00 (SD=7.35). Participants’ responses ranged from 450-800 and total mean scores ranged from 56.25 – 100. No participant scored a total of 0. Ceiling effects for this subscale was observed in 82 TD participants (27.2%). A detailed description of the physical subscale score frequencies and percentages of TD group are outlined in Table 9.46. According to the data shown in Table 9.46, more than a quarter (27.2%) of the TD participant population's subscale score = “800”, indicating they had never experienced the physical difficulties listed in the questionnaire. Participants’ responses were skewed to the highest scores of the subscale indicating less impact on physical functioning skills. Most frequent TD participant responses are highlighted in blue and CLP participants most frequent responses are highlighted in orange.

Table 9.46 : Frequencies and percentages of physical functioning subscale total score - TD and CLP groups

Subscale Total	TD/CLP	800	775	750	725	700	675	650	625	600	575	550	525	500	475	450	425
Frequency (n)	TD	82	24	45	19	28	30	21	12	9	8	7	6	5	5	1	0
Percentage (%)	TD	27.2	7.9	14.9	6.3	9.3	9.9	7.0	4.0	3.0	2.6	2.3	2.0	1.7	1.7	0.3	0
Frequency (n)	CLP	2	4	5	2	2	4	4	2	1	2	4	2	1	0	1	1

Percentage CLP (%)	5.4	10.8	13.5	5.4	5.4	10.8	10.8	5.4	2.7	5.4	10.8	5.4	2.7	0	2.7	2.7

9.1.20.2 Physical functioning subscale – CLP group (n=37)

The *physical functioning subscale* total mean score for the CLP group was 81.84 (SD=12.75). As outlined in Table 9.46, participants' responses ranged from 425-800, with individual mean scores from 53.13 – 100. No participant scored the minimum (0) indicating severe impact on the *physical functioning subscale*. A detailed description of physical subscale total score frequencies and percentages is displayed in Figure 9.18. More than half of the participants' (59.4%) *physical functioning subscale* scores were between 600-800 indicating that they did not adversely experienced physical problems listed in the questionnaire frequently within last three months. Two participants (5.4%) scored the ceiling core of 800.

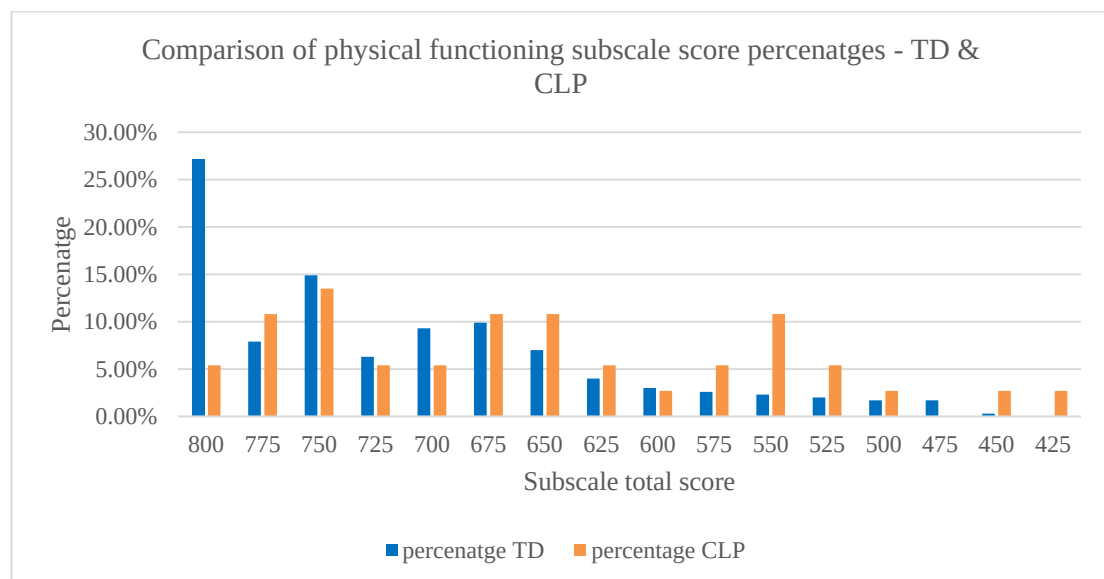


Figure 9.18 : Comparison of physical functioning scale responses between TD and CLP groups

In summary, as shown in Figure 9.18, 27.2% of TD adolescents scored the maximum possible highest score of the subscale compared to 5.4% adolescents with CLP. Moreover, TD participants' *physical functioning subscale* most responses tended towards the highest scores of the subscale while CLP participants' scoring were spread between 425-800. Hence it highlights that the CLP group experienced more QoL impacts listed in the *physical functioning subscale* than their TD peers. However, no participants in either group scored the lower end of the scale indicating adverse physical functioning impacts suggestive of low QoL.

9.1.20.3 Emotional functioning subscale – TD group (n=302)

The *emotional subscale* contains five questions, with total possible subscale scores ranging from 0 – 500, where high scores show a better emotional position and quality of life. The *emotional subscale* mean value was 80.74 (SD = 14.45). Study participants' responses to *emotional subscale* score ranged from 200 to 500, and individual mean scores ranged from 40 to 100. No participant scored "0" to indicate severe emotional issues listed in the subscale suggestive of low quality of life. Table 9.47 below illustrates a detailed description of the *emotional subscale* total scores. Most frequent TD participant responses are highlighted in blue and CLP participants' most frequent responses are highlighted in orange.

Table 9.47 : Frequencies and percentages of emotional functioning subscale total score – TD and CLP groups

Subscale Total		500	475	450	425	400	375	350	325	300	275	250	225	200
TD	Frequency (n)	42	29	42	45	36	19	24	27	19	7	5	6	1
TD	Percentage (%)	13.9	9.6	13.9	14.9	11.9	6.3	7.9	8.9	6.3	2.3	1.7	2.0	0.3
CLP	Frequency (n)	3	1	5	5	4	4	1	8	4	0	1	0	1

CLP	Percentage (%)	8.1	2.7	13.5	13.5	10.8	10.8	2.7	21.6	10.8	0	2.7	0	2.7

As shown in the table (Table 9.47), 13.9% of the TD participants' *emotional functioning subscale* total was "500", the maximum potential score. Hence, they never experienced emotional issues listed in the questionnaire in the previous three months. 64.2% of the TD adolescents scored between 400-500 indicating that the majority orated positively and had not been experiencing severe emotional functioning issues during the previous three months.

9.1.20.4 Emotional functioning subscale – CLP group ($n=37$)

In the Emotional functioning subscale, study participants' responses individual scores ranged from 200 - 500, and individual mean scores ranged from 40 - 100. As shown in Table 9.47, no participant scored "0" on the other hand, three (8.1%) scored the possible maximum total score of 500. 21.6% of the participants scored 325 indicating that some percentage of participants in this group had experienced emotional issues during the previous three-month period. The Emotional functioning subscale mean score for the CLP group was 75.94 (SD=14.47).

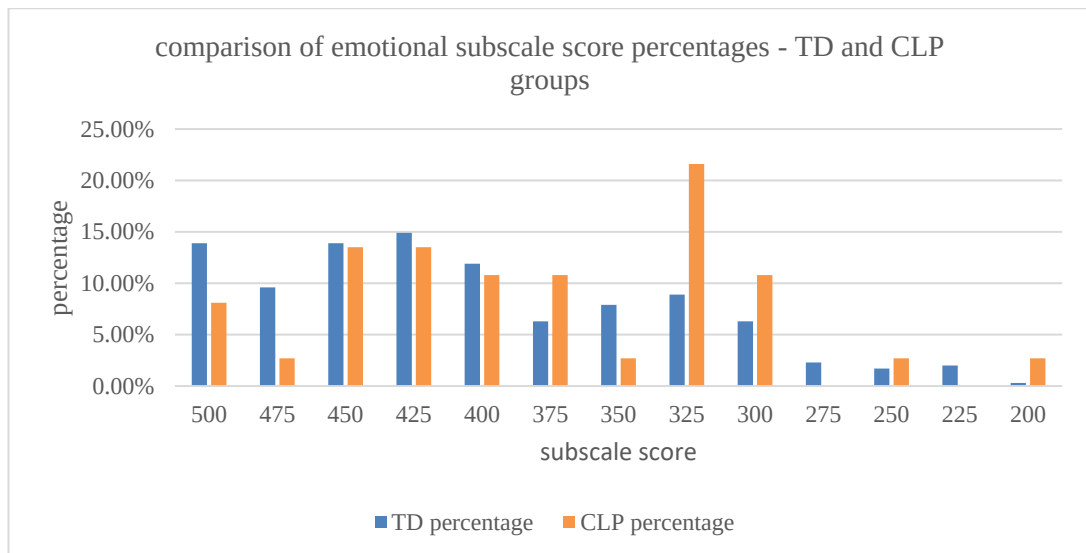


Figure 9.19 : Comparison of TD and CLP Emotional functioning Subscale Scores

In summary, it can be seen from Figure 9.19, that there was a notable difference in the responses between groups. Closer inspection of the data shows that the CLP group scored lower than the TD group for the *emotional subscale*. A significant percentage of adolescents with CLP scored between 300 – 400 while the majority of the TD peers scored between 400 - 500. Taken together these results suggest that adolescents with CLP experienced more emotional health issues than TD adolescents and this can affect their health-related quality of life.

9.1.20.5 Social functioning Subscale – TD group (n=302)

The *social functioning subscale* also contains five questions. The possible total scores range from 0 -500, where high scores indicate better social functioning. The social subscale mean value was 90.09 (SD = 11.74) for the TD participant group. Study participants' responses subscale score ranged from 150 to 500, and mean scores ranged from 30 -100. No participant reported the minimum score of 0. A detailed description of the *social functioning subscale* is displayed in Table 9.48. More than three-quarters

of the TD study population (86.1%) rated between 400 - 500 indicating that they had not experienced social issues during the past three months. Among those, 38.4% of the participant's subscale score was "500", indicating they never experienced problems listed in the social subscale. Most frequent TD participant responses are highlighted in blue and CLP participants most frequent responses are highlighted in orange.

Table 9.48 : Frequencies (as a %) of social functioning subscales scores in TD and CLP groups

Subscale	TD/ CLP	500	475	450	425	400	375	350	325	300	275	225	200	150
Total														
Frequency (n)	TD	116	45	45	28	26	13	15	6	2	4	0	1	1
Percentage (%)	TD	38.4	14.9	14.9	9.3	8.6	4.3	5.0	2.0	0.7	1.3	0	0.3	0.3
Frequency (n)	CLP	6	2	2	3	3	5	6	3	2	3	1	0	1
Percentage (%)	CLP	16.2	5.4	5.4	8.1	8.1	13.5	16.2	8.1	5.4	8.1	2.7	0	2.7

9.1.20.6 Social functioning subscale – CLP adolescents (n=37)

Participants' *social functioning subscale* scores ranged from 150 - 500, and individual mean scores ranged from 30 -100. No participant scored zero and indicated a very poor quality of life. Six participants (16.2%) reported the maximum highest total score of 500 in this group. The *social functioning subscale* mean score for the CLP group was 76.08 (SD=16.96). A detailed description of *social functioning subscale* score frequencies and percentages are outlined in Table 9.48. Nearly half of the participants (45.9%) scored between 300-400 while only 35.1% scored 400-500. Hence, it is apparent that CLP participants' responses were not skewed towards the low end of the possible scores, however, the majority experienced social functioning issues to some extent as a significant percentage (35.1%) scored below the highest scores.

As shown in Figure 9.20 : Comparison of TD and CLP social functioning subscale scores, comparison of the scores of the *social functioning subscale* between TD and CLP highlights that a higher percentage of TD adolescents scored at the upper end of the scale than adolescents with CLP whose scores ranged between the middle and upper level of the scale. A considerable percentage of CLP participants scored between 275 – 400 indicating that they experienced social functioning issues. In the TD group, 38.4% scored the maximum Social Functioning score, more than twice as many as CLP (16.2%). In conclusion, the results indicate that CLP participants experienced more social functioning issues impacting on to their QoL during the previous three months than their TD peers. However, no participant reported the lower scores of the subscale indicating that neither CLP or TD participants experienced severe social functioning issues.

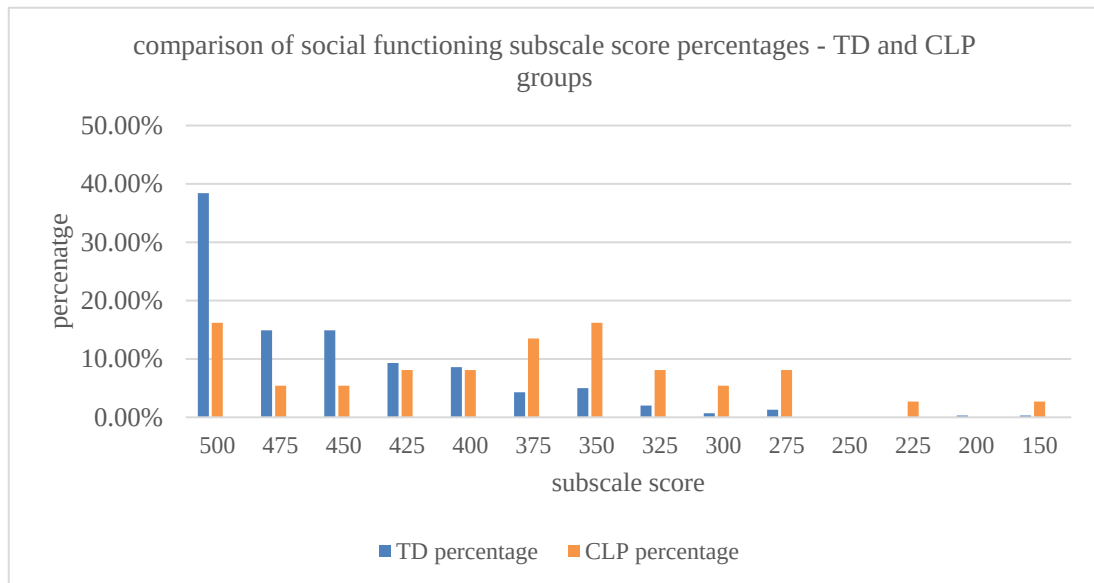


Figure 9.20 : Comparison of TD and CLP social functioning subscale scores

9.1.20.7 School functioning subscale – TD group ($n=302$)

The possible total score ranges between 0 - 500 in the *school functioning subscale* containing five questions. The total mean value of the *school functioning subscale* was 85.91 (SD=12.41), and the median was 90 for the TD participant group. Responses ranged from 225 -500, and mean scores ranged from 45 – 100. 24.2% of respondents scored the maximum score for the subscale (500). 75.8% of participants scored between 400 -500 indicating positive responses for the *school functioning subscale*. There were no participants who scored the minimum total of the subscale. A detailed description of the total scores is displayed in Table 9.49. Most frequent TD participant responses are highlighted in blue and CLP participants most frequent responses are highlighted in orange.

Table 9.49 : Frequencies (as a %) of school functioning subscales scores in TD and CLP groups

Subscale Total		500	475	450	425	400	375	350	325	300	275	250	225	75
Frequency (n)	TD	73	32	52	40	32	24	23	11	7	5	2	1	0
Percentage (%)	TD	24.2	10.6	17.2	13.2	10.6	7.9	7.6	3.6	2.3	1.7	0.7	0.3	0
Frequency (n)	CLP	5	3	4	6	2	3	5	1	4	1	1	0	2
Percentage (%)	CLP	13.5	8.1	10.8	16.2	5.4	8.1	13.5	2.7	10.8	2.7	2.7	0	5.4

9.1.20.8 School functioning subscale – CLP group (n=37)

The total scores of the *school functioning subscale* ranged from 75 - 500, and individual mean scores ranged from 15 - 100. As shown in Table 9.49, no participant scored the minimum; on the other hand, five participants (13.5%) scored the possible maximum total score of 500. The *school functioning subscale* total mean score for the CLP group was 76.48 (SD=20.50). 89.2% of the participants scored between 300 – 500 and the responses were skewed towards the higher end of the subscale.

In summary, school functioning is the least affected subscale within both groups. According to the comparison shown in Figure 9.21, the majority of the TD and CLP participants scored between 300 – 500 on this subscale. However, the adolescents with CLP scored slightly lower than the TD participants. Only 13.5% of CLP participants scored the achievable maximum score for the subscale while 24.2% of the TD peers achieved it. Hence, it can be inferred that CLP participants experienced more issues stated in the *school functioning subscale* during the past three months impacting to their health-related quality of life.

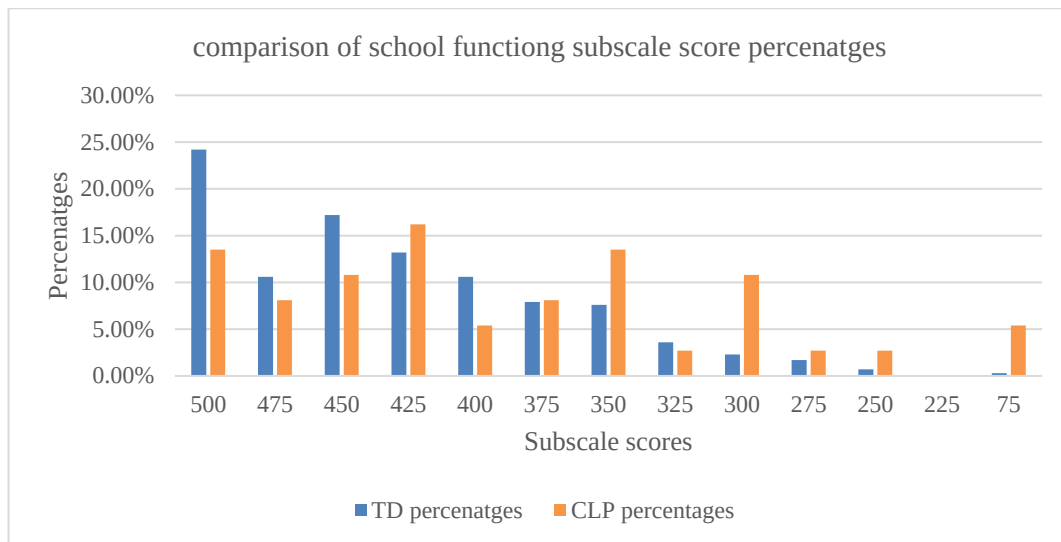


Figure 9.21 : Comparison of TD and CLP school functioning subscale scores

9.1.20.9 PedsQL-Sinhala total score analysis – TD group ($n=302$)

The PedsQL- Sinhala total score range is 0 -2300. The higher the total PedsQL-Sinhala score indicates a better quality of life. TD Participants responses total score ranged from 1325 - 2300 (Figure 9.20). Seventeen participants out of 302 (5.6%) scored the highest possible score of 2300 (suggesting ceiling effect). None of the participants achieved the minimum possible score (suggesting floor effect). Individual participants' PedsQL-Sinhala total score means ranged from 59.78 -100. The mean total score for the TD participants group was 86.77 (SD = 9.59), and the median was 89.13.

9.1.20.10 PedsQL-Sinhala total score analysis – CLP group ($n=37$)

CLP Participants responses total score ranged from 975 – 2225. None of the participants scored the highest achievable score of 2300. No participant achieved the minimum possible score of 0. Individual participants total PedsQL-Sinhala total score

means ranged from 42.39 -100. The mean total score was 78.14 (SD = 12.34), and the median was 80.43.

Subsequently, TD group scored higher total PedsQL-Sinhala total score than the CLP group. The statistical significance of the difference is outlined later in this chapter (9.1.23).

9.1.20.11 PedsQL-Sinhala subscales mean analysis summary

The previous section provided an overview of the ratings scored by participants. Further analysis of differences in subscale mean scores and total mean scores between participant groups was carried out. The subscale total mean scores of PedsQL- Sinhala was higher in TD group than the CLP group and subsequently the total PedsQL-Sinhala mean score was also higher in the TD adolescents' group than the CLP group (Table 9.50). These scores will be statistically compared (9.1.23) to find statistically significant differences between TD and CLP groups.

Table 9.50 : PedsQL –Sinhala Subscale total mean (SD) score summary

Scales	Physical functioning		Emotional functioning		Social functioning		School functioning		Total PedsQL	
Participant group	TD	CLP	TD	CLP	TD	CLP	TD	CLP	TD	CLP
Subscale Mean	89.0	81.84	80.74	75.94	90.09	76.48	85.91	78.14	86.77	78.14
SD	7.35	12.75	14.45	14.47	11.74	20.50	14.56	20.50	9.59	12.34

9.1.21 Physical Health Summary score and Psychosocial Health Summary score

As outlined in the scoring procedure of the PedsQL generic scale (8.8.2), the *physical functioning scale* score represented the Physical Health Summary Score. Psychosocial Health Summary score was calculated using the sum of the items in the *emotional*, *social*, and *school functioning* scales.

The Physical Health Summary score for the TD group is the same as the *physical functioning* scale score, thus the Physical Health Summary score $M = 89.00$ ($SD=7.35$). Similarly, the Physical Health Summary Score for the CLP group is the same as the physical functioning scale score. Hence, $M = 81.84$ ($SD=12.75$). As evidenced by the data, the Physical Health Summary score of TD adolescents is higher than CLP adolescents.

9.1.22 The Psychosocial Health Summary score of TD ($n=317$) and CLP participants ($n=37$) groups

The Psychosocial Health Summary score of the TD and CLP group was assessed using the three subscales (*emotional*, *social* and *school*) divided by the number of questions answered by each participant. The Psychological Health Summary score $M = 85.58$ ($SD = 10.57$) for the TD participant group. The TD mean scores range varied from 51.67 - 100. Moreover, the Psychological Health Summary score mean of the CLP group was 76.17 ($SD = 13.54$). The CLP mean scores range varied from 36.67 - 96.67. The mean score differences described above indicate that Psychosocial Health Summary score of the TD group was higher than the CLP group. This data requires

statistical analysis to evaluate the significance of the differences between the TD and CLP groups, which is reported below.

9.1.23 Statistical comparison of PedsQL-Sinhala total and subscale mean scores between groups

This section provides a statistical analysis of the PedsQL-Sinhala findings of both participant groups. The Kolmogorov – Smirnov test of normality was used to check the normal distribution of the PedsQL-Sinhala total score and four subscales total scores. Test of normality results was significant ($p < 0.05$) for PedsQL-Sinhala total and subscale totals to confirm the data was not normally distributed. Hence the non-parametric Mann-Whitney U test was used to compare the total PedsQL-Sinhala score and subscale total scores means between these two groups. The Mann – Whitney U test results are displayed in Table 9.51.

This analysis shows that the TD participants reported significantly higher PedsQL-Sinhala total and subscale scores than the CLP participants ($p < 0.05$) indicating significantly higher quality of life. The TD group reported a higher PedsQL-Sinhala total mean score (86.77) than the CLP group PedsQL-Sinhala total mean score (78.14).

Table 9.51 : Mann Whitney U test values comparing TD and CLP groups

Scale	Typically Developing sample (n=302) Mean (SD)	Cleft Lip and/or Palate sample (n= 37) Mean (SD)	Mann-Whitney U score	Z score	P-value
Total Score	86.77 (9.59)	78.14 (12.34)	3237.00	-4.180	0.000
Physical functioning	89.00 (7.35).	81.84 (12.75)	3656.00	-3.469	0.001
Emotional functioning	80.74 (14.45).	75.94 (14.47)	4482.00	-1.976	0.048

Social functioning	90.09 (11.74)	76.08 (16.96)	2807.00	-5.079	0.000
School functioning	85.91 (12.41)	76.48 (20.50)	4023.00	-2.811	0.005
Psychosocial Health	85.58 (10.57)	76.17 (13.54)	3267.00	-4.129	0.000

Furthermore, for all four subscales (*physical functioning subscale, emotional functioning subscale, social functioning subscale, and school functioning subscale*), total mean values were significantly different between the two groups at $p < 0.05$ level. All those subscales mean values are considerably higher in the TD group than the CLP group. TD group scored the highest mean scores for the social functioning subscale (90.09) and second highest for the physical functioning subscale (89.00). School functioning scored the third-highest mean (85.91) in this group, while the emotional functioning scale means (80.74) was the lowest. However, this pattern was not the same for the CLP group. The CLP group scored the highest mean score for the physical functioning subscale (81.84). The second highest was for the school functioning (76.48), and the social functioning subscale means (76.08) was slightly lower and the third highest. As well as the TD group, the CLP group also scored the lowest mean (75.94) for the emotional functioning subscale.

According to the error bars, the mean values show a wider variation in the CLP group than the TD group. As the cleft participants groups answers can be different depending on many factors such as their cleft type, surgical treatments received and Speech and Language therapy input etc., a wider variation is expected.

The next approach to analysis was to determine if there were significant differences in the QoL findings. Overall, the results indicate a significant difference between the

PedsQL-Sinhala scores between the TD and CLP groups. TD adolescents' QoL findings are significantly higher within each age group among TD and CLP groups.

9.1.23.1 Statistical comparison of PedsQL-Sinhala responses by age

Responses for the PedsQL-Sinhala were assessed according to four age groups in each group. Table 9.52 provides a summary of mean value statistics and statistical comparison test values (Mann Whitney U values) for each age group among TD and CLP participants. In TD group 14 and 15 year olds showed high mean scores for the total PedsQL-Sinhala and all subscale scores. These results confirmed a trend of improving QoL with age in TD adolescents.

Conversely, this pattern was not followed by the CLP participant groups. 14 and 15 years old participants reported a higher total PedsQL-Sinhala mean score than the 12 and 13 year olds. However, 12 year olds PedsQL-Sinhala total mean value was higher than 13 year olds. Thus, the highest mean value for subscales varied across different age groups indicating that QoL in adolescents with CLP did not improve with their age in this sample.

Table 9.52 : PedsQL- Sinhala total and subscale total mean distribution and Mann Whitney U values according to age groups in TD and CLP participants.

Age group	Participant group	N	PF scale Mean (SD)	EF Scale Mean (SD)	SF Scale Mean (SD)	School F Scale Mean (SD)	Psychosocial Health Total Mean (SD)	PedsQL Total Mean (SD)
12 years	TD	71	88.68 (10.63)	80.63 (14.24)	89.57 (13.08)	84.22 (13.85)	84.81 (11.37)	86.16 (10.06)
	CLP	7	80.35 (11.22)	70.71 (14.55)	78.57 (15.46)	80.71 (8.38)	76.66 (10.36)	77.95 (9.83)
			143.00	145.00	138.00	186.50	147.00	131.50

Mann Whitney U values			<i>p=0.06</i>	<i>p=0.06</i>	<i>p=0.04</i>	<i>p=0.27</i>	<i>p=0.07</i>	<i>p=0.04</i>
13 years	TD	109	87.61 (11.10)	78.11 (15.18)	89.12 (10.62)	85.87 (11.91)	84.37 (10.27)	85.50 (9.34)
	CLP	7	74.10 (16.10)	65.71 (14.55)	65.00 (21.60)	68.57 (29.25)	66.42 (18.31)	69.09 (17.00)
Mann Whitney U values			180.50 <i>p=0.01</i>	216.00 <i>p=0.05</i>	121.00 <i>p=0.00</i>	241.50 <i>p=0.10</i>	149.00 <i>p=0.00</i>	163.50 <i>p=0.01</i>
14 years	TD	71	90.43 (9.36)	84.22 (13.48)	91.83 (11.80)	87.25 (12.21)	87.77 (9.88)	88.71 (8.60)
	CLP	5	88.12 (10.45)	82.00 (13.50)	78.00 (16.04)	72.00 (10.95)	77.33 (9.39)	81.08 (8.78)
Mann Whitney U values			147.50 <i>p=0.52</i>	151.00 <i>p=0.57</i>	69.50 <i>p=0.01</i>	57.00 <i>p=0.01</i>	67.00 <i>p=0.20</i>	86.50 <i>p=0.05</i>
15 years	TD	51	90.37 (12.03)	81.66 (13.69)	90.49 (12.01)	86.47 (11.67)	86.20 (10.80)	87.65 (10.50)
	CLP	18	83.68 (11.91)	80.27 (12.88)	78.88 (15.39)	79.16 (22.11)	79.44 (12.66)	80.91 (11.14)
Mann Whitney U values			285.50 <i>p=0.01</i>	421.50 <i>p=0.60</i>	261.50 <i>p=0.00</i>	394.50 <i>p=0.37</i>	310.50 <i>p=0.04</i>	280.00 <i>p=0.01</i>

The Kolmogorov – Smirnov normality test was used to check the normal distribution of the PedsQL-Sinhala total score and four subscales total scores according to four age groups. Test of normality results was significant ($p<0.05$) for PedsQL-Sinhala total and most of the subscale totals in all age groups to confirm the data was not normally distributed. Hence the non-parametric Mann-Whitney U test was used to compare the total PedsQL-Sinhala score and subscale total scores between these age groups. As shown in **Error! Reference source not found.**, results confirmed a significant difference in PedsQL- Sinhala total score at $p<0.05$ level in every age group. TD adolescents of 12 years, 13 years, 14 years and 15 years PedsQL-Sinhala total score is

higher than the same aged CLP adolescents indicating that the quality of life is noticeably low in CLP group compared to the TD peer group.

Overall, these results indicate that the PedsQL-Sinhala total mean scores showed a significant difference ($p<0.05$) between TD and CLP participants. TD adolescents scored considerably higher than their CLP peers, and their scores improved with age. However, PedsQL-Sinhala total and subscale totals were not improved in adolescents with CLP with age. However, subscale scores were not always significantly different within this age groups. This may be due to the different participant numbers in each age group and different number of items in each subscale. In summary, these results confirm that the QoL in the CLP participant group may not improve during adolescence and vary depending on their cleft associated other factors.

9.1.23.2 Statistical comparison of PedsQL-Sinhala responses – male vs female

The following section focuses on determining differences according to male vs female in TD and CLP participants. Results are displayed in Table 9.53. It is apparent from this table that a higher mean score was reported for total PedsQL-Sinhala (87.79) and all the subscales by TD females compared to the CLP females (PedsQL-Sinhala total mean 79.04). Similarly, TD male adolescents scored higher mean values for PedsQL - Sinhala total (85.58) and all the subscales than CLP male adolescents (76.26).

Total PedsQL-Sinhala mean scores were statistically significant ($p<0.05$) between TD and female adolescents with CLP. All other subscales, other than *emotional functioning*, were statistically significant ($p<0.05$) between male and female participants in both TD and CLP groups. Similarly, Total PedsQL mean scores were

statistically significant ($p<0.05$) between TD male and CLP male adolescents. In male adolescents, except for the *emotional functioning* subscale, all other subscales scores were statistically significant at $p<0.05$ level between groups.

Table 9.53 : Mean values (Mann-Whitney U test) comparison male Vs female

Sex	Participant group	Values	Physical Functioning	Emotional Functioning	Social Functioning	School Functioning	Psychosocial Functioning	Total PedsQL
Female	TD	Mean	90.12	81.90	91.62	86.13	86.55	87.79
		SD	10.48	13.86	10.67	12.15	10.10	9.24
	CLP	Mean	82.87	76.60	76.00	78.40	77.00	79.04
		SD	12.30	15.79	16.58	19.82	12.61	11.27
		P	0.003	0.108	0.000	0.071	0.000	0.000
Male	TD	Mean	87.70	79.38	88.30	85.64	84.44	85.58
		SD	11.04	15.04	12.69	12.75	11.03	9.89
	CLP	Mean	79.68	74.58	76.25	72.50	74.44	76.26
		SD	13.94	11.76	18.47	22.20	15.75	14.69
		P	0.039	0.178	0.011	0.020	0.024	0.022

TD females consistently scored higher mean values for the PedsQL-Sinhala total scores, and all the subscale scores compared to their male peers. Interestingly, in the CLP group, the same pattern can be observed that CLP females recorded the highest mean value for the total PedsQL-Sinhala mean score and all the subscale scores than their male peers except for the social functioning subscale, where males recorded a slightly higher mean value as shown in Table 9.53, though the difference is marginal. Therefore, this sex analysis confirms that both TD females and males PedsQL- Sinhala scores are statistically significantly different compared to the CLP same gender peers. The most striking result to emerge from the gender-based analysis is that females had higher scores for the PedsQL questionnaire in both TD and CLP groups to indicate the

QoL in female adolescent are better than the same age male adolescent in these participant groups (Figure 9.22).

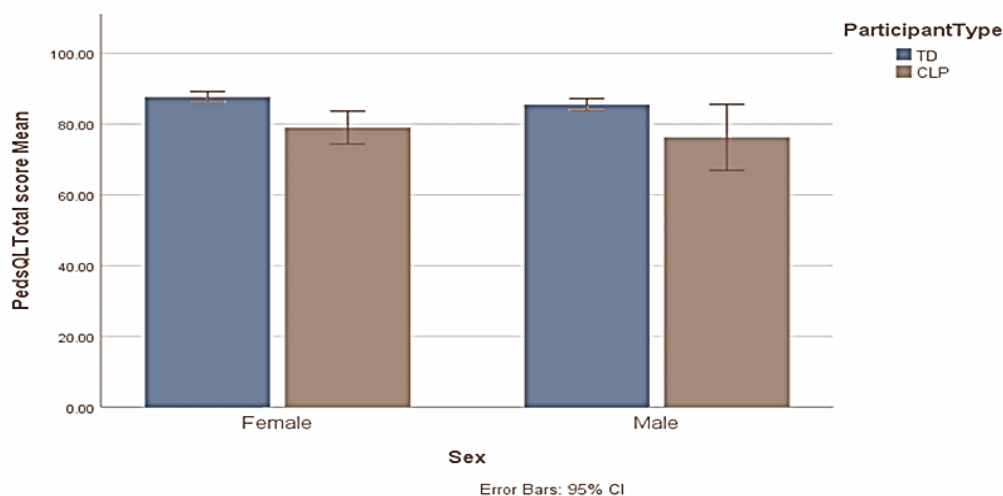


Figure 9.22 : PedsQL total score mean comparison (male Vs female)

9.1.24 PedsQL- Sinhala analysis summary

This section reported the findings of TD and CLP participants' responses for the PedsQL – Sinhala generic health-related quality of life questionnaire. This included item and subscale analysis comparing the two groups along with reporting the subscale and total scores for the two groups and the Physical Health and Psychosocial Health Scores. Results highlighted that:

- The adolescents with CLP scored lower for the PedsQL-Sinhala generic QoL questionnaire than TD adolescents, showing a statistically significant difference between two groups.
- TD adolescents PedsQL-Sinhala scores were higher in older age groups indicating their scores improved with age, but adolescents with CLP did not show this trend.

- Both TD males and females scored higher PedsQL-Sinhala scores than CLP males and females. In both groups females scored higher PedsQL-Sinhala scores than male adolescents.

Results supported the research hypothesis 3 “There will be a statistically significant ($p < 0.05$) difference between TD and CLP PedsQL-Sinhala scores indicating that adolescents with CLP also experienced issues assess by a generic quality of life measure” hence, the null hypothesis “There will be no statistically significant ($p > 0.05$) difference between TD and CLP PedsQL-Sinhala scores indicating that CLP adolescents are not experiencing issues assess by a generic quality of life measure” is rejected.

The next section of the results focuses on examining how a generic health-related quality of life questionnaire, the PedsQL-Sinhala correlates with a condition specific health-related quality of life questionnaire, the COHIP-S to determine the added value of using a condition specific health related quality of life questionnaire when evaluating QoL in CLP adolescents.

9.2 Results - Correlation between COHIP-S and PedsQL-Sinhala

This section statistically analyses the correlations between COHIP-S and PedsQL-Sinhala responses and summarises the most suitable measure for the CLP group with a descriptive analysis derived from responses.

9.2.1 Correlation between PedsQL-Sinhala and COHIP-S findings in CLP group

The PedsQL-Sinhala generic quality of life questionnaire was validated with 11-15 years old adolescents in Sri Lanka. Therefore, the strength of the correlation between PedsQL-Sinhala and COHIP-S could be considered as a positive indicator of the suitability of COHIP-S for measuring oral health related constructs in adolescents with CLP in Sri Lanka. The total scores of the PedsQL-Sinhala generic health-related quality of life measure and COHIP-S condition specific oral health-related quality of life measure were compared to identify which measure is most appropriate to use for the adolescents with CLP. As evidenced by the Kolmogorov – Smirnov normality test (9.1.10.2.2) the total COHIP-S scores were normally distributed ($p=0.20$) and the PedsQL-Sinhala total scores were not normally distributed ($p=0.05$) (9.1.23). Hence, the non-parametric Spearman's rho test was used to check the correlation between PedsQL- Sinhala total scores and COHIP-S total scores of adolescents with CLP. Spearman's correlation between the total COHIP-S score and PedsQL- Sinhala total score was statistically significant in the CLP study population ($r=0.361$, $p<0.05$) (Figure 9.23) signifying the direction and strength of the linear association between

two scales. Thus, both questionnaires identified health related and oral health related issues in adolescents with CLP. The (weak) positive correlation ($r=0.3$) between an established measure and a new measure proves concurrent validity of the new tool. The concurrent validity shows the extent of the agreement between two measures or assessments taken at the same time. It compares a new assessment with one that has already been tested and proven to be valid. Hence, it can be concluded that COHIP-S is more objective in measuring quality of life in CLP population than established PedsQL-Sinhala measure.

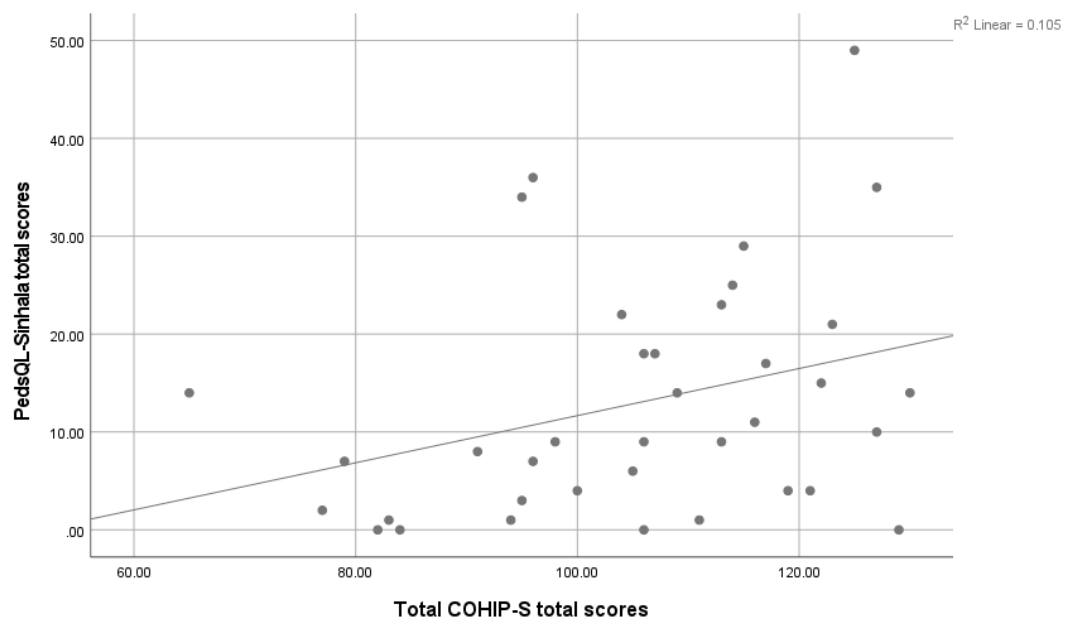


Figure 9.23 : Correlation between the PedsQL-Sinhala total score and COHIP-S total scores

Therefore, as evidenced by positive correlation, it can be highlighted that both generic and condition specific health related quality of life assessments are able to identify the QoL impacts in CLP adolescents. However, it will be still useful to analyse up to what extent each measure can identify the QoL impacts.

Together with COHIP-S, this study aimed to translate and validate ICS-SIN for TD and CLP adolescents and find out the speech intelligibility differences in TD and CLP. The next section will present the ICS-SIN questionnaire validation results with TD and CLP adolescence groups and comparison of parents' speech intelligibility ratings.

9.3 Results: Validity and reliability of the Intelligibility in Context Scale -Sinhala (ICS – SIN)

Authors' Declaration of publications

This chapter includes previously published work.

Mirihagalla Kankanamalage, I., Cleland, J., & Cohen, W. (2022). Translation and validation of the Intelligibility in Context Scale into Sinhala for adolescents in Sri Lanka with cleft lip and palate. *Clinical linguistics & phonetics*, 1–17. Advance online publication. <https://doi.org/10.1080/02699206.2022.2120417>

9.3.1 Overview

This section of the results chapter presents the descriptive data and statistical analysis from investigating the reliability and validity of the ICS-SIN that relate to research question 5: “What is the reliability and validity of the ICS-SIN?” and 6: “Do intelligibility ratings (defined by ICS-SIN score) differ between TD and CLP groups?” and 7: “Is there a correlation between parents’ ICS-SIN ratings and the QoL in adolescents with CLP?”. Section 9.3.2 outlines the TD participants characteristics and response rate follows by the item level analysis of responses for the ICS-SIN by parents of TD adolescents (section 9.3.3). CLP participants’ characteristics and response rate is described in section 9.3.4 followed by CLP parents’ responses (section 9.3.5). The reliability of the ICS-SIN for the TD group will be discussed in section 9.3.6 and for the CLP in section 9.3.7. Section 9.3.8 outlines the validity of the ICS-SIN for the TD and CLP groups followed by the correlation analysis of speech

intelligibility parents' ratings and adolescents QoL responses (section 9.3.9). Finally, a short summary section for section 3 will be presented in section 9.3.10.

9.3.2 TD participant characteristics and response rate

Two hundred ICS-SIN questionnaires were sent to parents of the TD adolescents aged 12-15 years identified from two schools in two districts randomly. This 200 were chosen among the 340 adolescents chosen for the study. Fifty-four (27%) parents sent back the completed ICS-SIN questionnaire within the given response time of one week. Three of those returned (5.55%) had to be excluded from the analysis due to errors or incomplete responses. Review of basic details of the returned questionnaires revealed one child's and parents' first language was not Sinhalese. According to the exclusion criteria (8.5.3) this questionnaire was excluded (1.85%) from analysis. In total, therefore, 50 (19.6% - overall response rate) questionnaires were included in the analysis. The sample comprised responses from parents of 19 female adolescents (38%) and 31 male adolescents (62%).

ICS –SIN Questionnaire was completed by a parent or an immediate family member of the child. 38 mothers (76%), 9 fathers (18%), 3 other immediate family members (brother, sister, grandmother) completed the ICS-SIN scale to rate their child's speech intelligibility for each of the communication partners.

9.3.3 ICS-SIN - TD parents' responses

The ratings for each of the seven questions for the TD group is presented in Table 9.54. According to the parents' ratings, the most common rating for all communication partners was "always": parents (96.0%), immediate family (92.0%), extended family

(88.0%), friends (92.0%), acquaintances (88.0%), teachers (92.0%) and strangers (86.0%). A small number of parents of TD adolescents reported that communication partners “usually” or “sometimes” understand their child (e.g. – few parents reported that extended family, teachers and strangers “usually” understand their child, a smaller number again reported that their child was understood “sometimes” by extended members of the family, acquaintances, teachers, strangers and “rarely” by strangers). As expected, none of the parents of TD adolescents rated their child as “never” understood. Mean score was calculated by adding all responses for each question and divide it by participant numbers. The highest possible mean score for each question is 5. Mean scores for the 50 participants showed that intelligibility rating was reported as highest for parents, followed by other communication partners: parents (M=4.96, SD=0.19), immediate family members (M=4.92, SD=0.27), friends (M=4.92, SD=0.27), teachers (M=4.90, SD=0.36), extended members of the family (M=4.86, SD=0.40), acquaintances (M=4.84, SD=0.46), strangers (M=4.80, SD=0.57). Therefore, parents rated themselves as understanding their child's speech the best (96.0%) (M=4.96, SD=0.19) and strangers the least (86%) (M=4.80, SD=0.57). The questionnaire total mean score was calculated as 34.20 (SD=2.0) out of maximum possible score of 35.

Table 9.54 : Parents’ ratings for the ICS-SIN - TD group ($n=50$)

Question	M	SD	Range	Always %	Usually %	Sometime %	Rarely %	Never %
1.Do you understand your child?	4.96	(0.19)	4-5	96.0	4.0	0.0	0.0	0.0
2.Do immediate members of your family understand your child?	4.92	(0.27)	4-5	92.0	8.0	0.0	0.0	0.0
3.Do extended members of your family understand your child?	4.86	(0.40)	3-5	88.0	10.0	2.0	0.0	0.0

4.Do your child's friends understand your child?	4.92	(0.27)	4-5	92.0	8.0	0.0	0.0	0.0
5. Do other acquaintances understand your child?	4.84	(0.46)	3-5	88.0	8.0	4.0	0.0	0.0
6.Do your child's teachers understand your child?	4.90	(0.36)	3-5	92.0	6.0	2.0	0.0	0.0
7.Do strangers understand your child?	4.80	(0.57)	2-5	86.0	10.0	2.0	2.0	0.0
Average total score (maximum = 35)	34.20	(2.03)	26-35					
Average total score (maximum = 5)	4.88	(0.29)						

9.3.4 CLP participant characteristics and response rate

Forty parents completed the questionnaire (100%). Two (5%) questionnaires had to be excluded from the analysis due to missing information. All the parents who completed the questionnaire declared their first language as Sinhala. In total 38 questionnaires (95%) completed by the parents of adolescents with CLP (25 female adolescents - 65.8%, 13 male adolescents- 34.2%) were included in this study. The ICS –SIN questionnaire was completed by a parent or an immediate family member of the CLP child. 28 mothers (56%), 6 fathers (12%), 4 (8%) other immediate family members (brother, sister, grandmother) completed the ICS-SIN scale to rate their child's speech intelligibility for each of the communication partners.

9.3.5 ICS-SIN – responses of parents - CLP group

As shown in Table 9.55, parents of the adolescents with CLP rated that they understood their child's speech the best, (84.2%) "always" and (15.8%) "usually." None of the parents rated they "sometimes", "rarely", or "never" understood their child's speech. For adolescents with CLP, the most common rating for all social communication partners was "always": parents (84.2%), immediate family (76.3%), extended family

(68.4%), friends (78.9%), acquaintances (68.4%), teachers (78.9%) and strangers (63.2%).

Table 9.55 : Parents' ratings for the ICS-SIN - CLP group ($n=38$)

Question	M	SD	Range	Always %	Usually %	Sometime %	Rarely %	Never %
1.Do you understand your child?	4.84	(0.37)	4-5	84.2	15.8	0.0	0.0	0.0
2.Do immediate members of your family understand your child?	4.68	(0.66)	2-5	76.3	18.4	2.6	2.6	0.0
3.Do extended members of your family understand your child?	4.55	(0.82)	1-5	68.4	23.7	5.3	0.0	2.6
4.Do your child's friends understand your child?	4.66	(0.81)	1-5	78.9	13.2	5.3	0.0	2.6
5. Do other acquaintances understand your child?	4.55	(0.82)	1-5	68.4	23.7	5.3	0.0	2.6
6.Do your child's teachers understand your child?	4.71	(0.65)	2-5	78.9	15.8	2.6	2.6	0.0
7.Do strangers understand your child?	4.47	(0.89)	1-5	63.2	28.9	2.6	2.6	2.6
Average total score (maximum = 35)	32.55	(4.7)	12-35					
Average total score (maximum = 5)	4.64	(0.67)						

Mean scores for the 38 participants with CLP showed that ratings were also highest in parents ($M=4.84$, $SD=0.37$), followed by teachers ($M=4.71$, $SD=0.65$), immediate family members ($M=4.68$, $SD=0.66$), friends ($M=4.66$, $SD=0.81$), extended members of the family ($M=4.55$, $SD=0.82$), acquaintances ($M=4.55$, $SD=0.82$) and strangers ($M=4.47$, $SD=0.89$). Parental perceptions of their children's intelligibility in different communication situations reflect that communication partners understood children's speech "always" or "usually". Moreover, only a small number of parents reported that immediate family, extended family, friends, acquaintances, and strangers "rarely" or "never" (2.6%) understand their child.

Interestingly, in both TD and CLP groups, parents rated that their adolescents are more intelligible to friends and teachers than extended family members, acquaintances, and strangers. However, in both groups parents rating mean score ratings stayed within the mean scores between 4-5 as shown in this below table (Table 9.56) indicating that parent's perception of adolescent's intelligibility between "always" to "usually".

Table 9.56: Mean scores by communication partners in TD and CLP groups.

	Parents	Immediate family	Extended family	Friends	Acquaintances	Teachers	Strangers
TD	4.96	4.92	4.86	4.92	4.84	4.9	4.8
CLP	4.84	4.68	4.55	4.66	4.55	4.71	4.47

9.3.6 Reliability of the ICS-SIN (TD group)

The ICS-SIN mean scores of the seven items for each participant were calculated. The Kolmogorov- Smirnov with Lilliefors test of normality was significant, indicating normal distribution was not assumed (Table 9.57).

Table 9.57 : Normality test results of the ICS-SIN (TD) mean scores

	Kolmogorov-Smirnov ^a			Shapiro-Wilk		
	Statistic	df	Significance	Statistic	df	Significance
Total Average	.474	50	.000	.462	50	.000

a. Lilliefors Significance Correction

9.3.6.1 Item correlations between items of ICS-SIN (TD)

Bivariate non-parametric correlation analysis (Spearman's Rank Order) was calculated to determine the relationship between individual items on the scale. Correlations between the seven items and average mean scores are illustrated in Table 9.58. All inter-correlations between the subscales showed moderate to high correlations (Field, 2000) ranging from $r = 0.344$ to 0.901 and were significant ($p < .05$). While most correlations were moderate (0.34 - 0.69), high correlations ($r > 0.7$) were observed between ratings for extended family members and strangers ($r = 0.9$) and friends and acquaintances ($r = 0.81$).

Table 9.58 : Spearman's rank-order correlations between the seven items and average mean score on ICS-SIN – TD group ($n=50$)

Item	Parent	Immediate family	Extended family	Friends	Acquaintances	Teachers	Strangers	Average Mean
Parent		0.69	0.54	0.69	0.56	0.70	0.48	0.50
Immediate Family	0.69		0.55	0.45	0.57	0.73	0.72	0.67
Extended family	0.54	0.55		0.55	0.64	0.34	0.90	0.82
Child's friends	0.69	0.45	0.55		0.81	0.46	0.49	0.66
Acquaintances	0.56	0.57	0.64	0.81		0.57	0.75	0.83
Teachers	0.70	0.73	0.34	0.46	0.57		0.52	0.65
Strangers	0.48	0.72	0.90	0.49	0.75	0.52		0.89
Average Mean	0.50	0.67	0.82	0.66	0.83	0.65	0.89	

9.3.6.2 Internal Consistency (TD)

The Internal consistency for each scale of the ICS-SIN completed by parents of TD adolescents ($n=50$) was measured using Cronbach's alpha. The correlations were significant, ($p < .05$), Cronbach's alpha was found to achieve a high level ($\alpha = 0.875$). The results for inter-correlations (Table 9.59) were all positive and showed good internal consistency in responses to the items of the scale. This finding suggests that the ICS-SIN is an appropriate tool for measuring speech intelligibility within TD adolescents.

Table 9.59 : Inter-Item Correlation Matrix of the ICS-SIN seven items

	Question1	Question 2	Question 3	Question 4	Question 5	Question 6	Question 7
Question 1		.692	.438	.692	.591	.793	.289
Question 2	.692		.449	.457	.535	.736	.547
Question 3	.438	.449		.449	.634	.319	.847
Question 4	.692	.457	.449		.853	.532	.287
Question 5	.591	.535	.634	.853		.623	.641
Question 6	.793	.736	.319	.532	.623		.392
Question 7	.289	.547	.847	.287	.641	.392	

9.3.7 Reliability of the ICS-SIN (CLP group)

The ICS-SIN mean scores of the seven items were calculated. The test of normality using Kolmogorov- Smirnov with Lilliefors was significant, indicating normal distribution was not assumed (Table 9.60).

Table 9.60 : Normality test results of the ICS-SIN (CLP) mean scores

	Kolmogorov-Smirnov ^a			Shapiro-Wilk		
	Statistic	df	Significance	Statistic	df	Significance
Total average	.329	38	.000	.592	38	.000
a. Lilliefors Significance Correction						

9.3.7.1 Item correlations between items of ICS – CLP

Bivariate non-parametric correlation analysis (Spearman's Rank Order) was calculated to determine the relationship between individual items on the scale. Correlations between the seven items and average mean scores are illustrated in Table 9.61. All inter-correlations between the subscales showed moderate to high correlations ranging from $r = 0.603$ to 0.910 and were significant ($p < 0.05$). While most correlations were high ($r > .70$), moderate correlations were observed between ratings for parents and strangers ($r = 0.6$), parents and extended family and acquaintances ($r = 0.65$).

Table 9.61 : Spearman's rank-order correlations between the seven items and average mean score on ICS-SIN - CLP group ($n=38$)

	Parent	Immediate family	Extended family	Friends	Acquaintances	Teachers	Strangers	Average Mean
Parent		0.79	0.65	0.66	0.65	0.85	0.63	0.67
Immediate Family	0.79		0.84	0.67	0.84	0.80	0.77	0.83
Extended family	0.65	0.84		0.69	0.89	0.80	0.91	0.93
Child's friends	0.66	0.67	0.69		0.80	0.86	0.74	0.80
Acquaintances	0.65	0.84	0.89	0.80		0.80	0.91	0.94
Teachers	0.85	0.80	0.80	0.86	0.80		0.73	0.80
Strangers	0.60	0.77	0.91	0.74	0.91	0.73		0.98
Average Mean	0.67	0.83	0.93	0.80	0.94	0.80	0.98	

9.3.7.2 Internal consistency (CLP)

The internal consistency for each scale of the ICS-SIN for adolescents with CLP ($n=38$) was measured using Cronbach's alpha. The correlations were significant, ($p < 0.05$), Cronbach's alpha was found to achieve a very high level ($\alpha = 0.97$). The results for inter-correlations showed high internal consistency in responses to the items (Table 9.64) of the scale. This finding further supports that the ICS-SIN is an appropriate tool for measuring speech intelligibility within adolescents with CLP.

Table 9.62: Inter-Item Correlation Matrix of the ICS-SIN seven items

	Question 1	Question 2	Question 3	Question 4	Question 5	Question 6	Question 7
Question 1		.785	.646	.624	.646	.812	.643
Question 2	.785		.918	.847	.918	.907	.901
Question 3	.646	.918		.888	.961	.902	.952
Question 4	.624	.847	.888		.928	.925	.898
Question 5	.646	.918	.961	.928		.902	.952
Question 6	.812	.907	.902	.925	.902		.890
Question 7	.643	.901	.952	.898	.952	.890	

9.3.8 Validity of the ICS -SIN (TD and CLP group)

9.3.8.1 Face validity

In this study, parents have completed the given questionnaires without any difficulty without asking for clarification from the SLT or researcher. Only a few completed questionnaires were excluded from the study due to missing basic information and incomplete ratings. Verbal feedback from a few parents about the questionnaire after completion indicated that it was easy to complete and clear what it was asking.

Some examples of parents answers;

- “It was very easy to understand.”
- “It was easy to complete.”
- “I am very clear what the questionnaire was asking.”
- “Very helpful questionnaire to explain about my child.”

This, together with the high internal consistency (TD) (9.3.6.2, and internal consistency (CLP) (9.3.7.2) results reported above confirms that this translation can be considered as a valid tool with high face validity.

9.3.8.2 Construct validity

The construct validity of the ICS-SIN was evaluated using internal and discriminant validity. The study did not check the true construct validity because there was no other similar speech intelligibility measure used in the study to check correlations; thus, the internal validity of the ICS-SIN was evaluated for construct validity. However, the correlation test was conducted between ICS-SIN findings and COHIP-S findings to further support discriminant validity. The internal validity of the ICS-SIN was evaluated using Spearman's correlations (two-tailed significance test) amongst the seven ICS-SIN item scores and the ICS-SIN total score in all TD and CLP participants ($n = 88$). The test of normality results was significant $p < 0.01$ for the total ICS-SIN average scores of the sample ($n=88$). Correlation test scores ranged between $r = 0.61$ to 0.95 , as shown in Table 9.63. All correlations were highly significant ($p < 0.05$) when the two groups were assessed independently.

Table 9.63 : Spearman correlation r between the ICS-SIN total score and the seven ICS-SIN items

ICS-SIN item	Total group ($n=88$)	TD ($n=50$)	CLP ($n=38$)
Parent	0.617	0.507	0.670
Immediate family	0.771	0.675	0.833
Extended family	0.890	0.821	0.934
Friends	0.744	0.664	0.804
Acquaintances	0.903	0.831	0.945
Teachers	0.740	0.654	0.802

Strangers	0.956	0.893	0.984

9.3.8.3 Discriminant validity

Discriminant validity was assessed by comparing ICS-SIN mean scores between two participant groups (TD and CLP). The mean average scores of the ICS-SIN questionnaire completed by the parents of the TD sample ($n=50$) and the CLP sample ($n=38$) were statistically compared. The ICS - SIN total average mean scores of both samples were not normally distributed, evidenced by the significant ($p<0.05$) normality tests results (Table 9.64).

Table 9.64 : Normality test results of the ICS-SIN (CLP) total Mean – TD & CLP groups

	Kolmogorov-Smirnov ^a			Shapiro-Wilk		
	Statistic	df	Significance	Statistic	df	Significance
Total average CLP	.329	38	.000	.592	38	.000
Total average TD	.442	38	.000	.540	38	.000
a. Lilliefors Significance Correction						

A Mann-Whitney U test was therefore used to compare the total average mean scores of these two speaker groups. There was a significant difference between the TD ($M=4.88$, $SD=0.29$) and CLP ($M=4.64$, $SD=0.67$) groups (Figure 9.24). The parents of the adolescents with CLP reported significantly lower speech intelligibility compared to the parents of TD adolescents ($U=758$, $p=0.037$) (Table 9.65) for each of the seven communication partners. Further, the results of the two groups were entered into an

online effect size calculator and Hedges' g was calculated as the sample sizes were not equal in the groups. Hedges' g was 0.488, which is a moderate effect size (Cohen, 1988).

Table 9.65 : Mann Whitney U test statistics

	Total average Mean
Mann-Whitney U	758.500
Wilcoxon W	1499.500
Z	-2.088
Asymp. Sig. (2-tailed)	.037

a. Grouping Variable: group

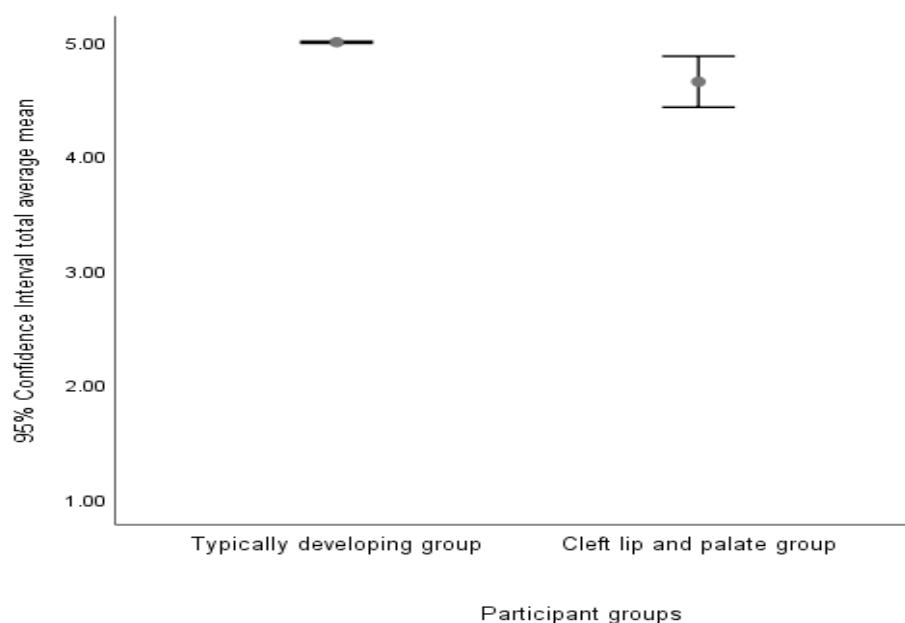


Figure 9.24 : Speech intelligibility rating scale average mean differences between the two groups.

The mean scores of the ICS-SIN were compared by age and sex for both participant groups. Child's sex information was collected via parent reports. The Spearman's rho test results revealed that there was no significant correlation between the ICS-SIN mean scores in the CLP group and the age of the child ($r = .17, p=0.30$). Similarly, in the TD group, the Spearman's rho test results revealed that there was no significant correlation between the ICS-SIN mean scores (TD) and the age of the child ($r = 0.11, p = 0.43$).

Nevertheless, there was a difference found between ICS-SIN mean scores (CLP) and the sex of the adolescents [females ($n=25$) $M=4.53$, $SD=0.80$] [males ($n=13$) $M=4.86$, $SD=0.23$] in this participant group, Males with CLP rated slightly higher than females with CLP. There was also a difference between TD ICS-SIN mean scores and sex [females ($n=19$) $M=4.96$, $SD=0.11$] [males ($n=31$) $M=4.83$, $SD=0.35$], however, converse to the CLP findings, TD females were rated slightly higher than TD males.

ICS-SIN data analysis proved its discriminant validity by results presented in Figure 9.24 showing a significant difference in the mean scores for the two groups, as demonstrated by the nonoverlap of their 95% confidence intervals [ICS-SIN scores were lower for the CLP group ($M=4.64$) than the TD group ($M=4.88$)]. Moreover, the Mann Whitney U test statistics ($U = 758, P < 0.05$), and effect sizes (Hedges' $g=0.48$) also supported this. In addition, the ICS-SIN test was able to use to find correlations and mean differences between gender groups. These findings indicate that the ICS-SIN measure is effective in discriminating adolescents who have and have not been having speech intelligibility problems with a good effect size.

9.3.9 Correlation between parents' intelligibility ratings and the QoL in adolescents with CLP

The ICS-SIN total score, PedsQL-Sinhala total score and COHIP-S total scores were not normally distributed. Thus, Spearman's correlation coefficient nonparametric statistic test was used to find the degree of association between speech intelligibility parents' ratings and QoL ratings gathered via PedsQL-Sinhala and COHIP-S. As shown in Table 9.66, there was not a significant relationship between the parents' speech intelligibility (ICS-SIN) ratings and adolescents COHIP-S total scores ($r=-.066$, $p=.696$) and PedsQL-Sinhala scores ($r=-.006$, $p=.973$) was observed. The association between ICS parents' ratings and adolescents QoL ratings were negative and very weak (close to 0) indicating that there is no association between two ratings. Moreover, the relationship between ICS-SIN ratings and subscales of each QoL questionnaires were analysed (Table 9.67, Table 9.68). There was no significant ($p>0.05$) relationship found between ICS-SIN scores and the subscale total mean scores. Again, the associations were very weak in each subscale. Hence, in this CLP adolescents' sample there was no association between parents' speech intelligibility ratings and adolescents' quality of life scores was observed.

Table 9.66 : Correlation between Speech intelligibility scores (ICS-SIN) and QoL scores (PedsQL-Sinhala & COHIP-S)

			ICS-SIN total mean	PedsQL- Sinhala mean	COHIP-S total mean
Spearman's rho	ICS-SIN total mean	Correlation coefficient		-.006	-.066

	Sig. tailed)	(2-	..	.973	.696
	<i>n</i>		38	37	43

Table 9.67 : Correlation between speech intelligibility (ICS-SIN) scores and PedsQL-Sinhala subscale scores

				ICS-SIN total mean scores
Spearman's rho	Social Domain Total Mean		Correlation coefficient Sig. (2-tailed) <i>n</i>	.106 .532 37
Spearman's rho	School Domain Total Mean		Correlation coefficient Sig. (2-tailed) <i>n</i>	.001 .994 37
Spearman's rho	Emotional Functioning Domain Mean		Correlation coefficient Sig. (2-tailed) <i>n</i>	-.050 .767 37
Spearman's rho	Physical functioning Domain Total Mean		Correlation coefficient Sig. (2-tailed) <i>n</i>	-.110 .517 37

Table 9.68 : Correlation between speech intelligibility (ICS-SIN) scores and COHIP-S subscale scores

				ICS-SIN total mean scores
Spearman's rho	Oral health Mean	Total	Correlation coefficient Sig. (2-tailed) <i>n</i>	-.051 .763 38
Spearman's rho	Functional wellbeing Mean	Total	Correlation coefficient Sig. (2-tailed) <i>n</i>	-.001 .994 37
Spearman's rho	Social emotional wellbeing Mean	total	Correlation coefficient Sig. (2-tailed) <i>n</i>	-.018 .914 38
Spearman's rho	School environment Mean	Total	Correlation coefficient Sig. (2-tailed) <i>n</i>	.013 .938 38

Spearman's rho	Self-image mean	Total	Correlation coefficient	-.040
			Sig. (2-tailed)	.811
		<i>n</i>		38

Moreover, the non-correlation of the COHIP-S and ICS-SIN scores supports the discriminant validity of the ICS-SIN. Two tests that reflect different constructs should not be highly related to each other, hence, discriminant validity is an indication of the extent of the difference between constructs. The oral health related quality of life and speech intelligibility are unrelated concepts. The non-significant correlation between the scores of these two tests that measures speech intelligibility and oral health related quality of life therefore confirms the constructs are unrelated. The constructs that theoretically should not be related to each other are in fact unrelated, and results shows that there is no correlation between the OHRQoL and speech intelligibility, therefore the ICS-SIN and COHIP-S have high discriminant validity.

9.3.10 Summary – validity and reliability of the ICS-SIN

The results presented in section 3 highlighted that ICS-SIN was shown to have a good internal consistency, face, discriminant, construct validity together with good diagnostic accuracy for both the TD and CLP adolescent groups. Moreover, the analysis revealed that parental ratings of speech intelligibility in CLP adolescents is lower than in TD adolescents. The analysis answered the research questions 5 & 6; “what are the psychometric properties of ICS-SIN in TD and CLP, 12–15-year-old adolescents”? and “Do intelligibility ratings (defined by ICS-SIN score) differ between client (TD and CLP), age and sex groups?”. The findings supported the research hypothesis 5; “ICS-SIN translations will demonstrate acceptable psychometric properties and can be considered appropriate tools to use with TD and

CLP adolescents in Sri Lanka” and research hypothesis 6; “There will be a statistically significant ($p < 0.05$) difference in ICS-SIN scores between TD and adolescents with CLP”. As the results analysis supported the hypothesis, the null hypotheses 5 and 6 are rejected (4.6). Hence, the ICS-SIN can be considered an appropriate parent-report screening measure that can be used to describe children and adolescents’ speech intelligibility with different communication partners. Providing an answer for the research question 7; “Is there a correlation between parents’ ICS-SIN ratings and the QoL in adolescents with cleft lip and palate?”, data analysis showed that there is no significant relationship between parents’ speech intelligibility ratings and QoL findings gathered by COHIP-S and PedsQL-Sinhala. Therefore, research hypothesis 7 will be rejected as the results do not support it and null hypothesis 7 was supported (4.6) “There will be a negative correlation ($r > -1$, $p > 0.05$) between speech intelligibility scores and quality of life scores in adolescents with CLP”.

9.4 Results Summary

This chapter provided the answers to research questions 1-7 (4.6). Section 9.1 provided data about the psychometric properties of the COHIP-S in 12–15 year old TD and adolescents with CLP. The results indicate that COHIP-S has good psychometric properties evidenced by good reliability for both TD and CLP groups (9.1.5.1, 9.1.10.1), good face validity (9.1.5.3.1, 9.1.10.2.1) good convergent validity (9.1.5.3.2, 9.1.10.2.2) and good discriminant validity (9.1.5.3.3, 9.1.10.2.4) as set out to achieve in research question 1 (4.6.1). Having concluded that the COHIP-S has good psychometric properties, this supports research hypothesis 1 (4.6.1).

The second aim in section 9.1 was to compare quality of life differences using a condition specific OHRQoL assessment (the COHIP-S) between TD and adolescents with CLP as stated in research question 2. This analysis found that CLP participants' total COHIP-S scores were significantly lower than the TD groups total COHIP-S scores, indicating that CLP groups oral health related quality of life is lower than their TD peers. The statistical analysis confirmed this difference, therefore the results provided answer for research question 2 (4.6.2) and favour the research hypothesis 2 (4.6.2). Consequently, null hypotheses 1 and 2 (4.6.1, 4.6.2) are rejected.

Section 9.2 aimed to investigate QoL findings of the TD and CLP groups using a generic quality of life measure called PedsQL-Sinhala and compare the QoL findings between TD and CLP groups. Item level analysis highlighted that CLP participants experienced health related QoL issues during the previous three months (9.1.17).

However, few items were identified as “most often” experienced problems. On the other hand, TD adolescents reported more issues in the item level analysis (9.1.16). Conversely, the subscale level analysis and total score analysis highlighted that adolescents with CLP reported lower health related quality of life (assessed by PedsQL-Sinhala) (PedsQL-Sinhala subscales mean analysis summary) when compared to TD same age peers. The PedsQL total mean scores were significantly different between TD and CLP groups, reporting a lower mean value in CLP group (Statistical comparison of PedsQL-Sinhala total and subscale mean scores) as set out to achieve through research question 3 (4.6.3) and supports research hypothesis 3 (4.6.3).

Moreover, in section 9.2 COHIP-S and PedsQL-Sinhala questionnaire total scores were statistically compared to find the correlation. There was a positive correlation observed between COHIP-S and PedsQL-Sinhala scores indicating that both questionnaires are potential measures to identify QoL in CLP adolescents (9.2). In addition, COHIP-S as a new measure has the strength to measure the QoL in TD and CLP adolescents. The descriptive analysis of the responses showed that adolescents with CLP reported issues related to their cleft condition when using COHIP-S (**Error! Reference source not found.**). Hence, the COHIP-S highlighted to be more appropriate to use for adolescents with CLP to measure QoL as it can identify more condition specific issues as set out to achieve through research question 4 and supported to prove the research hypotheses 4. Thus, the null hypotheses 3 and 4 are rejected (4.6.4).

The first aim of Section 9.3 was to investigate the psychometric properties of the ICS-SIN defined by internal consistency, face, convergent and discriminant validity for TD and CLP adolescents aged 12-15 years old. The results of section 3 indicate that ICS-SIN showed a good reliability for both TD and CLP groups. The Cronbach's alpha value of >0.7 indicates that the strength of the consistency is good (9.1.5.2, 9.1.10.1). Moreover, ICS-SIN showed good face validity (9.3.8.1), convergent validity (9.3.8.2) and discriminant validity (0) as set out to achieve through research question 5 (4.6.5). Having concluded that ICS-SIN has good psychometric properties supports research hypothesis 5 (4.6.5).

The second aim in section 9.3 was to investigate the speech intelligibility differences between TD and CLP adolescents as stated in research question 6 (4.6.6). The ICS-SIN analysis pointed out that the CLP adolescent's speech intelligibility was lower than the TD adolescents according to parents' ratings. The statistical analysis between

TD and CLP groups also confirmed the speech intelligibility difference between two groups as set out to achieve through research question 6. Therefore, the results favour the research study hypothesis 6 (4.6.6). Consequently, null hypotheses 6 (4.6.6) is rejected.

The third aim of section 9.3 was to find the correlation between speech intelligibility scores and adolescents QoL scores as stated in research question 7 (4.6.7). The Spearman's correlation coefficient analysis pointed out that the parents' speech intelligibility ratings about their child did not positively correlate with the adolescents QoL scores reported using COHIP-S and PedsQL-Sinhala. Thus, the results supported the null hypothesis 7 (4.6.7). Accordingly, the research hypothesis 7 is not supported by the results (4.6.7)

In chapter 9, section 9.1, 9.2 and 9.3 together answered the research question 1-7 in this study. The purpose of this stage of the current study was to determine the psychometric properties of COHIP-S and ICS-SIN, investigate the quality of life between TD and CLP adolescents using a generic health related quality of life measure, find out whether generic or condition specific quality of life is more appropriate for CLP adolescents, compare speech intelligibility scores between TD and CLP adolescents and find the association between speech intelligibility and QoL scores. All of the research study hypotheses 1-6 were supported by the results analysis except study hypothesis 7, therefore, 1-6 null hypotheses of this study were rejected. The possible reasons for results not supporting hypothesis 7 will be discussed in the discussion chapter. The results analysis shown that COHIP-S and ICS-SIN has good reliability and validity, hence can be used as potential tools to measure OHRQoL and speech intelligibility in adolescents with repaired CLP. Moreover, the study results

revealed that both QoL and speech intelligibility are lower in CLP adolescents when compared to the same age TD peers. However, there was no relationship found between parents' speech intelligibility ratings and adolescents QoL recordings.

10 DISCUSSION

10.1 Overview

This chapter reviews the findings of the study in relation to the research questions documented in Chapter 2 (Research questions, research hypotheses and null hypotheses). The overarching aim of the present study was to investigate the quality of life in adolescents with repaired CLP living in Sri Lanka. Speech and Language Therapy is a young profession in Sri Lanka, hence there are only limited standardised Sinhala tools available in clinical practice to evaluate the QoL and speech intelligibility, which are key aspects to evaluate in the assessment and treatment of children and adolescents with CLP. SLTs are the professionals who are frequently and continuously involved in the multidisciplinary treatment process of the CLP patients until their adulthood. Hence, tools to measure their QoL in SLT clinics as well as their speech intelligibility are necessary to identify appropriate support services and to evaluate the impact of any interventions. To fulfil the overarching aim of the study the oral health-related quality of life assessment (COHIP) and a speech intelligibility rating scale (ICS) were developed into Sinhala (COHIP-S and ICS-SIN) based on an evaluation of existing tools in other languages and discussed the findings in Chapter 7. Thereafter, the translated and culturally adapted measurements used with normative and CLP samples. This chapter discusses the findings of the validation process and how QoL differs in TD and CLP adolescents. This chapter is split into sections. Section 10.2 discusses the psychometric properties of COHIP-S questionnaire focusing its reliability, face, convergent, discriminant validity. Section 10.3 discusses the QoL

findings of the adolescents with CLP when compared to the same-aged TD adolescents. Section 10.4 discuss the importance of an OHRQoL measure when investigating adolescents with CLP, given that a condition specific measure is more sensitive in identifying oro-facial related issues than a generic QoL measure. This is followed by section 10.5, which discusses the psychometric properties of the ICS-SIN focusing on its reliability, content, discriminant and convergent validity and the correlation between speech intelligibility and QoL findings in CLP group. Section 10.6 discusses correlation results of speech intelligibility and QoL followed by section 10.7 that explores the limitations and methodological issues of the present study. This is then followed by a summary of the research study's contribution to clinical practice (section 10.8) and research (section 10.9). Finally, section 10.10 outlines directions and suggestions for future research.

10.2 Psychometric properties of COHIP-S

This study aimed to evaluate the psychometric properties of the COHIP-S. The findings of this validation study are based on the responses of 317 TD school children aged 12-15 years old and 38 same-aged adolescents with repaired CLP. The results strongly supported the reliability and validity of the COHIP-S version.

10.2.1 Explanation of the TD cohort COHIP-S responses

Almost 98% of TD adolescents reported experiencing at least one COHIP-S impact over the previous three months. It is somewhat surprising as minimal QoL issues defined by the COHIP-S were expected in the normative group. Nonetheless, this finding is consistent with that of Ahn et al. (2012) who found that 96.2% of participants

(school children) experienced one COHIP impact in the Korean validation study. However, the overall impact is higher compared to a recently published oral health related quality of life assessment validation completed also in Sinhala. The Sinhala “Oral Impact on Daily Performance” (OIDP) validation (Amilani et al., 2020), conducted with 220 school aged children aged between 15-19 years reported that nearly 48% of the responders experienced at least one oral impact compared to the 97.9% of participants in this thesis with the COHIP-S. This difference may be explained by the shorter OIDP scale (8 items) compared to the COHIP-S scale (34 items) indicating that a wider range of oral health aspects are covered in COHIP-S compared to the OIDP. Additionally, age may be a participating factor given that the participants in this thesis were slightly younger than those in Amilani et al. (2020).

More than 5% of the TD adolescents “*fairly often*” or “*all of the time*” experienced oral health-related problems stated in Questions 3, 4, 8, 9 and 10 which are categorized under the *oral-health* subscale. The most common (above 10%) “*sometimes*” experienced problems by the TD participants were *had pain in your tooth, been breathing through nose/snoring, had sores or sore spots in the mouth, had food sticking in or between teeth, had pain or sensitivity in teeth with hot or cold things, had dry mouth or lips, nervous/anxious about the treatments that need for teeth, mouth and face* that associated directly with oral health. These issues can be categorized as common oral health-related issues that adolescents could experience at any time in their life. However, depending on the access to free/private dental services available and willing to continue the treatments can vary the degree of the problem experiencing. This finding broadly supports the highlights of Sinhala OIDP validation (Amilani et al., 2020) where the most prevalent (36.8%) oral health impact of the 15 –19 years TD

cohort was related to chewing and enjoying food. In this study, most of the TD group participants responded *never* or *almost never* for all items in the COHIP-S. No TD participant rated their overall health as poor while the majority (77.9%) rated it as *good* or *excellent*. Therefore, the item level responses distribution of the TD adolescents skewed towards a higher oral health related QoL and showed an upward trend in this study when they grow old. A similar finding was reported in the original COHIP, albeit that sample was a community sample of 8 -15 year olds from a range of clinical groups (Broder & Wilson-Genderson, 2007). Their item-level analysis pointed out that participants utilized a full range of response choices for the COHIP, and item distributions tended to be skewed towards a higher oral health-related quality of life.

The COHIP-S total value could range from 0-136 and in this study, participants' responses ranged from 62-136. The total mean value for the TD group was 118.68 (12.93). Subsequently, the oral health subscale mean value was 33.54 (5.26) out of a maximum potential score of 40, functional well-being subscale total mean value is 22.65 (2.12) out of a maximum potential score of 24, social-emotional wellbeing subscale mean value is 29.57 (4.21) out of a maximum score of 32, school environment subscale total mean value is 15.42 (1.38) out of a maximum score of 16 and self-image subscale total mean score was 17.49 (5.63) out of a maximum score of 24. The COHIP-S total mean value and subscale mean values yielded in this study were higher compared to those of other studies. In Broder & Wilson (2007) the total COHIP mean of the community sample ($n=104$) was 102.3 (3.0), the *functional well-being* subscale mean was 20.0 (0.62), *social-emotional well-being* mean was 25.8 (1.1) and the *school environment* mean value was 14.4 (0.4). As pointed out previously, the age range in that study was wider (with children as young as 8) perhaps indicating that children's

oral health-related quality of life could increase with age, particularly given the trend of higher scores in the older age range in this thesis. It could be argued that until the age of 8-9 years, issues related to oral health may focus on the natural loss of primary dentition and the emergence of adult teeth. By the age of 12 years (Vithanaarachchi et al., 2021), most children already have their adult teeth.

Moreover, the Korean COHIP validation (Ahn et al., 2012) was conducted with ($n=2236$) 8,10,12,15 years school children and reported a COHIP score mean of 103.3 (13.3). The French COHIP validation in New Caledonia evaluated the 12 years old adolescents and reported the COHIP score mean as 101.9 (16.84). While these findings cannot be compared directly due to differences in participants' socio-demographic and socio-economic backgrounds and resource levels for oral health care facilities from country to country, they do support the argument that the possible higher mean score of the COHIP-S is a feature of the age range in this thesis, which is older than participants compared to US-English (8-15 year olds) (Broder & Wilson-Genderson, 2007), French (12 years) (Osta et al., 2015) and Korean (8-15 years old) (Ahn et al., 2012) validations.

10.2.2 Explanations of the CLP cohort responses

All 38 adolescents with CLP (100%) experienced one or more impact of the COHIP-S during the last three months. While the majority rated positively; the most frequently experienced (“fairly often” or “almost all the time”) oral health problems within this cohort were *‘upset or uncomfortable with being asked questions, people had difficulty understanding what you were saying, felt that you look different, had difficulty in saying certain words, being teased, bullied or called names, not wanted to speak/read*

out loud, felt worried or anxious, been unhappy or sad, had crooked teeth/spaces and been breathing through mouth, snoring'. These impacts are somewhat different to the impacts recorded by the TD adolescents. The findings contribute a clear understanding that most of these reported difficulties are linked with their craniofacial condition and not just related to oral health but mostly associated with their emotions and social interactions. These socio-emotional impacts experienced by adolescents with clefts are supported by other studies (Hunt et al., 2005). Between 15% - 35% "sometimes" experienced the oral health and functional impacts such as *had pain in teeth, had discolored teeth or spots on teeth, had sores or sore spots in/around mouth, had food sticking in or between teeth, had trouble biting, chewing food, had difficulty eating foods what you like to eat, felt that you look different, had difficulty keeping your teeth clean*. Moreover, these findings generally agree with Ward et al. (2013) and Christophe et al. (2020) who pointed out that people with repaired CLP are more likely to have difficulties with chewing and certain word pronunciation errors as well as difficulties being understood by others when they speak. These chewing difficulties could be related to malocclusions due to the anomaly in position, shape of the teeth and number of teeth (Freitas et al., 2012). Likewise, even post-surgery, persistent oro-nasal fistula or velopharyngeal insufficiency may cause speech intelligibility issues. Oral hygiene issues are consistent with rotated and mispositioned teeth which are often associated with orofacial clefts (Gorlin et al., 2001). In Sri Lanka, these impacts could vary in different provinces, because of the resource gaps as participants in this study cohort had been receiving care from an institution where there is a good multidisciplinary cleft clinic. It is interesting to see that TD group reported more items

related to oral health as mostly experiencing problems while CLP reported items related to socio-emotional status and oral health related issues as “sometimes”.

More than half (55-62%) of the participants rated positively to the treatment expectations questions while around 35% were “sometimes”, “fairly often” or “all the time” nervous about the treatments and 11.6% “never” or “almost never” feel better when treatment is completed. 25.6% reported their perceived overall health as excellent, but 58.1 % were responded as “good” and 16.3% as average. No participant reported perceived overall health rating as “poor”. Again, it may be that these participants benefited from receiving standard treatments, awareness education and follow-ups from a multidisciplinary team from birth similarly to reports by Lin et al. (2020) in their Chinese COHIP validation. Here there were similar findings in relation to treatment expectations, overall health findings and they pointed out that girls are more pessimistic about future treatments and general health. However, caution must be applied, as the findings might not be same with a child living in a rural area who has challenges accessing services as the current study conducted with a small CLP sample size and based in one specialized center.

This thesis hypothesized that the overall COHIP-S scores of the adolescents with CLP would be lower than their TD peers. CLP participants' COHIP-S response range was 65 - 130 and the mean value was 104.46 (6.59). No participant scored the maximum potential score of 136. Confirming the hypothesis, results clearly indicated that adolescents with CLP scored lower overall COHIP-S score compared to TD peers in this study cohorts. This finding is supported by other studies who report that oral health related quality of life in adolescents with craniofacial conditions are lower when compared to healthy controls in other languages (Broder and Wilson-Genderson

(2007) Christophe et al. (2020) in Cameroon, Leopoldo-Rodado et al. (2021) in Spain, Ward et al. (2013) . Even after surgical interventions, orthodontic and SLT follow-up, functional difficulties associated with orofacial clefts such as speech, eating and oral hygiene may persist. These difficulties are attributed to clinical findings such as missing and mispositioned teeth, constricted maxillary arch form, skeletal discrepancies, oronasal fistulas, and velopharyngeal incompetence (Gorlin et al., 2001). Therefore, psychological adjustment is often challenging for children and adolescents with orofacial clefts when compared to TD children and adolescents.

In this thesis, in line with the hypothesis, the CLP cohort reported a lower overall COHIP-S total mean value when compared to same-aged TD adolescents. Subsequently, the total mean values of *oral health*, *functional well-being*, *social-emotional well-being*, *school environment* and *self-image* subscales were also lower in the CLP cohort when compared to TD adolescents. This data contributes a clearer understanding that adolescents with CLP experience low oral health related QoL when compared to normally developing even though they received multidisciplinary care. The difference was obvious in subscale levels indicating that adolescents with CLP experience problems related to areas covers in the questionnaire such as speech, appearance, oral hygiene, peer-relationships and expectations. These results should be taken into account when considering multidisciplinary intervention for CLP adolescents to provide an overall quality care to uplift oral health related QoL.

Table 10.1 : COHIP total score and subscale scores in CLP groups in different studies

Study	Total COHIP	Oral Health subscale Mean (SD)	Functional Well-being subscale	Social-emotional	School environment subscale	Self-image subscale Mean (SD)

	Mean (SD)		Mean (SD)	well-being subscale Mean (SD)	Mean (SD)	
Sinhala (12-15 years)	104.46, (6.59)	31.46 (4.98)	19.27 (3.88)	24.79 (6.67)	13.74 (3.10)	15.18 (5.83)
Ward et al. (2013) (8-18 years)	95.6 (18.3)	24.8 (5.9)	17.7 (4.7)	24.3 (6.7)	13.1 (3.0)	15.7 (4.3)
Broder and Wilson- Genderson (2007) (8-15 years)	87.1(3.0)	----	14.7 (0.61)	21.6 (1.2)	11.9 (0.40)	----
Ali et al. (2021) (8-16 years)	89.41 (19.97)	29.84 (6.11)	16.13 (4.19)	17.18 (9.75)	11.66 (3.92)	14.58 (4.33)

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These results are consistent with the findings of other studies. Ward et al's (2013) study of 8–18 year olds (with the same inclusion and exclusion criteria of the current thesis) reported a lower COHIP overall and subscale mean values compared to the TD controls (Table 10.1). However, in Ward et al., (2013) the oral health and functional wellbeing scale values are a little lower than in this thesis while the other subscales report similar findings. A possible explanation here also relates to age as Ward et al. (2013) included a younger age from 8 years old. Moreover, the difference in overall mean value between CLP ($M = 95.6$) and TD ($M = 108.6$) in Ward et al. (2013) is very similar to the findings in this thesis (Discriminant validity (Participant groups) – Mean score comparison (TD and CLP)). Broder and Wilson-Genderson (2007) also reported a similar pattern of lower COHIP overall mean score, and subscale mean scores in 8-15 years old children and adolescents with craniofacial conditions compared with community, paediatric and orthodontic samples. Furthermore, Ali et al. (2021) reported similar results for overall COHIP mean value and subscale mean values using

⁴ SD=standard deviation

the Arabic version of COHIP with 8–16 years old children and adolescents with CLP in Sudan (Table 10.1). Christophe et al. (2020) also reported lower overall COHIP mean and subscale scores in Yaounde, Cameroon in 4–18 year olds with CLP when compared to a control group of healthy children. In addition, Lin et al. (2020) in China, Corcoran et al. (2020) in Northern Finland and Leopoldo-Rodado et al. (2021) in Spain found out lower scores in long (34 items) and short COHIP (contains lower items) in children and adolescents with orofacial clefts. In contrast, some studies (Wogelius et al. (2009), Locker and Allen (2007), Warschausky et al. (2002), Jokovic et al. (2004) have found that orofacial clefts have less impact on health-related quality of life in children and adolescents. These findings may be due to resource levels available in different countries, differences in sample sizes/participants age groups, the severity of the orofacial clefts and the use of different OHRQoL and HRQoL questionnaires.

Interestingly, the overall COHIP-S mean and subscale mean scores in this thesis are slightly higher compared to (Broder & Wilson-Genderson, 2007) in the CLP group. There are several possible explanations for this result. As a key factor, this study included only 4 older age groups of 12, 13, 14 and 15 year olds and among them, the majority were 15 year olds. Hence, by this age adolescents may have received a more intervention to correct errors that can cause problems with speech intelligibility, facial appearance and dentures. Similar findings of high overall COHIP score were reported by Abebe et al. (2018) in non-syndromic cleft children and adolescents who received multidisciplinary cleft care in Ethiopia. Their sample was similar to that in this thesis, consisting of children and adolescents with CLP (also without other associated syndromes affecting hearing, speech and language and the overall development of the child that might separately contribute to the CLP towards health-related quality of life

impacts). Additionally, the CLP sample in this thesis was recruited from an institution equipped with resources and a well-organized multidisciplinary cleft team, so the CLP sample may have been receiving a standard quality intervention since birth. Hence, slightly high overall and subscale mean values are a possibility assuming similarity in treatments available, follow-up care, support, and awareness education for children and their families as this may contribute to positive ratings of CLP group. Finally, the questionnaire was completed in the clinics while they were waiting for SLT and orthodontic treatments, so the adolescents were in a more focused and supported atmosphere to complete a questionnaire about the difficulties related to condition rather than at home. As long-standing patients of the SLT clinic together with the relationship they have with the SLT, adolescents may feel more supported in this setting that can impact on ratings.

10.2.3 Reliability and validity of the COHIP-S for TD and CLP adolescents

The reliability of the COHIP-S was assessed using Cronbach's alpha. The Cronbach's alpha values indicated excellent internal consistency of the overall COHIP-S in TD and CLP groups. Moreover, when analyzed according to five subscales; *oral health*, *social-emotional well-being*, *functional well-being*, *school environment* and *self-image* each subscale showed evidence of high internal consistency (Cronbach's alpha > 0.7). This pattern was similar in both groups. The high Cronbach's alpha value indicated

the higher agreement between the items and subscales of the questionnaire, therefore confirmed the consistency and the stability of the COHIP-S.

Adolescents with CLP reported lower OHRQoL compared to TD peers showing the sensitivity of the COHIP-S as a measure that can differentiate two groups according to clinical differences. This proves its discriminant validity. Moreover, the COHIP-S demonstrated good convergent by correlating the scores with the global health score and face validity by analysing participants' feedback. Moreover, it's concurrent validity was also proved by the scores positively correlating with the PedsQL-Sinhala scores (Correlation between PedsQL-Sinhala & COHIP-S responses). Thus, COHIP-S 34 items questionnaire exhibited excellent validity and reliability supporting its use for TD and CLP child populations of similar age in Sri Lanka.

The results corroborate the findings of a great deal of the previous COHIP validation studies. The COHIP original English (Broder & Wilson-Genderson, 2007) OHRQoL assessment has been translated into Korean (Ahn et al., 2012), French (Osta et al., 2015), Dutch (Geels et al., 2008), and Persian (Asgari et al., 2013), Amharic (Abebe et al., 2018) Chinese (Lin et al., 2020), Persian (Asgari et al., 2013), Arabic (Ali et al., 2021) and proved to have good reliability and face, discriminant and convergent, concurrent validity as shown in Table 10.2.

Table 10.2 : Published reliability and validity details of the COHIP questionnaire

COHIP Translation	Participant groups	Age range	Reliability information	Types of validity assessed
English (Broder & Wilson-Genderson, 2007)	TD, CLP, Paediatric, orthodontic	8-15 years	ICC=0.84 Cronbach α = 0.91	Convergent, discriminant validity

Dutch (Bos & Prah, 2011)	CLP	8-15 years	Cronbach's α = .81	Discriminant & exploratory analysis
Korean (Ahn et al., 2012)	TD	8-15 years	ICC=0.88 Cronbach α =0.88	Face validity
Persian (Asgari et al., 2013)	TD	13-18 years	Cronbach α =0.89	Discriminant validity Convergent validity
French (Osta et al., 2015)	TD	12 years	ICC=0.904 Cronbach's alpha coefficient = 0.880	Concurrent validity Discriminant validity Factor analysis reproducibility
Amharic (Abebe et al., 2018)	CLP	8-17 years	Cronbach α 0.979 (children)	-----
Chinese (Lin et al., 2020)	CLP	8-15 years	ICC=0.34 Cronbach α 0.85 (children)	Discriminant validity age, gender and cleft groups. Exploratory analysis
Arabic (Ali et al., 2021)	CLP	8-16 years	ICC=0.63-.87 Cronbach α = .75 (children)	-----
Sinhala This thesis (2023)	TD CLP	12-15 years	Cronbach α (TD) = 0.75 (CLP) = 0.76	Face convergent, discriminant validity

Internal consistency – (COHIP-S) total score - The Cronbach alpha coefficient indicated excellent internal consistency for the overall COHIP-S score for both TD and CLP groups. All subscale Cronbach's alpha values were satisfactory for both groups except the *functional wellbeing* subscale, which scored a slightly lower value for the TD (α =0.61) and CLP (α =0.69) group. The *social-emotional well-being* and the *self-image* subscales had excellent alpha values for both TD and CLP groups. These results demonstrate the homogeneity of the items of the COHIP-S scale.

In accordance with the findings in this thesis, previous COHIP validation studies have demonstrated excellent reliability for overall COHIP-S. Cronbach's alpha (α) value for the overall COHIP-S for TD adolescents in this study was 0.75 and 0.76 for the adolescents with CLP. This value is somewhat lower than other studies listed below; though still significant and above 0.7.

- $\alpha = 0.91$ was observed in American English (Broader & Wilson-Genderson, 2007) study conducted with a community and cleft sample of 8-15 year olds.
- $\alpha = 0.88$ was observed in (French version of COHIP) New Caledonia in 12-years old TD adolescents (Osta et al., 2015)
- $\alpha = 0.88$ was observed in (Korean version of COHIP) 8–15 year olds community sample in Korea (Ahn et al., 2012).
- $\alpha = 0.89$ was observed in (Persian version of COHIP) 13-18 years TD Iranian adolescents (Asgari et al., 2013)
- $\alpha = 0.81$ was observed in 8-15 years Dutch children and adolescents with CLP (Bos & Prahl, 2011).

In contrast, this study reported a slightly higher than the Cronbach's alpha value of 0.70 observed in 8-16 years old children and adolescents with CLP in Sudan (Ali et al., 2021). Therefore, the Cronbach's alpha value observed in this study is satisfactory because it stands between the highest and lowest Cronbach's alpha value figures reported in previous studies. Moreover, in this study Cronbach's alpha value is above the accepted definition as "good" where the Cronbach's alpha value is greater than 0.70 (Field, 2018).

Internal consistency (COHIP-S) Subscales - The internal consistency of the subscales was also relatively well-matched with previous study findings (Table 10.3). This result indicates the subscales are well correlated with each other. In this thesis, the *functional wellbeing* subscale ($\alpha=0.61$) reported a slightly lower Cronbach's alpha value. Nonetheless, the other four subscales reported >0.7 Cronbach's alpha values. *Social-emotional wellbeing* ($\alpha=0.86$), and *self-image* ($\alpha=0.80$) subscales scored the highest for TD adolescents. This same pattern was observed for adolescents with CLP as well. Apart from the *functional wellbeing* subscale ($\alpha=0.69$) other four subscales exhibited above 0.7 Cronbach's alpha value, recording the highest for *social-emotional wellbeing* ($\alpha=0.87$) and *self-image* ($\alpha=0.81$).

This finding is consistent with Broder and Wilson-Genderson (2007) who reported the lowest alpha value for the *functional wellbeing* subscale ($\alpha=0.57$) in the craniofacial sample and the highest value for the *social-emotional wellbeing* subscale ($\alpha=0.88$) in the US study. However, in this thesis, three other subscales (*oral health, school environment and self-image*) reported a higher internal consistency than the US study for CLP children and adolescents. Similarly, in the US study community sample, the highest scores were observed for the *social-emotional wellbeing* and *self-image* subscales in accordance with this thesis findings for TD adolescents. Interestingly, the US study recorded a high alpha value ($\alpha=0.8$) for the *functional wellbeing* subscale for the community sample while this thesis reported the lowest value ($\alpha=0.61$) for this subscale in TD adolescents' group. The closeness of the items relationship in this subscale was different in two countries. A possible reason could be the individual differences in the adolescents in the two countries such as problems related to dentures, frequency of seeing a dentist and level/access of care receiving in this age.

Table 10.3 : Comparison of COHIP-S subscale Cronbach's alpha values with previously published reliability figures

COHIP Subscale	This thesis	US study	Sudan	New	Dutch	Korea
	Sinhala (α)	English (α)	Arabic (α)	Caledonia	(α)	Korean
	(12-15 years)	(8-15 years)	(8-16 years)	French (α) (12 years)	(8-15 years)	(α) (8-15 years)
Oral-health	TD = .75 CLP = .72	TD = .67 CLP = .69	- CLP = .75	TD = .70 -	- CLP = .50	TD = .75 -
Functional wellbeing	TD = .61 CLP = .69	TD = .80 CLP = .57	- CLP = .74	TD = .66 -	- CLP = .73	TD = .73 -
Social- Emotional wellbeing	TD = .86 CLP = .87	TD = .90 CLP = .88	- CLP = .65	TD = .84 -	- CLP = .78	TD = .87 -
School environment	TD = .70 CLP = .71	TD = .50 CLP = .64	- CLP = .75	TD = .66 -	- CLP = .45	TD = .62 -
Self-Image	TD = .80 CLP = .81	TD = .83 CLP = .69	- CLP = .75	TD = .70 -	- CLP = .03	TD = .70 -

The subscales Cronbach's alpha values observed in COHIP validation in Dutch; 8-15 years old children and adolescents with cleft were noticed to be lower compared to the findings in this thesis. In the Dutch study, *oral health* ($\alpha=0.50$) and *school environment* subscales ($\alpha=0.45$) alpha values were found to be the lowest and *functional wellbeing* ($\alpha=0.73$) and *emotional wellbeing* ($\alpha=0.78$) subscale alpha values were reported to be the highest (Bos & Prahl, 2011).

Likewise, the COHIP – French validation with 12 years old TD adolescents in New Caledonia exhibited that internal consistency was moderate for the *functional wellbeing* subscale ($\alpha=0.66$) and satisfactory for the *socio-emotional wellbeing*

subscale ($\alpha=0.85$) which is in accordance with this thesis findings (Osta et al., 2015). Moreover, the Korean COHIP validation with 8–15 years old TD children and adolescents showed above 0.7 internal consistency for all subscales except the *school environment* ($\alpha=0.62$) subscale (Ahn et al., 2012).

However, in Sudan using the Arabic COHIP in 8–16-years old children and adolescents with CLP the authors reported internal consistency above 0.7 for all subscales except *social wellbeing* ($\alpha=0.65$) that differs from this study (Table 10.2) because this study reported the highest value for the *social wellbeing* subscale (Ali et al., 2021)).

In this study internal consistency of the subscales showed differences. In previous American English (Broder & Wilson-Genderson, 2007), Korean (Ahn et al., 2012), Arabic (Ali et al., 2021), French (Osta et al., 2015), Persian (Asgari et al., 2013) validations also highlighted differences between subscales. The possible reasons for this inconsistency are the differences in the different age groups, sample size, resources available and severity of the cleft. The key difference is, this study used an older age group of 12-15 year olds while most of the studies included children from 8 years of age. When children are younger their ratings could be lower than older children. Most of the 8–9 years TD children experience oral health issues due to their adult teeth appearing and CLP children as well undergo this. Some CLP children and adolescents may need surgical corrections to close palatal fistulas with an alveolar bone graft at the age of 8-12 years (Luque-Martín et al., 2014) and children and adolescents with CLP may experience nasality differences in their speech which results in reduced speech intelligibility (Nagarajan et al., 2009). These factors can negatively impact their oral health, functional well-being, socio-emotional wellbeing, school

environment, and self-image concerns; thus, subscale ratings could change in different study samples. In this study, participants were in the age range beyond dentition change and surgical interventions for bone grafting. Therefore, the subscale scores may be slightly different and higher to the previous studies because this study was planned as a point in time to evaluate oral health QoL beyond the main intervention stage and critically identify the needs at this age.

The results of the item analysis for each subscale for both TD and CLP groups suggested that values of all items in each subscale related to each other and related to the total COHIP score appropriately. Moreover, the values of “corrected item total correlation” for both groups were 0.195 or over and there was no item considered to be deleted as the α value was above .7, confirming satisfactory organization of the items within each subscale. This adequate organisation of items in COHIP questionnaire was also confirmed in the American English study (Broder & Wilson-Genderson, 2007) and Korean validation (Ahn et al., 2012) studies.

Consistent with the literature (as shown in Table 10.1 and Table 10.2), the current study results also support that the COHIP-S has a satisfactory overall reliability for both CLP and TD adolescents in this age group.

Convergent validity of the COHIP-S was proved by almost all correlation coefficients being positive implying that when all subscale scores and the overall score were higher (e.g.- the OHRQoL is higher); the self-perceived health score was also higher in TD adolescents. In the CLP sample, total COHIP-S score, *oral health subscale*, *functional wellbeing subscale*, *social-emotional wellbeing subscale* and *school environment subscale* scores showed a positive correlation with the self-perceived health score (A

single statement to rate on how they feel about their overall health). However, *self-image* subscale did not correlate with self-perceived health score and the r value was 0 ($r = .00$) indicating no relationship. A possible reason for this was most adolescents with CLP rated neutral possible answers rather than using the full range of the scale. This study's findings of a positive correlation observed between perceived health score and COHIP-S total scores in both TD and CLP groups support those of previous studies conducted in US and Korea (Broder & Genderson, 2007, (Ahn et al., 2012). Hence, COHIP-S proves good convergent validity as the variables that measure same or similar constructs were positively correlated.

The findings of this study demonstrate that the COHIP-S was able to discriminate between adolescents with or without CLP. The TD adolescents showed better oral health-related quality of life scores by rating high in overall COHIP-S scores when compared to the adolescents with CLP. Mann-Whitney U test statistically significantly proved this difference ($p < 0.01$). Accordingly, all COHIP-S subscales showed significantly higher total scores in TD adolescents when compared with CLP same age peers ($p < 0.05$). The CLP group found to report negative impact on their OHRQoL than TD adolescents as demonstrated by the lower overall COHIP-S scores and *oral health, functional wellbeing, social-emotional wellbeing, school environment and self-image* subscale scores. The findings in this thesis on discriminant validity reflect Broder and Wilson-Genderson (2007), Geels et al. (2008) and Osta et al. (2015) albeit that the comparison populations were different orofacial and orthodontic populations. Furthermore, discriminant validity testing on TD and CLP groups included demographic variables such as age and sex. The overall COHIP-S score showed higher scores in the older TD participants. Therefore, COHIP-S is a tool that can differentiate

the four age groups in the same sample. This adds further to the sensitivity of COHIP-S as it can identify the changes that can be generally expected according to the age of TD adolescents. In contrast, the total COHIP-S score in adolescents with CLP did not increase with age. 14 years old adolescents with CLP recorded the highest overall COHIP-S value following 12 year olds, 15 year olds and the lowest among 13 years old adolescents with CLP. This may be explained by the fact that adolescents with CLP are different from one another due to the severity of the cleft and persisting structural anomalies (e.g., fistula,), nasality and intelligibility of the speech (due to velopharyngeal insufficiency), treatment expectations and their ratings will be different regardless of their age. In addition, the cleft sample is smaller, hence a much variation may not be probable. Moreover, outcomes for the CLP sample are consistent with Broder and Wilson-Genderson (2007) who reported a similar finding in their craniofacial cohort. However, the results were discussed as a whole sample without delineating the craniofacial sample. In somewhat agreement with our CLP group findings, Ward et al. (2013) reported that older children with CLP reported lower OHRQoL scores when compared to younger children in some subscales possibly because concerns about appearance and the opinions of others change when they grow older. Likewise, Bos and Prahl (2011) also reported CLP younger groups scored higher in oral symptoms, emotional well-being and overall COHIP.

Analyzing COHIP-S overall scores according to sex revealed TD male adolescents scored slightly higher ($M=121$) than the female ($M=119$) adolescents. In this thesis, TD group sex differences are in contrast with Ahn et al. (2012), who highlighted girls had higher mean scores than boys in a community sample of 2236 children and adolescents aged 8-15 years. It is difficult to explain these differences, but it might be

related to the sample size and broad age range compared to the current study. Moreover, girls may have reported lower QoL because of cultural differences in two countries related to appearance and self-confidence along with any changes in society since 2011.

In contrast to the TD group, female adolescents with CLP scored higher overall COHIP-S score ($M = 104$) than male adolescents with CLP ($M = 103$) in this study cohort. This outcome is contrary to that of Bos and Prahl (2011) who found there was no significant sex effect on the OHRQoL in children and adolescents with CLP. These results need to be carefully interpreted as the sample consisted of 122 young people with CLP ranging from 8-15 years of age which is bigger and wider compared to this thesis sample. In the present study, female adolescents with CLP had higher COHIP-S scores might have a cultural impact as well. Because parents are generally getting more worried about the facial appearance of a girl than a boy and tend to be actively involved in the treatment process as it can become problematic when it comes to arrange marriages for females (Abeyasekera, 2016). Girls in nature also tend to turn up for appointments when they grow old as they are more concerned about their appearance, making friends, establishing intelligible speech in order to integrate into the society and employments (Caldwell, 1996). Paganini et al. (2021) also reported that while appearance-related distress is present in both sexes, women expressed more distress than men. Hence this motivation to seek treatments may be a possible reason to show higher overall COHIP-S scores in female adolescents than male adolescents in this Sri Lankan 12–15 years old CLP cohort. In accordance with results, Lin et al. (2020) pointed out that the overall COHIP and subscale scores were slightly higher in girls than boys in Chinese CLP patients (8-15 years old). These results further show

that the COHIP-S is a sensitive measure that can identify impacts in children and adolescents with craniofacial anomalies such as CLP.

Therefore, the psychometric properties of the COHIP-S are consistent with the validity and reliability figures of the original English validation (Broder & Wilson-Genderson, 2007) and other language validations proving the Sinhala version could be considered as a valid and reliable measure.

10.2.4 Summary

The COHIP is one of the most frequently used oral health-related quality of life indexes for children and adolescents and it has been found to be a high-quality instrument (Gilchrist et al., 2014) translated and validated into many languages with excellent validity and reliability. The COHIP-S transcultural adaptation and validation into Sinhala further supports its cross-cultural usability and psychometric properties. The COHIP-S was successfully developed following a standardized procedure for cross-cultural adaptation of a self-reported instrument. Hence, in this assessment designed for 8–15year olds, cultural adaptations were applied accordingly to match the language and age. The excellent internal reliability, face validity, convergent validity and discriminant validity of the COHIP-S 34 item scale in a representative sample of TD and CLP 12–15 years old Sri Lankan, Sinhala speaking adolescents were confirmed in this study. The COHIP-S is therefore confirmed as a valid, reliable tool to investigate oral health-related quality of life in TD and adolescents with CLP in Sri Lanka with similar psychometric properties to other versions currently used across the world.

10.3 Quality of life analysis in adolescents with repaired CLP

10.3.1 Main objectives, hypothesis, and key findings

In this study, the Sinhala PedsQL™ generic scale was used to analyse health-related QoL in CLP adolescents 12- 15 year olds compared to the same age healthy peers in Sri Lanka. Children and adolescents with CLP commonly have difficulties in speaking, hearing, appearance, oral hygiene and mental pressure which may cause psychometric discomfort and poor quality of life (Lin et al., 2020) when compared to healthy peers. In Sri Lanka, Prabodha et al. (2017) highlighted the importance of addressing the psychological aspects of cleft subjects, which will help enhance these patients' QoL. In this thesis, one of the key aims was to investigate the QoL of adolescents with repaired CLP when compared to same aged healthy peers. The investigator hypothesised that HRQoL in adolescents with repaired CLP will be significantly lower when compared with TD peers. Findings from this study supported this hypothesis and TD adolescents reported higher PedsQL-Sinhala total scores than CLP adolescents. The PedsQL- Sinhala total mean scores of the two groups showed a statistically significant difference. Subsequently, *physical functioning*, *emotional functioning*, *social functioning*, *school functioning* and *psychosocial functioning*; the five subdomains of the PedsQL-Sinhala inventory showed significantly lower values in the CLP group than TD group.

10.3.2 Quality of life comparison findings between CLP and TD subjects

In the item level analysis, as hypothesized, most of the TD adolescents reported they “never” or “almost never” experienced the problems explained in PedsQL-Sinhala. However, more than 20% of TD adolescents “sometimes” experienced issues such as “*I hurt or ache*”, “*I have low energy*”, “*I feel afraid or scared*”, “*I feel sad or blue*”, “*I feel angry*”, “*It is hard to pay attention in the class*”. These issues may be considered as short term in TD adolescents as the parents declared that they do not have any long-term medical conditions.

On the other hand, above 10% adolescents with CLP reported “*I feel angry*” and “*I miss school because of not feeling well*”, “often” or “almost always”. A possible explanation may relate to the absences necessary due to their ongoing medical treatments. Attending frequent medical appointments are the most common possible reasons for school absences. It is challenging to arrange appointments in Sri Lanka minimising disruption to school attendance, because of the transport facilities, the distance people have to travel for specialized hospital clinics, school open time (7.30am-1.30pm) and health care clinic service operational hours (8-4pm). Consistent with this thesis findings, high school absence rates were highlighted even in developed countries such as UK and Australia (Bell et al., 2017; Fitzsimons et al., 2021) in CLP children and adolescents. Adolescents with CLP may report “anger” due to their appearance when compared to TD peers, ongoing treatments, peer-relationship issues such as bullying and persisting difficulties with speech. In this study cohort, adolescents with CLP experienced more issues associated with social skills and emotions when compared to TD peers. This may be partly due to the impacts associated with people’s perceptions on disability and cultural differences in Sri Lanka.

PedsQL-Sinhala generic scale is consisted of four dimensions, *physical functioning*, *emotional functioning*, *social functioning* and *school functioning*. In the TD group, the total mean score for the *physical functioning* dimension was 89 (SD=7.35), *emotional functioning* dimension was 80.74 (SD=14.45), *social functioning* subscale was 90.09 (SD=11.74) and *school functioning* subscale was 85.91 (SD=12.41). These results are consistent with Danansuriya and Rajapaksa (2012) who reported PedsQL-Sinhala subscale values; *physical functioning* mean as 88.7 (SD=11.0), *emotional functioning* mean = 81.1 (SD=14.9), *social functioning* scale mean=89.9 (SD=11.5) and *school functioning* mean =87.8 (SD=11.2) of 142 healthy adolescents aged 12-14 years in Sri Lanka. Interestingly, both study participants were recruited from the same district in the country and within the same age range.

Moreover, Devanarayana et al. (2014) reported close, but slightly higher PedsQL-Sinhala subscale mean values for *physical*, *emotional* and *social functioning* subscales in 13–18 years old TD control group in the same province in Sri Lanka. However, the *school functioning* subscale mean was reported a little lower to the present thesis. These results are likely to be related to the age difference as Devanarayana et al. (2014) included a significant proportion of adolescents (until 18 years) when compared to this study.

In the CLP cohort, no one scored the lowest possible score of the *physical* subscale. The mean value reported by the CLP cohort is notably lower when compared to the TD cohort *physical* subscale mean value. This difference was statistically significant ($p<0.01$). Interestingly, 27.2% of the total TD sample reported the maximum possible score of the subscale while 5.4% of the total CLP sample was able to achieve the maximum possible score of 800 for the *physical* subscale.

A similar trend was observed in all other three subscales. Adolescents with CLP reported lower mean values for *emotional functioning*, *social functioning*, and *school functioning* subscales than TD adolescents. These differences were statistically significant at the $p < 0.05$ level. For the *emotional functioning* subscale, 13.9% of the TD cohort scored the best possible score while 8.1% of the CLP sample scored this. Consequently, for the *social functioning* subscale, 38.4% of the TD total sample scored the highest possible score while 16.2% of the CLP sample reported this and 24.2% of the total TD sample scored the maximum score for the *school functioning* sample compared to 13.5% of the CLP sample achieved the maximum possible score. According to the CLP cohort responses, the most impacted subscales were social and school functioning. The standard deviation of these subscales is larger to indicate that the mean values were largely spared away from the average mean. The possible reasons for this are, the differences in adolescents with CLP according to their structural abnormalities and persisting issues related to speech, appearance, and other areas until the adolescents. There are statements that are closely linked with the issues experienced by the CLP children and adolescents in the social functioning and school functioning subscales such as “*other kids tease me,*” “*other kids do not want to be my friends,*” “*I miss school to go to the doctor or hospital*” “*I miss school because of not feeling well*” in this generic quality of life measure. Therefore, these two subscales may have shown a greater impact in the CLP cohort. Children and adolescents with CLP often report problems with peer relationships as they may not easily accepted by their peers. These findings are in agreement with Thompson et al. (2021) findings which reported peer relationship issues identified by PedsQL, that were moderately correlated with lower quality of life in New Zealand CLP children.

In this thesis, the TD adolescent cohort's *social functioning* subscale had the highest mean score ($M=90.09$, $SD = 11.74$) followed by the physical *functioning* subscale ($M=89.00$, $SD=7.35$) while the *emotional functioning* subscale had the lowest mean scores ($M=80.74$, $SD=14.45$). This finding is consistent with that of Danansuriya and Rajapaksa (2012) who reported an indistinguishable trend in Sri Lankan school adolescents. These results seem to be consistent with other research which also found higher mean scores in physical, social subscales and lower mean score in emotional functioning scale (Upton et al., 2005), (Gkoltsiou et al., 2008). The psychosocial health subscale had a slightly high mean score in this cohort ($M=85.58$, $SD=10.57$) compared to Upton et al., 2005 (UK), (Gkoltsiou et al., 2008) (Greek) and (Danansuriya & Rajapaksa, 2012) (Sri Lanka). This difference could be due to the age group imbalances and ceiling effects of three subscales included in the psychosocial health subscale (*social functioning* -38.4% reported the maximum score, *school functioning* 24.2% reported the maximum score and *physical functioning* - 27.2% reported the maximum score). The PedsQL is a generic HRQoL measure designed to apply to a wide range of population groups. Hence, the ceiling effects can be expected when tested with healthy adolescents. There was no floor effect recorded in this group.

To the investigator's knowledge, this is the first study to compare the health-related quality of life between TD and adolescents with CLP in Sri Lanka using the PedsQL-Sinhala questionnaire and report detailed subscale scores. Though the period of adolescence is generally considered a healthy period of life (van Sluijs et al., 2021), due to the transitional nature of the adolescent period, many adolescents are more likely to experience a range of physical and psychosocial health issues. Along with those, adolescents with CLP may undergo further surgical corrections, orthodontic

treatments and therapeutic interventions that could result in physical and psychosocial distress leading to poor quality of life. Supporting this, the findings in this thesis revealed that the HRQoL in adolescents with CLP was significantly lower than TD adolescents in this study cohort. The PedsQL-Sinhala total and all subscales mean scores were statistically significantly different in these two groups. The TD adolescent's group PedsQL-Sinhala total mean score was 86.77 (SD=9.59). The CLP group PedsQL-Sinhala total mean score was 78.14 (SD=12.34). The PedsQL-Sinhala total mean score between the TD and CLP groups was statistically significant at the $p<0.01$ level. In this thesis, the TD cohort mean total score is within the range reported in earlier studies of TD adolescents in Sri Lanka. For example, Danansuriya and Rajapaksa (2012) reported the mean total score of 87.2 in the Sri Lankan PedsQL validation study which included adolescents aged 12-14 years. Moreover, the total PedsQL-Sinhala mean score of TD adolescents is in accordance with studies of adolescents in Korea (Kook & Varni, 2008) and Brazil (Klatchoian et al., 2008). However, some other PedsQL studies reported relatively lower mean scores in TD children and adolescents; Upton et al., 2005 – total PedsQL $M = 83.89$ (SD=11.84), Gkoltsiou et al., 2008 – total PedsQL $M = 82.52$ (SD=11.28). The reasons for a higher mean score in this TD cohort could be due to exclusion of chronically ill children and adolescents and cultural differences in perception of issues related to HRQoL.

Adolescents with CLP are at risk for reduced QoL as they may have compromised functional well-being as a result of impaired speech intelligibility, dental development and visible defects such as facial appearance (Broder et al., 2014). In agreement with this, adolescents with CLP PedsQL-Sinhala total mean and subscale scores were lower than their TD peers. The cleft cohort included in this study received care from a CLP

multidisciplinary care team, however, their health-related quality of life was lower than same age healthy adolescents. These results are likely to be related to the ongoing treatments, persistent difficulties related to speech and appearance. In accordance with this study findings, a study that included Finnish adolescents aged 11-14 years, reported a considerably poorer health-related quality of life when compared to a same-aged school sample of healthy peers (Kortelainen et al., 2016). Moreover, in Sudan, children and adolescents with CLP (mean age of 11.3 years) reported a low quality of life compared to healthy controls (Ali et al., 2021). Despite that, some studies that included adolescents with CLP reported that there was no difference found in overall QoL in CLP adolescents. However, those studies still reported lower scores in some areas such as speech, intelligibility and social interactions (Aravena et al., 2017; Nolte et al., 2019; Sundell et al., 2017).

The PedsQL-Sinhala analysis shows the most impacts are related to social and emotional wellbeing in this adolescents' group. Structural abnormalities as a result of cleft affect feeding, smiling, speaking, and socialization in children. The facial appearance and its relationship with body image, self-esteem, and emotional well-being play an important role in social interaction. Thus, interfering in these functions will influence the QoL of these children and adolescents. Negative feelings regarding facial aesthetics make the child believe that oral health negatively affects their daily life activities. Hence, the OHRQoL is an important auxiliary measure for clinical indicators to assess health, especially in children (Rando et al., 2018).

Even though, QoL is an important area to assess throughout the treatment process this has been not well integrated into the cleft care system in Sri Lanka yet. There were no routine psychological screening and counselling for cleft patients. This may be due to

various reasons such as time constraints as one professional is handling many patients, limited staff and resources and lack of research evidence to support the importance of identifying quality of life issues early as possible and provide necessary services to enhance the overall outcome of treatments. Prabodha et al. (2017) study conducted in southern province of Sri Lanka, accentuated the importance of addressing the psychological aspect of cleft palate subjects with the concomitant correction of cleft deformity and other follow-ups treatments which will help to enhance the quality of life of the cleft palate patients. Many studies proved the impact of oral alterations on QoL of children of different ages and their families (Gomes et al., 2017; Ward et al., 2013). This study's findings provide initial evidence of low QoL in adolescents with CLP in Sri Lanka, therefore, QoL assessment in the treatment process can add valuable insights of patients' perceptions to increase the care and provide necessary help.

PedsQL is a generic QoL questionnaire designed to capture issues related to generic health in broad range of patients. Though, it was able to identify QoL difference associated with cleft condition as a group, it is questionable whether the measurement identifies all issues specifically related to the cleft condition that may lead to an underestimation of QoL in CLP adolescents when used with individual patients. As we discussed in the PedsQL-Sinhala item level analysis, the measurement is sensitive in identifying cleft condition related issues, but as a generic QoL questionnaire, this only includes few questions that can directly associated with impacts of having a cleft. Therefore, it is important to investigate the limitations of a generic questionnaire when measuring QoL in adolescents with CLP and the importance of using a subjective (oral health related) QoL measurement.

10.4 Generic vs condition-specific QoL measures

(PedsQL-Sinhala Vs COHIP-S)

This thesis included PedsQL-Sinhala as a generic QoL measure and COHIP-S as a condition-specific OHRQoL measure to gather data from a normative sample and adolescents with repaired CLP. The PedsQL-Sinhala total scores and COHIP-S total scores in the CLP cohort positively correlated ($r = .36$) with each other highlighting that both questionnaires measure the same constructs. The COHIP-S is a new measure validated in Sinhala; therefore, this positive correlation confirms its concurrent validity. In accordance with this thesis results, Broder et al. (2014) reported a positive correlation ($r = .52$) between COHIP and PedsQL total scores in 7-18 years CLP children and adolescents. The possible explanation for this slightly above r value is the broad age range and the sample size ($n=1200$). Even though, PedsQL-Sinhala and COHIP-S both indicated lower QoL in adolescents with CLP compared to their TD peers, descriptive analysis of the responses revealed that COHIP-S was able to identify more condition specific issues (as shown in Figure 9.20) in CLP adolescents while PedsQL-Sinhala identified more issues in TD adolescents (Figure 9.21). This would suggest that the COHIP-S is more sensitive when using with adolescents with CLP than a generic quality of life measure. Moreover, adolescents with CLP will be able to point out issues that are directly associated with speech and appearance such as “Had difficulty saying certain words”, “Upset or uncomfortable being asked questions” and “felt that you look different” as result of their CLP condition. These type of condition related questions are not included in a generic questionnaire like PedsQL, some issues related to QoL may not be identified and the overall QoL impacts could be

underestimated when using a generic questionnaire. This view that conditions specific measures for CLP is supported elsewhere. Broder et al. (2014) reported that the COHIP showed larger effect sizes than the PedsQL in their large ($n=1200$) study sample with the difference larger in COHIP scores than PedsQL in surgical and non-surgical groups. Moreover, Broder et al. (2014) discussed how CLP respondents reacted differently to the focus of the questions, when comparing items with similar concepts in the emotional functioning domain of the PedsQL and the socio-emotional well-being domain in the COHIP. As an example, the PedsQL item “I feel sad or blue” matched with the COHIP question “been unhappy or sad because of your teeth, mouth or face” was pointed out by the authors as more closely related to feelings of oral health while the PedsQL item does not. Adolescents with CLP have stronger feelings regarding wellbeing associated with the mouth or face (Broder et al., 2014), thus COHIP is a more appropriate measure within this population than a generic questionnaire. Thompson et al. (2021) reported high QoL findings in New Zealand between 5-7 and 8–12 year olds cleft children and adolescents but, highlighted that the PedsQL measure covers only a small psychosocial domain and not including potentially important concepts relevant to CLP population such as satisfaction with appearance and self-esteem as a limitation of the tool.

This conclusion has been drawn when using another generic HRQoL measure (SF-36) and OHRQoL measure (OHIP-14) (Broder et al, 2000). While these two measures scores were correlated, the condition specific OHIP-14 appeared to be highly associated with the oral health conditions more than the generic measure (SF-36). (Hettiarachchi et al., 2019)

Furthermore, Thompson et al. (2021) argued “*specifics of oral/dental differences are a separate outcome and should be measured with tools that are designed for that purpose, in conjunction but not in place of general measures*” (p 784) which the findings in this thesis support.

10.5 Psychometric properties of ICS-SIN

Authors' Declaration of publications

This section includes previously published work.

Mirihagalla Kankanamalage, I., Cleland, J., & Cohen, W. (2022). Translation and validation of the Intelligibility in Context Scale into Sinhala for adolescents in Sri Lanka with cleft lip and palate. *Clinical linguistics & phonetics*, 1–17. Advance online publication. <https://doi.org/10.1080/02699206.2022.2120417>

Another aim of this study was to evaluate the psychometric properties of the ICS-SIN concerning validity and reliability. Parents of 50 Sinhala speaking TD (12-15 years old) adolescents and 38 Sinhala speaking adolescents with CLP completed the ICS-SIN questionnaire. It is essential to consider the data from TD adolescents, as it provides a good reference level for the language used in ICS-SIN. From the available 18 published study data of the ICS validation studies, 12 studies included TD samples in their studies (McLeod, 2020). In this thesis, the mean ICS-SIN score for our TD adolescents was 4.88 (SD = 0.29), was consistent with findings from Sprunt and Marella (2018) who reported mean scores within the range of 4 to 5 for 257 TD children and adolescents aged 5–15. However, it is slightly higher than values reported for other international studies of TD children and adolescents, many of which report results from much younger children than those in this study sample. For example, ICS-Fiji; Mean age = 9.7 (SD = 4.4), ICS-Fiji-English, Mean age = 4.5 (SD=0.5); (Hopf, 2017). It is widely accepted that speech intelligibility continues to develop as children grow, and Ching Eugena Kok and To (2019) highlighted significantly higher scores in older children in their study using ICS-Traditional Chinese. The study reported in this

thesis included only TD adolescents aged between 12–15-year-olds, hence a higher intelligibility mean score than younger TD children was expected. The high TD mean score result may be explained by the fact that by the age of 12 -15 years, speech is well developed in TD adolescents and intelligibility of speech is also expected to be “usually to always” intelligible to any communication partners, unless they have any acquired speech difficulties such as stammering (dysfluency), voice problems or speech sound disorders.

In terms of ratings on the new ICS-SIN, this results in this thesis suggest that most TD adolescents were understood ‘always’ by all communication partners. However, a small number of parents rated ‘usually’ or ‘sometimes’ mainly for strangers, acquaintances, and extended family. In summary, TD adolescents were most intelligible to their parents (96.0%), followed by immediate family members (92.0%), friends (92.0%), teachers (92.0%), extended family (88.0%), acquaintances (88.0%) and strangers (86.0%). McLeod (2015) described the same trend in data, albeit with lower overall scores in younger children. Moreover, the results follow the trend of those of previous studies involving TD children (regardless of the age group differences) confirming that parents themselves are most able to understand their child with strangers as least able (Neumann et al., 2017, Ng et al., 2014, Piazzalunga et al., 2020; Van Doornik et al., 2018).

In line with the hypothesis, adolescents with CLP had lower scores in the ICS-SIN than the TD adolescents ($M = 4.64$, $SD = 0.67$). This may be due to the persisting speech difficulties such as articulation difficulties and VPI. Seifert et al. (2021) provide comparison data on the ICS for a sample of 412, three-year-old English-speaking children born with any cleft type. The mean average ICS score of their total sample

was 3.75 (SD = 0.76), suggesting intelligibility in children with CLP likely increases with age, similar to TD. In addition, Hashemi Hosseinabad et al. (2022) also reported lower ICS mean scores in children and adolescents aged 4–12 years (mean age = 6.97) with velopharyngeal insufficiency. Moreover, in a recent study by McLeod (2020) summarising the use of ICS across 18 international studies, 10 studies reported higher ICS mean scores for typical children compared to children with speech sound disorders, again highlighting the trend of reduced intelligibility in atypical children more generally. McLeod (2020) highlighted those higher total scores were reported by children identified with typical speech than children with atypical speech in cross-cultural validation studies. Sprunt and Marella (2018) reported a lower mean score of $M=1-2.43$ of the atypical sample of 5-15 years old children and adolescents, which is significantly lower than this study findings. However, these findings cannot be extrapolated to all situations because the atypical groups in previous studies belonged to different age groups and were diagnosed with other speech and language-related conditions. None of the ICS validation published studies included a study sample of adolescents with CLP. These results, therefore, need to be interpreted with caution. Nevertheless, in this study sample, the CLP average ICS-SIN mean was notably higher than those reported in McLeod's (2020) summary. This is likely because the sample included an older age range than the children included in other ICS studies.

In terms of the ratings across individual ICS-SIN items, the trend in the CLP group was similar to that of the TD group. These adolescents were most intelligible to their parents (84.2%), followed by teachers (78.9%), friends (78.9%), immediate family (76.3%), extended family (68.4%), and acquaintances (68.4%) and strangers (63.2%). A similar trend of most intelligible to mothers and least intelligible to strangers was

also reported by Seifert et al. (2021) in CLP children using English as their first language and Hashemi Hosseinabad et al. (2022) in CLP children and adolescents with VPI using American English.

However, the TD adolescents were second-most understandable to immediate family members and friends while CLP adolescents were secondly most intelligible to teachers and friends rated in the fourth place. This is an interesting finding, and these results may be explained by the fact that teachers are regular communication partners of the child, hence, most likely to understand the child's speech. The results in this thesis generally showed the same trend reported by Seifert et al. (2021) and (McLeod, 2015); intelligibility decreased depending on how well the communication partner knew the child. This demonstrates the influence of environmental context on intelligibility.

There appeared to be a ceiling effect in CLP parents' ratings on how well strangers could understand their child, as this was reported with the lowest mean score ($M=4.47$) compared to other communication partners. Although 63.2% of parents reported that strangers could "always" understand their child and 28.9% reported strangers could "usually" understand their child's speech. The parents reported a significant mean difference in how well they understood their child ($M=4.84$) compared with how well strangers understood their child ($M=4.47$). A similar ceiling effect on parents' ratings was also reported by Ng et al. (2014) with preschool children with speech sound disorders. These results may be explained by the fact that parents were aware that strangers might find it challenging to understand their child compared to other communication partners.

Reliability & validity - This thesis supports that the ICS-SIN is an appropriate, valid, parent report screening tool for assessing speech intelligibility of Sinhala-speaking adolescents in Sri Lanka. The scale had high internal reliability between items ($\alpha = 0.87$) and moderate-to-high correlations between items, ranging from $\rho = 0.344$ to 0.901 ($p < 0.05$) for both the TD group and for the CLP group ($\alpha = 0.97$) ($\rho = 0.603$ to 0.910 , $p < 0.05$). To assess the consistency of results across items, internal consistency/reliability was examined in 10 published studies to date and found to be very high ($\alpha = 0.91$ – 0.98) (McLeod, 2020). In this study results are in line with those of previous findings, and the internal consistency of ICS-SIN was recorded within this range for the CLP group. However, the findings report a slightly lower Cronbach's alpha value for the TD group, although this was still at an acceptable level. Similarly, there were slightly lower values than those reported by Hopf et al. (2017) and Lagerberg et al. (2019) who included participants up to 10 years of age. These results are likely to be related to the age range of the adolescents in the current thesis.

This study results demonstrated that the ICS-SIN has high internal reliability between items ($\alpha = 0.87$) and moderate to high correlations between items (range $r = 0.344$ to $r = 0.901$, $p < 0.05$) for the TD group. Moreover, the ICS-SIN showed excellent internal reliability between items ($\alpha = 0.97$) and moderate to high correlations between items (range $r = 0.603$ to $r = 0.910$, $p < 0.05$) for the CLP group. The internal consistency of ICS-SIN results shared many similarities with other ICS validation studies. For example, internal consistency in parents' responses to the items of the ICS was $\alpha = 0.93$ in the original English validation by McLeod et al. (2012), $\alpha = 0.98$ in Croatian validation by Tomić and Mildner (2014), $\alpha = 0.83$ in Fiji and $\alpha = 0.79$ in Fiji English validation by Hopf et al., 2017, $\alpha = 0.91$ in Jamaican validation by Washington

et al., 2017, $\alpha = 0.94$ in German validation by Neumann et al., 2017, $\alpha = 0.94$ in Vietnamese validation by Pham et al., 2017.

The construct validity of the ICS-SIN was examined correlating seven ICS-SIN item scores for both TD and CLP groups with the total group scores. The results showed moderate to high significant correlation ranging between $r = 0.568$ - 0.904 , proving an excellent construct validity of the tool. A similar approach was followed by Neumann et al. (2017) in a German ICS validation study with TD and SSD young children and confirmed a correlation between $r = 0.71$ - 0.93 for the entire group of 151 participants. Moreover, McLeod (2020) summarised the findings of eighteen ICS validation studies and reported that “*ICS construct validity was examined in nine studies to demonstrate that the test measures the construct of interest from several perspectives*”. The construct validity of the ICS-SIN demonstrated moderate to high correlations, similar to other studies using ICS as shown in Table 10.4.

Table 10.4 : Comparison of Psychometric properties of the ICS between studies that included typical and atypical participants.

Language/(n)/ Authors	Mean ICS score (SD): TD	Mean ICS score (SD): Atypical	Internal reliability (α)	Construct validity Range
Sinhala (n=88) (Mirihaigalla Kankanamalage et al., 2022)	4.88 (0.29)	4.64 (0.67)	TD - 0.87 CLP – 0.97	$r = 0.344$ to $r = 0.901$, $P_s < 0.05$ $r = 0.603$ to $r = 0.910$, $P_s < 0.05$
English (n=803) McLeod et al. (2012)	4.6	3.9	0.94	$r = 0.54$ to $r = 0.80$. $P_s < 0.001$
Vietnamese (n=181) Pham (2017)	4.63 (0.67)	3.96 (0.70)	0.94	$r = 0.51$ to $r = 0.85$, $P_s < 0.001$

Cantonese (n=72) Ng (2014)	4.56 (0.48)	4.14 (0.65)	-	r=0.56 to r=0.89, Ps<0.001
German (n=181) Neumann et al. (2017)	4.49	3.97	0.94	r=0.71 to r=0.93, Ps<0.001
Fiji (n=65) Hopf (2017)	-	-	Main Language – 0.83 Fiji English – 0.79	r=0.31 to 0.78, Ps<0.05 r=0.29 to 0.68, Ps<0.05
Korean (n=178) Lee (2019)	4.64 (0.41)	3.67 (0.62)	0.945	r=0.656 to r=0.943, Ps<0.001

The ICS-SIN was able to differentiate adolescents with typical speech development from adolescents with CLP suggesting its clinical value. This supports previous findings. McLeod et al. (2012) confirmed that ICS could discriminate children who were identified by their parents and teachers as having concerns about how they talked comparing the overall measure mean scores in her original English validation. Ng et al. (2014) described the discriminant validity of the ICS-TC, with pre-schoolers in Hong Kong showing that the ICS-TC could differentiate children with typical development from children with Speech Sound Disorders (SSD). Neumann et al. (2017) showed that ICS-G has a good discriminant validity by testing with German pre-schoolers with and without SSD.

Furthermore, this study investigated how ICS-SIN average scores vary according to gender and age in both TD and CLP groups. There was no association found between age and ICS-SIN average mean scores. This finding was also reported by Hopf et al. (2016) where there was no influence of age on ICS score for primary school students in Fiji. McLeod (2015) also reported that there was no association between ages with the scores as Australian pre-schoolers had lower ICS scores than younger children. In

contrast, Pham et al. (2017) found a significant but weak impact of age on the ICS – VN (Vietnamese) score to prove intelligibility scores increase with age. Even though our results support the general theory of higher ratings of speech intelligibility in the older children with high average ICS-SIN mean scores in both groups, the scores did not statistically show evidence that the scores increased within four age groups.

A significant difference was found in ICS-SIN scores between female and male adolescents in the present study. Interestingly, in the CLP group, males ICS-SIN scores were slightly higher than females; in contrast, in the TD group, females ICS-SIN scores were somewhat higher than males. These results differ from Pham et al. (2017), who found no differences between female and male ICS –VN scores, but somewhat agrees with McLeod et al. (2015) that the ICS for females were higher than for males. Hence, the findings of this study are significant since this is the first study to compare ICS-SIN scores in TD and CLP according to age and gender groups in Sri Lanka.

The high internal consistency and psychometric properties of the ICS-SIN for the CLP group highlight that this is a good potential tool for measuring functional speech intelligibility in Sinhala speaking adolescents with CLP. These results support previous research suggestions by Seifert et al. (2021) and Hashemi Hosseinabad et al. (2021) using ICS with CLP children and adolescents. Hashemi Hosseinabad et al. (2021) conducted a study to evaluate the clinical application of the ICS in individuals with different degrees of VPI aged 4-12 years (as a result of different cleft types) by relating it to the standard measures of intelligibility and confirmed that ICS could be used as a clinical tool in the measurement of intelligibility, as it is strongly related to the gold standard measure of intelligibility. Seifert et al. (2021) investigated mothers reports of intelligibility in children born with any cleft type at age three and used ICS

as the speech intelligibility measure and their findings are consistent with other studies using the ICS, indicating that this tool could be considered as a valid clinical tool for use with CLP children and adolescents.

CLP adolescents' speech intelligibility was reported as low by their parents compared to the same-aged, typically developing peers. In this study, ICS-SIN average mean scores were high in the TD adolescents, and statistically, a significant difference in speech intelligibility was revealed. A similar finding was reported by Seifert et al. (2021) that intelligibility in children born with a cleft palate is typically lower than that of the noncleft population. In conclusion, this study results support the first and second hypotheses; The ICS-SIN will have good validity and reliability for TD, CLP adolescents and speech intelligibility ratings of CLP adolescents will be lower than their TD peers' ratings.

10.6 Association of QoL and speech intelligibility in adolescents with CLP

This thesis indicated that there is no association between the QoL scores (PedsQL-Sinhala scores and COHIP-S scores) and parents speech intelligibility ratings (ICS-SIN) in the CLP cohort in line with our null hypothesis. Parents did not report low speech intelligibility scores in adolescents who reported low quality of life defined by PedsQL-Sinhala and COHIP-S. Some suggestions for reasons for this follow. Firstly, ICS-SIN is a preliminary screening tool for parents that consists of 7 items to rate on how they feel that their child being understood by others, but not a descriptive speech analysis measure. Professional listeners, native listeners, immediate family and patient may perceive speech differently (Munson et al., 2012). By the age of 12-15 years adolescents' speech may be mostly or adequately intelligible to listeners even though there can be persisting speech errors related to articulation and velopharyngeal insufficiency that can be identified by a full speech assessment. Hence, ICS-SIN may not always capture these. Parents may rate by focusing on one aspect of speech using ICS-SIN but their children's perception of speech or difficulties they experience related to QoL can be different to the parents' perception, though it's not tested in this study. Secondly, COHIP-S and PedsQL-Sinhala cover a broad range of QoL aspects in different domains such as social-emotional, self-image, schooling, and oral health. By the age of 12-15 years, adolescents QoL may be mainly concerned by other sub domains such as appearance, forming relationships, confidence and social integration (Hunt et al., 2005) but not just related to perception of speech. Hence, a parent

perception speech intelligibility rating may not correlate with broad range of QoL issues.

While children with CLP can continue to have speech issues related to production that can lead to social educational and emotional challenges (Cleland et al., 2022) previous studies highlight that parents', patients' and SLTs' speech analysis does not always correlate. Bickham et al. (2017) revealed that patients and parents have different perceptions of the quality of the child's speech, and their ratings differ from SLP perceptual speech analysis. Furthermore, speech ratings can vary widely in CLP when rated by native listeners and SLTs (Morén et al., 2022). However, Bickham et al. (2017) reported that both cleft lip ± palate patient speech self-perception and SLT analysis correlate with aspects of QoL. Moreover, Pedersen et al. (2021) highlighted that there's a moderate improvement in QoL when as speech improves in CLP children aged 3-18 years. Baghban et al. (2021) also pointed out a significant and positive relationship with speech intelligibility (using a detailed speech assessment) and Persian PedsQL in 3-7 years CLP children – a group much younger than the participants in this thesis. It may be argued therefore that the relationship between speech and QoL is more important in younger children than in adolescents, hence these findings provide a baseline for further study.

Measurement of intelligibility forms a vital role in clinical decision-making and monitoring (Miller, 2013). Reduced intelligibility can impact adolescents' day today functional speech, hence could cause QoL concerns. Hence, this could be considered as an exploratory study and a subjective speech assessment data may needed to identify persisting speech issues and perception of the patient together with ICS-SIN to confirm the association between QoL and speech intelligibility in adolescents with CLP.

10.7 Study Limitations & Methodological Issues

Although all efforts were made to reduce the impact of limitations to the study design, some were unavoidable, and thus need to be acknowledged.

The data collection process of this study was conducted in Sri Lanka requiring travel to Sri Lanka for a specific time period for data collection. Hence, the data was gathered during a short time period, restricting the number of CLP participants of the right age range who could be invited to take part. This may explain the relatively low CLP participants when compared to previous studies.

The prevalence of CLP in Sri Lanka was researched and documented in 1989, but there are no recent reports updating information about the incidence of CLP during the last decade. Thus, it was impossible to determine a meaningful representative sample, however, the study was conducted at the leading children's hospital and the cleft unit in Sri Lanka where approximately one third of the country's CLP children will be referred to capture as a wide range of participants as possible.

The current TD and CLP sample is not evenly spread across all the four age groups due to a combination of convenience sampling, parental consent and the availability of adolescents who happened to be attending the SLT clinic during the data collection period.

Due to the time constraints and lack of standardised tests in Sri Lanka, there were no objective speech assessment or oro-facial examination assessment included into the data collection process. Hence, it cannot be concluded to what extent the severity of

the CLP impacts to the participants' quality of life nor correlations made with other measures of speech intelligibility.

The ICS-SIN was tested using a subset of participants and the age range was not typical of other studies validating different language versions of the ICS McLeod's (2020) summary. Furthermore, this study did not include objective speech measurements due to the lack of standardised tests in Sri Lanka, nor did it gather demographic information of the participants in order to carry out comprehensive data analysis. Therefore, although the results support the appropriateness of using ICS-SIN in clinical settings, they should be considered as a preliminary validation of the ICS-SIN. Future studies using the ICS-SIN with younger children and children with a wider range of speech sound disorders is necessary. Hence, a future study of reliability and validity of the ICS-SIN including test-retest reliability is highly recommended with a broader age range.

This study included adolescents who can read and write Sinhala as COHIP-S and ICS-SIN were only translated into Sinhala. There is a second official language in Sri Lanka (Tamil) and some potential participants would have been excluded based on speaking Tamil as L1 over Sinhala as L1. This is a limitation of this study. While undertaking this thesis, the ICS has been translated into Tamil (Bathina et al., 2022), widening applications of this tool within Sri Lanka for future research.

The ICS-SIN was completed by parents of TD and CLP. As this thesis focused on the QoL in CLP adolescents, the correlation analysis between the ICS-SIN responses and QoL findings was only conducted in CLP participant group. The TD parents' responses for the ICS-SIN analysis did not show a ceiling effect indicating that some

of the TD adolescents had speech intelligibility issues. It would be interesting to investigate the underlying course for the reduced speech intelligibility in TD adolescents and how this will be affecting to their QoL by doing a detailed correlation analysis with their COHIP-S and PedsQL-Sinhala responses. The results can direct these adolescents for necessary services such as counselling, speech therapy or orthodontic services. The ICS-SIN responses and QoL findings did not correlate in the CLP participant group, hence this analysis will inform us whether the control group will follow the same trend or not and help to justify that speech is not only the contributing factor in the control group as well. In addition, this analysis could emphasize the suitability of the ICS-SIN as a potential screening tool to use within general population to identify issues related to speech. Moreover, the analysis will support the wide use of ICS-SIN, COHIP-S and PedsQL-Sinhala with TD adolescents in future research studies. Hence, a detailed analysis of the TD parents' responses for the ICS-S and QoL findings is recommended as a future expansion of this study.

The TD participants were recruited from the Western province of Sri Lanka, covering urban and rural areas, nevertheless, they do not represent a full island-wide sample. The CLP participants were recruited from a leading hospital in the capital city, which provides a specialised service to most parts of the country, however this service is not available in other general hospitals in the country and may not reflect speech intelligibility outcomes in all children with CLP born in Sri Lanka.

Initially, it was planned to record test-retest reliability of the COHIP-S and ICS-SIN. However, because of Covid-pandemic travel restrictions, this step had to be cancelled. Virtual completion was not possible due to closure of both clinics and schools during

the restrictions. A future study is recommended to test this component of both COHIP-S and ICS-SIN questionnaires.

10.8 Contribution to clinical practice

The findings from this study make several contributions to the speech and language therapy (SLT) clinical practice in Sri Lanka. Firstly, the transculturally adapted COHIP-S and ICS-SIN can be used as valuable resources for the assessment and monitoring outcomes for adolescents with CLP adolescents in Sri Lanka. The aim of multidisciplinary care for children with CLP is to improve quality of life, normalize physical configuration and facilitate intelligible speech. Hence, it is very important to measure these aspects frequently when working with CLP patients. Because these translations followed the standard and rigorous translation and cultural adaptation process and are shown in this study to be reliable and valid, these questionnaires are acceptable tools to measure oral health related quality of life and one aspect of speech intelligibility in Sri Lankan young children. As mentioned earlier in this thesis, the addition of the COHIP-S and ICS-SIN resources to the speech and language therapy profession in Sri Lanka are welcome to help with any limitations in SLT service provision in Sri Lanka. COHIP-S is a condition specific questionnaire that designed to use with children and adolescents who have oro-facial anomalies. Hence, this can be used as a condition specific QoL measure for people with CLP Sri Lanka. Another OHRQoL measurement (OIDP) has been validated into Sinhala (Amilani et al., 2020) after the initiation of this study and available now. However, OIDP is relatively short and it measures the impacts and extent to which an individuals' daily activities are affected by their oral health condition. Though this can still be used as a quick screening tool, COHIP-S 34 item questionnaire is able to provide QoL impacts in great detail. Given the limited number of validation studies into QoL scales in adolescents

and children with cleft lip and palate, the present study represents a step forward in the field.

The COHIP-S tool will be useful for the SLTs or their MDT colleagues to evaluate the perception of adolescents about their QoL. Given their long term follow up within Sri Lanka, any QoL issues can be identified early to allow onward referral where appropriate.

Similarly, the ICS-SIN is now available as a screening, therapy outcome and assessment tool for measuring speech intelligibility in Sri Lankan clinical settings. It will supplement the SLTs own professional evaluation of speech through providing additional insight about how child's communication matters in everyday settings. As the assessments foot notes give directions on how this tool can be adapted to use with adults there is also opportunity to adapt its use with adults who have communication difficulties due to neurological conditions such as stroke, motor neurone disease and Parkinson's disease. Secondly, the translation and cultural adaptation process followed a standard and rigorous methods. The questionnaires' reliability and validity were statistically proved. The methods used in this thesis can be applied to other suitable non-Sinhala assessments, to translate and validate them into Sinhala and expand the assessment resources available to SLT clinics. Thirdly, the insights about speech intelligibility in CLP adolescents, gained from this study may be of assistance to SLT's and other medical professionals engaged in multidisciplinary care of the CLP children to understand that the prevalence of speech intelligibility issues in young adolescents even after many years of intervention. This will be a good indicator to reflect and support the case for frequency of SLT or other appropriate MDT services.

Finally, to the investigators' knowledge, this project is the first comprehensive, rather than anecdotal investigation of QoL of adolescents with CLP in Sri Lanka. This study's findings contribute in several ways to our understanding of QoL in adolescents with CLP and provide a basis for the SLT's to consider including QoL assessments in their practice. This will help the SLT to get the child's perception of quality of life, identify issues, shape the intervention to match those needs or refer on to appropriate other services such as counselling or health psychology. The findings of this study will be provided in a report as a requirement of the ethics approval from Lady Ridgeway Hospital - Sri Lanka to highlight and convey the importance of including QoL assessments in MDT clinics.

Furthermore, the findings will be of interest to dentists and orthodontists in general as the study revealed that there are TD adolescents who are experiencing oral health related QoL issues. Hence, it will be important to encourage young age children to see their dentist more often or arrange regular dental clinics at schools in Sri Lanka.

10.9 Contributions to research

Quality of life is an important concept and target for research and practice in the fields of health and medicine. Intelligibility in speech is used as a primary measure to measure success of the speech therapy services during past. Hence, the Sinhala translated and validated questionnaires to assess oral health related quality of life (COHIP-S) and the speech intelligibility measure (ICS-SIN) are fruitful resources to use in future research studies focusing on QoL and speech intelligibility in Sri Lanka. This study lays the groundwork for future research into transcultural adaptations and validations of assessments for SLT clinics and develop resources. ICS questionnaire has been translated into 60+ languages and broadly using in clinical research worldwide. This work contributes to existing knowledge of its excellent validity and reliability for other languages by providing ICS-SIN, which also showed an excellent validity and reliability. The Sinhala questionnaire has been added to its website as another successful translation and worldwide researchers will be able to use it. ICS has been used with young children in most of the studies and use among CLP population in very limited so far. Hence, this study findings also contribute positively for the growing literature of its suitability of using with CLP and older age children. The reliability and validity of the ICS-SIN has been published as a free access peer reviewed journal article; thus, the published data can be accessible to researchers worldwide and add a significant contribution to the field.

The present study appears to be the first study of comparing quality of life differences in CLP with TD peers in Sri Lanka. The study results give a good insight about the value of this area for future interventions. Hence, these findings add an important

contribution into the current literature to plan more studies on this aspect in Sri Lanka. There have been inconsistent findings reporting variable QoL in this population. However, this study reports findings consistent with the most widely published finding that QoL in CLP adolescents are lower when compared to TD adolescents. The study also supports the view that a condition specific measure is more appropriate to use with adolescents with CLP compared to a generic QoL measure. Therefore, this study findings add to the growing body of research related to QoL in CLP.

10.10 Directions for future research

This study lays the groundwork for future research into the transcultural adaptation and validation of assessments into Sinhala. Future research should consider applying this methodology to transculturally adapt and validate assessments that can be used in SLT clinics and improve the resource level. Secondly, this study only focused on translating the assessment into Sinhala, the main language spoken in Sri Lanka, research is needed to transculturally adapt and validate these assessments into Tamil. Thirdly, a future study of reliability and validity of the COHIP-S including test–retest reliability is highly recommended with a broader age range. Finally, further research could be beneficial to transculturally adapt and validate the COHIP short form (a reduced questionnaire version of COHIP-English).

A key research priority is assessing the validity and reliability of the ICS-SIN for younger age groups (below 12 years) in Sri Lanka. This study was part of a larger study investigating QoL of adolescents with CLP in Sri Lanka. Therefore, the ICS-SIN was tested using a subset of participants and the age range was not typical of other studies validating different language versions of the ICS McLeod's (2020) summary. Hence, future studies using the ICS-SIN with younger children and children with a wider range of speech sound disorders should be prioritised. A future study of reliability and validity of the ICS-SIN including test–retest reliability is highly recommended with a broader age range. This assessment then can be used as a main assessment/screening/evaluation tool along with the case history in all paediatric SLT clinics for the SLT's to start getting family's and other communication partners' perception of child's speech as it's a typical component in cleft assessments.

Moreover, given that the ICS-SIN can be adapted for use with adult patient groups there now presents an opportunity to widen the use of this tool across SLT services in Sri Lanka. Moreover, as reported by parents of adolescents with CLP, speech intelligibility is lower when compared to TD adolescents. A greater focus on to further researching CLP speech intelligibility at different age points by SLT's using speech samples together with parent ratings throughout the intervention process could produce interesting findings. It would be interesting to study in more precise details the correlation between the speech intelligibility records by the clinician using a standard assessment and parents' ICS-SIN reporting and how this varies with the cleft type.

This study discussed quality of life in CLP adolescents measured by only a generic and a condition specific questionnaire in one setting. This would be a fruitful area for future work. Thus, this study sample only included a specific age range and small CLP sample size, further research is required with a large sample size covering island wide to explore the quality of life as this is a broad multidimensional concept. Considerably more work needs to be done by investigating the quality of life longitudinally, at different time points, starting from young age to determine the impact of CLP on to their lives. It will help SLT's to get a broader understanding, increase the frequency of the service, make necessary referrals at early stages and broaden the quality of the service. As a condition specific QoL measurement translated and validated into Sinhala (COHIP-S) is now available, and it provides valuable insights about the QoL in adolescents with CLP as highlighted by this study, this could be used in further research studies related to QoL in CLP and develop the evidence base in order to support to enhance the QoL in CLP population in Sri Lanka.

11 CONCLUSION

The aims of this thesis were to transculturally adapt and validate an oral health related quality of life questionnaire; Child Oral Health Impact Profile - COHIP (Broder & Wilson-Genderson, 2007) and a speech intelligibility questionnaire; Intelligibility in Context Scale – ICS (McLeod et al., 2012) into Sinhala, determine the validity and reliability of COHIP-S and ICS-SIN, investigate quality of life in adolescents with repaired cleft lip and palate and explore any correlation between speech intelligibility ratings and QoL findings in CLP adolescents. The results were discussed in two chapters in this thesis. The COHIP and ICS assessments were translated into Sinhala (as COHIP-S and ICS-SIN) following a standard translated method by a professional committee and necessary cultural adaptations were applied and piloted. These steps were discussed in detail Chapter 7 of this thesis. After completing the cross-cultural translation process, the validity and reliability of both the COHIP-S and ICS-SIN were analysed. The quality of life of adolescents with CLP when compared with TD peers was investigated using an already existing generic quality of life assessment: PedsQL-Sinhala. The condition specific oral health related quality of life assessment results (COHIP-S) was also considered and the correlation between those two (COHIP-S and PedsQL-Sinhala) was determined. The importance of using a condition specific assessment was discussed and finally the correlation between the quality of life and speech intelligibility in CLP adolescents were investigated. These findings were discussed in Chapter 10 two of this thesis.

The major conclusions are now outlined.

- The Child Oral Health Impact Profile (COHIP) original English version (34 items questionnaire) was successfully translated and culturally adapted into Sinhala (COHIP-S) following forward-backward-forward method by professional speech and language therapists.
- The Intelligibility in Context Scale (ICS) original English questionnaire was successfully translated and culturally adapted into Sinhala (ICS-SIN) following forward-backward-forward method by professional speech and language therapists.
- The COHIP-S, condition specific oral health quality of life questionnaire proved to have a good reliability (measured by Cronbach's alpha > 0.7), face, convergent and discriminant validity for TD adolescents and adolescents with CLP (age 12-15 years old).
- Adolescents with CLP had significantly lower ($p < 0.05$) oral health related quality of life compared to TD adolescents measured by the condition specific COHIP-S.
- Adolescents with CLP had significantly lower ($p < 0.05$) quality of life when compared to TD adolescents measured by the generic PedsQL-Sinhala.
- The COHIP-S positively correlated ($r > +1$) with the PedsQL-Sinhala data in CLP group confirming the concurrent validity of the new measure (COHIP-S).
- COHIP-S appeared to be a sensitive measure to identify condition specific QoL issues in adolescents with CLP.
- The ICS-SIN proved to have a good reliability (measured by Cronbach's alpha > 0.7), face, convergent and discriminant validity for TD and adolescents with CLP (age 12-15 years old).

- Parents' responses of adolescents with CLP were significantly lower ($p<0.05$) on speech intelligibility when compared with TD adolescents' parents' responses.
- There was no association found between quality of life in adolescents with CLP, informed by COHIP-S and PedsQL-Sinhala and parents speech intelligibility ratings.

This thesis results matched with the previous evidence identified by the narrative literature review and successfully addressed the literature gap. This thesis was the first attempt to investigate the quality of life in adolescents with CLP in Sri Lanka. This two-phase study exposed the QoL issues and experienced by the adolescents with CLP when compared to their typically developing same age peers. Moreover, thesis revealed preliminary data on parents' perceptions on speech intelligibility in their young children. This information provides a good overview of information relevant to the SLTs, and other health professionals involved in the multidisciplinary care management process in CLP population in Sri Lanka to understand the importance of integrating QoL assessments as part of the assessment process and direct individuals for necessary services. This thesis voiced findings of QoL in adolescents with CLP, provided with a tool to measure QoL in clinical settings. The results of this study will be shared with relevant authorities and hospitals where services for cleft people available to influence the government authorities to facilitate psychology services in multidisciplinary management. As a valuable outcome of the research study two assessments were translated and validated into Sinhala to assess quality of life and speech intelligibility in children and adolescents with CLP that were already added as resources to SLT clinics in Sri Lanka. Having validated Sinhala assessments for the

CLP group helps to overcome challenges faced by the SLTs in the assessment process without a range of validated Sinhala assessments. SLT, as a developing, young profession in Sri Lanka, could use these resources to gather data and expand the evidence base in QoL and speech in cleft population in Sri Lanka. As such this thesis has outlined directions for future research and uncovered steps that can be taken to improve the overall care and enhance QoL in children born with CLP.

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APPENDICES

Appendix 1: Publication – Journal article

Translation and validation of the Intelligibility in Context Scale into Sinhala for adolescents in Sri Lanka with cleft lip and palate

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ABSTRACT

The Intelligibility in Context Scale (ICS) is a parent-report screening tool used to measure parents' perceptions of children's functional intelligibility. This tool has been translated into over 60 languages and found to have a good reliability and validity. The purpose of the current study was to translate the ICS into Sinhala (the ICS-SIN), the main language spoken by the Sinhalese people in Sri Lanka, and to validate it with both typically developing (TD) children and children with repaired cleft lip and/or palate (CLP). The translation process followed the forward- backward-forward method. A total of 88 parents of TD children and children with CLP aged 12–15 years old (TD $n = 50$, CLP $n = 38$) completed the ICS-SIN questionnaire. Parents of TD and CLP children reported their children's speech as most intelligible to parents and least intelligible to strangers. The ICS-SIN had high internal consistency for both groups (TD $\alpha = 0.87$, $p < 0.05$, CLP $\alpha = 0.97$, $p < 0.05$). The ICS-SIN total scores and item scores showed significant correlations, indicating a good construct validity. TD participant group's ICS-SIN average mean scores ($M = 4.88$, $SD = 0.29$) were significantly higher compared to the CLP ICS-SIN average mean scores ($M = 4.64$, $SD = 0.67$) and varied according to gender in both groups, suggesting good discriminant validity. The ICS-SIN has overall good psychometric properties. Therefore, this tool has the potential to be used as a valid parent- rating screening tool for clinical and research purposes in Sri Lanka.

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Introduction

A key issue for speakers with cleft lip and palate (CLP) is achieving speech that can be readily understood by others. Despite the fact that in most countries surgery to repair CLP early in life leads to intelligible speech, there remains a proportion of adolescents

and adults who have difficulty making themselves understood. For example, a recent study conducted in Sweden showed that around 87% to 91% of 19-year-olds born with unilateral CLP report good intelligibility, leaving around 10% with ongoing intelligibility issues (Peterson et al., 2022). In the United Kingdom, Timmons et al. (2021) reported age-appropriate speech intelligibility in only 47% of 12-year-olds with CLP. In Italy, Rullo et al. (2009) reported normal intelligibility in 47.05% of five- to eight-year-olds with non-syndromic CLP. While the figures may vary across countries, it's clear that intelligibility remains an issue in a proportion of speakers with CLP. Moreover, intelligibility is a key surgical outcome for

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CLP, and measurement of it across childhood is crucial in determining whether individuals with CLP require speech and language therapy or further surgical interventions (Sell, 2005).

There are various methods of measuring intelligibility in speakers with CLP. Perceptual evaluation is the most common method because the aim of interventions is to achieve speech that is perceptually accurate, and therefore has good face validity. Kuehn and Moller (2000) highlighted that perceptual judgements are practical, appropriate to use with young children, and not easily replaced with instrumental techniques. The gold standard approach, phonetic transcription, can be used to record a speaker's productions which can then be analysed to determine, for example, percentage consonants correct. This in turn is used to quantify either the degree of difficulty or any improvements in speech over time. However, despite this being the

‘gold standard’, reliability can be low (Sell & Sweeney, 2020) and approaches such as this may not represent a speaker’s capacity to be comprehensible in context (Hashemi Hosseinabad et al., 2022).

There have therefore been calls for a more functional approach that measures outcomes that matter to patients and their families: that is, how well the speaker is understood by others. Examples of more functional approaches include ordinal and visual analogue scales (Bettens et al., 2018) and use of multiple listeners comparing speech to a hypothetical adult model (Roxburgh et al., 2016). The International Consortium for Health Outcomes details a list of suggested outcome measures for CLP (Apon et al., 2021). Among the set of suggested outcomes for measuring articulation and intelligibility is the Intelligibility in Context Scale (ICS; McLeod et al., 2012a).

The ICS is a subjective rating scale completed by parents or carers. It was developed by McLeod et al. (2012a) as a parent-report screening tool for English-speaking preschool children as a quick and easy way of measuring speech intelligibility with seven different communication partners (McLeod, 2020). It considers perceptions of a child’s functional speech intelligibility with a range of communication partners differing in levels of authority and familiarity in real-life situations (Neumann et al., 2017). The ICS fits within the International Classification of Functioning, Disability and Health for Children and Youth (ICF-CY; World Health Organization, 2007). That is, in contrast to other measures of intelligibility that look mainly at speech production (body function within the ICF-CY) the ICS also looks at contextual factors (McLeod et al., 2012). The scale is relatively quick to complete, consisting of only seven items rated by parents or caregivers on a 5-point Likert scale. All seven questions must be answered, producing a maximum score of 35. An average score is then reported for the

seven items, with a higher total score indicating a higher speech intelligibility rating (McLeod et al., 2012). Each item of the questionnaire focuses on relevant contexts identified in the ICF-CY such as support and relationships, immediate and extended family, friends, acquaintances, peers, colleagues, neighbours and community members, people in positions of authority and strangers (Pascoe & McLeod, 2016).

The ease with which the scale can be completed by parents/carers makes it an attractive clinical and research tool. Moreover, the original English language version was initially validated on 120 Australian English-speaking children aged 3;11 to 5;8 years and has high internal reliability ($\alpha = 0.93$), construct validity and sensitivity (McLeod et al., 2012), making it a robust tool for measuring functional intelligibility in a range of speech sound disorders. Subsequently, the ICS has been translated into over 60 languages by speech and language pathologists, phoneticians, linguists and accredited translators. There are 18 validation/norming studies of the ICS including 4235 children in 14 countries (Australia, Croatia, Fiji, Germany, Hongkong SAR China, Italy, Korea, Jamaica, The Netherlands, New Zealand, Portugal, Slovenia, Sweden, Viet Nam) published to date (McLeod, 2021). Some of these validation studies included typical children only (Washington et al., 2017; Kim et al., 2016) and some SSD only (Lagerberg et al., 2019) and some with both TD and SSD (Ng et al., 2014, Kok and To, 2019; McLeod et al., 2012b; Neumann et al., 2017) aged from 1; 2 to 15 years; however, most studies focus on preschool-aged children.

The ICS has been used as an outcome measure in research on speech sound disorders (McLeod et al., 2017), including children with cleft lip and palate (Hashemi Hosseinabad et al., 2022; Seifert et al., 2021) and also in a study of adults who speak other languages than English (McLeod, 2020). Neumann et al. (2017), reported high

internal reliability (mothers $\alpha = 0.918$, fathers $\alpha = 0.917$) and construct and criterion validity in the Italian language ICS validation of 364 typically developing children and 356 children with speech disorders aged 3;0 to 5;11. The Korean ICS validation (Lee, 2019) demonstrated high internal reliability ($\alpha = 0.945$), satisfactory test, retest reliability, and good construct validity. Furthermore, the Vietnamese ICS validation (Phạm et al., 2017) results showed excellent internal reliability ($\alpha = 0.94$) and construct validity in children aged 2; 0–5; 11 years.

A recent paper using the ICS with three-year-old English-speaking children with CLP found that parents were able to understand their child most of the time, but strangers were less likely to find the child intelligible (Seifert et al., 2021). In this study mothers of 412 children with CLP completed the ICS and the average total score was 3.75 ('sometimes' to 'usually intelligible') of a possible five ('always intelligible'). Moreover, children with cleft lip only were more intelligible than children with any type of palatal cleft, who in turn were more intelligible than children with CLP associated with a syndrome. Hashemi Hosseinabad et al. (2022) investigated the clinical application of the ICS in 20 children aged four to 12 with CLP and velopharyngeal insufficiency (native speakers of American English) and findings supported the use of ICS in practice with CLP children. This study also highlighted the high correlation between ICS scores and articulation accuracy. The ICS, therefore, shows potential as a suitable tool for measuring intelligibility in CLP, both within research and clinical contexts.

The current study is a translation and validation of the ICS in Sinhala, the main language spoken in Sri Lanka. Sinhala is an Indo-Arya Language, written in the Sinhala script. It has around 16 million speakers, mostly concentrated in Sri Lanka.

Speech and Language Therapy is a young profession in Sri Lanka, beginning only in 2000 and moving to a degree-level profession in 2008 (Wickenden et al., 2003). As a young profession, there are few validated questionnaires or standardised assessments for the evaluation of speech in Sinhala. To our knowledge, there is only one published assessment, the Common Token Test (COT), a measurement of speech perception in children with cochlear implants (Jeyaraman et al., 2016). There are also few single-word articulation or phonology assessments validated in Sinhala for different age groups. It is therefore clear that an easy-to-use parent/carer reported measure of intelligibility translated into Sinhala for use with speakers with CLP, and potentially other types of speech sound disorders would be a valuable addition for speech and language therapists and researchers in Sri Lanka. Although the ICS was primarily designed for preschool-aged children, the current study focuses on older children with and without CLP for two reasons. Firstly, we assume that older children without speech disorders will show no difficulties with intelligibility, and secondly, the ICS has been used with children aged up to 15 years old so far and found to be an acceptable tool.

Aims

The aims of this study were as follows: 1. to translate the Intelligibility in Context Scale to Sinhala; 2. to determine both typically developing (TD) and repaired cleft lip and/or palate (CLP) ICS scores in Sinhala-speaking adolescents and 3. to determine the psychometric properties of the Sinhala Intelligibility in Context Scale.

Method

The original ICS English-language questionnaire (McLeod et al., 2012a) was translated into Sinhala (ICS-SIN) following standard translation and cross-cultural

adaptation guidelines (the Forward – Backward – Forward method, Guillemin et al., 1993) and validated with adolescents with cleft lip and palate (CLP) and typically developing (TD). The study was conducted with approval from the Ethics committees at the University of Strathclyde, Glasgow and Lady Ridgeway Hospital for Children (LRH), Colombo, Sri Lanka.

Participants

Fifty parents of typically developing (TD) children and 38 parents of children with repaired cleft lip and palate (CLP), ages ranging from 12 to 15 years completed the ICS-SIN questionnaire. The mean age of the TD group was 13.22 (SD = 0.86) and the CLP group was 14.16 (SD = 1.05). There were 31 males (62.0%) and 19 females (38.0%) children in the TD group and 13 males (34.2%) and 25 female (65.8%) children in the CLP group. Inclusion and exclusion criteria were applied. Children who speak Sinhala as their first language were included and children with long-lasting medical conditions who require daily medication and children with learning/cognitive difficulties were excluded from the study. According to teachers' reports, none of the TD children had been diagnosed with cognitive difficulties or other developmental disorders, and none used hearing amplification. In the TD group, 38 mothers (76.0%), nine fathers (18.0%) and three immediate family members (6.0%) such as brother, sister or grandmother completed the ICS-SIN questionnaire. In the CLP group, the ICS-SIN was completed by 28 mothers (56.0%), six fathers (12.0%) and four other immediate family members (8.0%) such as brothers, sisters or grandparents.

Procedure of translating ICS into Sinhala

Permission to translate the scale into Sinhala was obtained from the original author of the ICS, Sharynne McLeod. A systematic approach was taken in translating the ICS into Sinhala using the guidelines recommended by Guillemin et al. (1993), the protocol for translation and adaptation of instruments proposed by the World Health Organization (World Health Organization, 2007). The questionnaire was translated according to the forward- backwards–forward technique, as illustrated in Figure 1. This approach required three independent translators. In step 1, ‘first forward translations’, two translators, both bilingual qualified speech and language therapists whose first language is Sinhala, translated the English ICS into Sinhala. These two translators worked independently, considering the entirety of the original, including instructions, design, and headers and footers. The translators followed the guidelines by Guillemin et al. (1993), WHO (see, Youhan et al., 2019 for

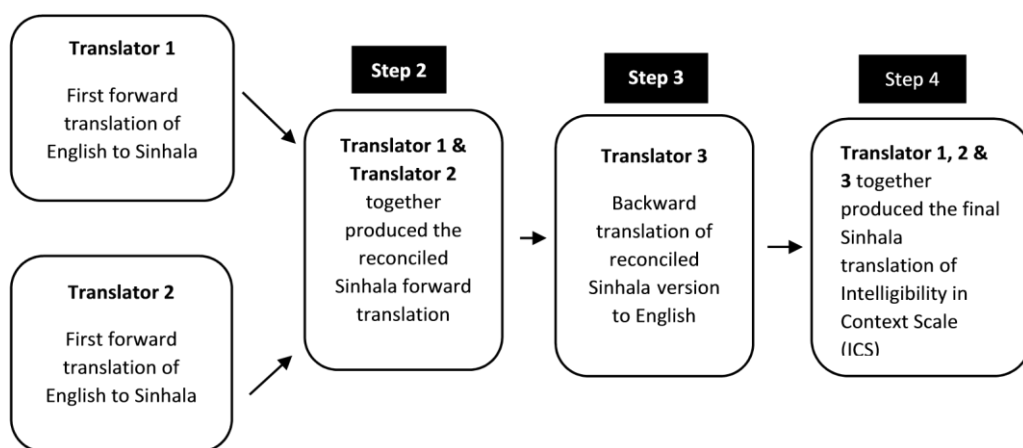


Figure 1. The translation process of the ICS-Sinhala.

a description), and considered linguistic and cultural factors throughout the translation process, aiming to use acceptable language for a broad audience and ensure that the meaning and concepts behind the original scale were preserved in the translated versions.

In step 2- the ‘reconciliation step’, the two translators reviewed the two forward individual translations. Together they created a reconciled forward Sinhala translation, meeting all demands of linguistic and conceptual equivalence of the original English draft. Next, in step 3, a ‘backward translation’ was performed. The reconciled forward Sinhala translation was translated back into English by a third bilingual English – Sinhala speech and language therapist (translator 3) who was blind to the original English version. This third translator’s first language was English.

Finally, in step 4- ‘final forward translation’ – as a committee, all three translators reviewed the forward and respective backward translations and looked for discrepancies with the original ICS. The differences were then discussed, and using structured techniques to find solutions, further alterations were made to the translations. The committee generated the final forward Sinhala translation of the ICS-SIN maintaining its conceptual equivalence, while ensuring the questions remained linguistically appropriate and understandable for a wide range of speakers. This final questionnaire was formatted according to the ICS standard format with guidance from the original author, and approval confirming completion of the translation process (aim 1) before undertaking piloting and validation (<https://www.csu.edu.au/research/multilingual-speech/ics>).

Piloting

The final ICS-SIN questionnaire was piloted with parents of five typically developing Sinhala-speaking adolescents aged 12–15 years old; parents of two Sinhala-speaking adolescents with repaired cleft lip and palate aged 12–15 years old; and five Sinhala-speaking parents who have younger children to check the equivalence in source and

final versions. These participants were chosen as a representative match with the ICS study participant group and the general wider population. The probe technique was used to check face validity (by asking verbally) to confirm the questions were understandable. There were no changes made to the ICS-SIN questionnaire after piloting. The speech and language therapists (SLTs) in the cleft clinic were consulted regarding the translation process and given the final ICS-SIN questionnaire. They were informed about the current evidence base for the use of the ICS in other languages with children with CLP and other speech sound disorders. The SLTs checked the appropriateness of the language of the translated version, listened to parents' feedback on how easy the ICS was to use further confirming clinical feasibility of the ICS-SIN questionnaire.

Validation

The scale was validated with typically developing adolescents and adolescents with repaired cleft lip and palate. In this study, the traditional approach of using a single-word articulation test to identify speech intelligibility difficulties was not employed due to lack of such tools in Sinhala. Hence, an older participant (12–15 years) typically developing group without underlying health conditions was included, with the assumption that typically developing children would be 100% intelligible by this age. Moreover, participants were chosen randomly from schools and clinics according to the inclusion and exclusion criteria to reduce sample bias. Furthermore, consideration was given to previous validity evidence of the ICS (McLeod, 2020) along with piloting the ICS-SIN before use in the study to account for any practical issues parents reported while administering the questionnaire.

Recruitment procedure and response rate

Participants were recruited from urban and non-urban mainstream schools in the western province of Sri Lanka. A study information leaflet, consent form and a translated copy of the ICS-SIN questionnaire were sent to the parents via the schools. CLP participants were recruited from the Lady Ridgeway Hospital for Children, Colombo, Sri Lanka. This children's hospital is one of the leading children's hospitals in Sri Lanka, where all specialised craniofacial treatments are provided. All children declared Sinhala as their primary language. The cleft-type for CLP participants was identified from medical notes. Fifty-four (27.0% response rate) parents of TD children returned completed ICS-SIN questionnaires within the response time of 7 days. Three questionnaires (5.5%) had to be excluded from the analysis because the parents did not respond to one or more items of the ICS-SIN. One further questionnaire was not included in the analysis after the respondent reported that Sinhala was not their first language. This left a total of 50 complete ICS-SIN questionnaires from TD children.

Parents of the children with CLP were invited to complete the questionnaire while waiting for clinics at the cleft department. Parents of children with CLP were asked to read the participant information sheet and sign the consent form before completing the questionnaire. All invited parents or carers of CLP children completed the questionnaires (100.0% response rate). Two questionnaires had to be excluded (5.0%) because parents or carers did not respond to all seven items on the scale. All respondents declared their first language as Sinhala. Consequently, 38 complete ICS-SIN questionnaires were included in the final analysis.

Analysis

Parents' responses to the ICS-SIN were entered into Excel™ and subsequently converted into SPSS version 25. The frequency and percentage of responses for each of the seven items were calculated to determine TD and CLP ICS-SIN values in the sample (aim 2). The Kolmogorov Smirnov with Lilliefors test of normality was used to check the distribution of the data. The psychometric properties of the ICS-SIN (aim 3) were then evaluated. Item-by-item inter-correlations (non-parametric – Spearman's rho) and Cronbach's alpha test of internal reliability were conducted to determine the consistency of the seven items on the ICS-SIN. This study referred to the Field (2013) recommended thresholds to interpret correlations and Cronbach's alpha values. The original ICS questionnaire already has good face validity (McLeod, 2020). ICS-SIN face validity was determined by asking the respondents and SLTs verbally about the accuracy and whether the items are good enough to measure the issues that the items intend to. Construct validity of the ICS-SIN was checked using Spearman's correlations (two-tailed significance test) among the seven ICS-SIN item scores and the ICS-SIN total score in the whole group. Discriminant validity was assessed by comparing ICS-SIN total mean scores between the TD and CLP groups and comparing gender groups in both samples.

Results

Translation and cultural adaptations

The translation and adaptation process were conducted by Sinhala-English bilingual speech and language therapists, who reported that it was culturally appropriate to use the original structure of the questionnaire. There were no changes applied to the ICS original English format: content only was translated into Sinhala. In Sinhala,

‘acquaintances’ could not be translated into a single word. Therefore, two Sinhala words were combined to provide an equivalent meaning. Similarly, there are two appropriate Sinhala words for ‘strangers’ that are in common usage, we therefore used one word and gave the alternative word in a footnote. For ‘friends’ we used the word in common usage, rather than the dictionary translation that is a formal version. After piloting, no further changes were made to the questionnaire, and the translating committee agreed that the ICS-SIN achieved cultural appropriateness while maintaining the purpose of the tool.

ICS-SIN ratings for typically developing children

The ratings for each of the seven questions for the TD group is presented in [Table 1](#). In the TD group the most common rating for all communication partners was ‘always’: parents (96.0%), immediate family (92.0%), extended family (88.0%), friends (92.0%), acquaintances (88.0%), teachers (92.0%) and strangers (86.0%). A small number of parents of TD children reported that communication partners ‘usually’ or ‘sometimes’ understand their child. None of the parents of TD children rated their child as ‘never’ understood. Mean scores for the 50 TD participants showed that ratings were highest for parents, followed by other communication partners: parents ($M = 4.96$, $SD = 0.19$), immediate family members ($M = 4.92$, $SD = 0.27$), friends ($M = 4.92$, $SD = 0.27$), teachers ($M = 4.90$, $SD = 0.36$), extended members of the family ($M = 4.86$, $SD = 0.40$), acquaintances ($M = 4.84$, $SD = 0.46$),

Table 1. Parents’ ratings for the ICS-SIN -Typically developing group (N = 50).

Question	M	SD	Range	Always %	Usually %	Sometime %	Rarely %	Never %
1. Do you understand your child?	4.96	(0.19)	4–5	96.0	4.0	0.0	0.0	0.0
2. Do immediate members of your family understand your child?	4.92	(0.27)	4–5	92.0	8.0	0.0	0.0	0.0

3. Do extended members of your family understand your child?	4.83 (0.40)	3–5	88.0	10.0	2.0	0.0	0.0
4. Do your child's friends understand your child?	4.92 (0.27)	4–5	92.0	8.0	0.0	0.0	0.0
5. Do other acquaintances understand	4.84 (0.46)	3–5	88.0	8.0	4.0	0.0	0.0
6. Do your child's teachers understand your child?	4.90 (0.36)	3–5	92.0	6.0	2.0	0.0	0.0
7. Do strangers understand your child?	4.80 (0.57)	2–5	86.0	10.0	2.0	2.0	0.0
Average total score (maximum = 35)	34.20 (2.03)	26–35					
Average total score (maximum = 5)	4.88	4.88					

strangers ($M = 4.80$, $SD = 0.57$). Therefore, parents rated themselves as understanding their child's speech the best (96.0%) ($M = 4.96$, $SD = 0.19$) and strangers the least (86%) ($M = 4.80$, $SD = 0.57$).

ICS-SIN ratings for children with CLP

As shown in Table 2, parents of the children with CLP rated that they understood their child's speech the best, (84.2%) 'always' and (15.8%) 'usually'. None of the parents rated they 'sometimes', 'rarely', or 'never' understood their child's speech. For children with CLP, the most common rating for all social communication partners was 'always': parents (84.2%), immediate family (76.3%), extended family (68.4%), friends (78.9%), acquaintances (68.4%), teachers (78.9%) and strangers (63.2%). Mean scores for the 38 participants with CLP showed that ratings were also highest in parents ($M = 4.84$, $SD = 0.37$), followed by teachers ($M = 4.71$, $SD = 0.65$), immediate family members ($M = 4.68$, $SD = 0.66$), friends ($M = 4.66$, $SD = 0.81$), extended members of the family ($M = 4.55$, $SD = 0.82$), acquaintances ($M = 4.55$, $SD = 0.82$) and strangers ($M = 4.47$, $SD = 0.89$). Parental perceptions of their children's intelligibility in different communication situations reflect that communication partners understood children's speech 'always' or 'usually'. Moreover, only a small

number of parents reported that immediate family, extended family, friends, acquaintances, and strangers ‘rarely’ or ‘never’ (2.6%) understand their child.

Table 2. Parents’ ratings for the ICS-SIN – Cleft lip and/or palate group (N = 38).

Question	M	SD	Range	Always %	Usually %	Sometime %	Rarely %	Never %
1. Do you understand your child?	4.84	(0.37)	4–5	84.2	15.8	0.0	0.0	0.0
2. Do immediate members of your family understand your child?	4.68	(0.66)	2–5	76.3	18.4	2.6	2.6	0.0
3. Do extended members of your family understand your child?	4.55	(0.82)	1–5	68.4	23.7	5.3	0.0	2.6
4. Do your child’s friends understand your child?	4.66	(0.81)	1–5	78.9	13.2	5.3	0.0	2.6
5. Do other acquaintances understand your child?	4.55	(0.82)	1–5	68.4	23.7	5.3	0.0	2.6
6. Do your child’s teachers understand your child?	4.71	(0.65)	2–5	78.9	15.8	2.6	2.6	0.0
7. Do strangers understand your child?	4.47	(0.89)	1–5	63.2	28.9	2.6	2.6	2.6
Average total score (maximum = 35)	32.55	(4.7)	12–35					
Average total score (maximum = 5)	4.64	(0.67)						

Internal consistency and correlations between items of ICS-SIN Item correlation (TD)

The ICS-SIN mean scores of the seven items for each participant were calculated. The Kolmogorov- Smirnov with Lilliefors test of normality was significant, indicating normal distribution was not assumed. Bivariate non-parametric correlation analysis (Spearman’s Rank Order) was calculated to determine the relationship between individual items on the scale. Correlations between the seven items and average mean scores are illustrated in Table 3. All inter-correlations between the subscales showed moderate-to-high correlations (Field, 2013) ranging from $r = 0.344$ to 0.901 and were significant ($p < 0.05$). While most correlations were moderate (0.34 – 0.69), high correlations ($r > 0.7$) were observed between ratings for extended family members and strangers ($r = 0.9$) and friends and acquaintances ($r = 0.81$).

Internal consistency (TD)

The Internal consistency for each scale of the ICS-SIN completed by parents of TD children ($N = 50$) was measured using Cronbach's alpha. The correlations were significant ($p < 0.05$), Cronbach's alpha was found to achieve a high level ($\alpha = 0.875$). The results for inter- correlations showed good internal consistency in responses to the items of the scale. This finding suggests that the ICS-SIN is an appropriate tool for measuring speech intelligibility within typically developing adolescents.

Item correlation (CLP)

The ICS-SIN mean scores of the seven items were calculated. The test of normality using Kolmogorov—Smirnov with Lilliefors was significant, indicating normal distribution was not assumed. Bivariate non-parametric correlation analysis (Spearman's Rank Order) was calculated to determine the relationship between individual items on the scale. Correlations between the seven items and average mean scores are illustrated in Table 4. All inter-correlations between the subscales showed moderate-to-high correlations ranging from $r = 0.603$ to 0.910 and were significant ($p < 0.05$). While most correlations were high ($r > 0.70$), moderate correlations were observed between ratings for parents and strangers ($r = 0.6$), parents and extended family and acquaintances ($r = 0.65$)

Table 3. Spearman's rank-order correlations between the seven items and average mean score on ICS- SIN – Typically developing group ($N = 50$).

Item	Parent	Immediate family	Extended family	Friends	Acquaintances	Teachers	Strangers	Average Mean
Parent		0.69	0.54	0.69	0.56	0.70	0.48	0.50
Immediate Family	0.69		0.55	0.45	0.57	0.73	0.72	0.67

Extended family	0.54	0.55		0.55	0.64	0.34	0.90	0.82
Child's friends	0.69	0.45	0.55		0.81	0.46	0.49	0.66
Acquaintances	0.56	0.57	0.64	0.81		0.57	0.75	0.83
Teachers	0.70	0.73	0.34	0.46	0.57		0.52	0.65
Strangers	0.48	0.72	0.90	0.49	0.75	0.52		0.89
Average Mean	0.50	0.67	0.82	0.66	0.83	0.65	0.89	

Table 4. Spearman's rank-order correlations between the seven items and average mean score on ICS- SIN – Cleft lip and/or Palate group (N = 38).

	Parent	Immediate family	Extended family	friends	Acquaintances	Teachers	Strangers	Average Mean
Parent		0.79	0.65	0.66	0.65	0.85	0.63	0.67
Immediate Family	0.79		0.84	0.67	0.84	0.80	0.77	0.83
Extended family	0.65	0.84		0.69	0.89	0.80	0.91	0.93
Child's friends	0.66	0.67	0.69		0.80	0.86	0.74	0.80
Acquaintances	0.65	0.84	0.89	0.80		0.80	0.91	0.94
Teachers	0.85	0.80	0.80	0.86	0.80		0.73	0.80
Strangers	0.60	0.77	0.91	0.74	0.91	0.73		0.98
Average Mean	0.67	0.83	0.93	0.80	0.94	0.80	0.98	

Internal consistency (CLP)

The internal consistency for each scale of the ICS-SIN for children with CLP ($N = 38$) was measured using Cronbach's alpha. The correlations were significant ($p < 0.05$), Cronbach's alpha was found to achieve a very high level ($\alpha = 0.97$). The results for inter-correlations showed high internal consistency in responses to the items of the scale. This finding further supports that the ICS-SIN is an appropriate tool for measuring speech intelligibility within adolescents with Cleft Lip and Palate.

Validity of the ICS-SIN Construct validity

The construct validity of the ICS-SIN was evaluated using Spearman's correlations (two- tailed significance test) among the seven ICS-SIN item scores and the ICS-SIN total score in the total group (Total $N = 88$). Scores ranged between $r = 0.61$ to 0.95 , as shown in Table 5. All correlations were highly significant ($p < 0.05$) when the two groups were assessed independently.

Discriminant validity

The mean average scores of the ICS-SIN questionnaires were compared between groups. The ICS-SIN total average mean scores of both samples were not normally distributed, evidenced by the significant ($p < 0.05$) normality test results. A Mann–Whitney U -test was therefore used to compare the total average mean scores of these two speaker groups. There was

Table 5. Spearman correlation r between the ICS-SIN total score and the seven ICS-SIN items.

ICS-SIN item	TD (N = 50)	CLP (N = 38)
Parent	0.507	0.670
Immediate family	0.675	0.833
Extended family	0.821	0.934
Friends	0.664	0.804
Acquaintances	0.831	0.945
Teachers	0.654	0.802
Strangers	0.893	0.984

ICS-SIN – Intelligibility in Context Scale – Sinhala, TD – Typically Developing.

CLP – Cleft Lip and Palate.

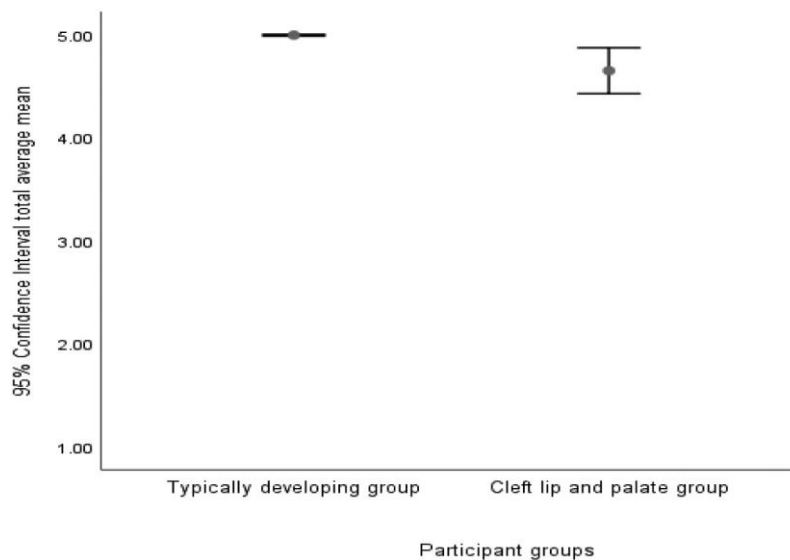


Figure 2. Intelligibility in Context Scale – Sinhala – average mean differences between the two groups.

a significant difference between the TD ($M = 4.88$, $SD = 0.29$) and CLP ($M = 4.64$, $SD = 0.67$) groups (Figure 2). The parents of the children with CLP reported significantly lower speech intelligibility compared to the parents of TD children ($U = 758$, $p = 0.037$) for each of the seven communication partners. Further, the results of the two groups were entered into an online effect size calculator and Hedges' g was calculated as the sample sizes were not equal in the groups. Hedges' g was 0.488, which is a moderate effect size (Cohen, 1988).

The mean scores of the ICS-SIN were compared by age and sex for both participant groups. Child's sex information was collected via parent reports. The Spearman's rho test results revealed that there was no significant correlation between the ICS – SIN mean scores in the CLP group and the age of the child ($r = 0.17$, $p = 0.30$). Similarly, in the TD group, the Spearman's rho test results revealed that there was no significant correlation between the ICS – SIN mean scores (TD) and the age of the child ($r = 0.11$, $p = 0.43$). There was a difference found between ICS-SIN mean scores (CLP) and the sex of the children [females ($N = 25$) $M = 4.53$, $SD = 0.80$] [males ($N = 13$) $M = 4.86$,

SD = 0.23] in this participant group, Males with CLP rated slightly higher than females with CLP. There was also a difference between TD ICS-SIN mean scores and sex [females ($N = 19$) $M = 4.96$, $SD = 0.11$] [males ($N = 31$) $M = 4.83$, $SD = 0.35$]; however, converse to the CLP findings, TD females were rated slightly higher than TD males.

Discussion

This study aimed to translate the ICS English-language questionnaire into Sinhala and to validate the questionnaire on both typically developing adolescents and adolescents with cleft lip and palate living in Sri Lanka. With minimal adaptations, ICS-SIN achieved cultural appropriateness while maintaining the purpose of the tool. Pascoe and McLeod (2016) also emphasised the importance of ensuring the translated versions of the ICS convey the original intent of the tool as much as possible, while achieving cultural relevance. ICS has been translated to over 60 languages, is available in languages that do not have standardised assessments and is considered a ‘user-friendly’ tool (McLeod, 2020).

Pilot data for the ICS-SIN

The mean ICS-SIN score for our TD children was 4.88 ($SD = 0.29$), which is consistent with findings from Sprunt and Marella (2018) who reported mean scores within the range of 4 to 5 for 257 TD children aged 5–15. In the current study, the TD mean value is within this range. However, it is slightly higher than values reported for other international studies of typically developing children, many of which report results from much younger children than those in our sample. For example, ICS-Fiji (Mean

age = 9.7, SD = 4.4), $M = 4.5$ (0.6), ICS-Fiji-English, $M = 4.5$ (0.5; Hopf et al., 2017).

It is widely accepted that speech intelligibility continues to develop as children grow, and Kok and To (2019) highlighted significantly higher scores in older children in their study using ICS-Traditional Chinese. The current study included only TD children aged between 12–15-year-olds, hence a higher intelligibility mean score than younger TD children was expected.

In terms of ratings on the new ICS-SIN, our results suggest that most TD children were understood ‘always’ by all communication partners. However, a small number of parents rated ‘usually’ or ‘sometimes’ mainly for strangers, acquaintances, and extended family. In summary, TD children were most intelligible to their parents (96.0%), followed by immediate family members (92.0%), friends (92.0%), teachers (92.0%), extended family (88.0%), acquaintances (88.0%) and strangers (86.0%). McLeod et al. (2015) describe the same trend in data, albeit with lower overall scores in younger children. Our findings were explored in detail as we expected TD participants would rate intelligible for all communication partners as they have normal speech development. From this we noted low intelligibility with all communication partners in one participant due to voice concerns and in two participants where there are language issues related to their bilingual social context.

The children with CLP had lower scores in the ICS-SIN than the typically developing children ($M = 4.64$, SD = 0.67). Seifert et al. (2021) provide comparison data on the ICS for a sample of 412, three-year-old English-speaking children born with any cleft type. The mean average ICS score of their total sample was 3.75 (SD = 0.76), suggesting intelligibility in children with CLP likely increases with age, similar to typically developing children. In addition, Hashemi Hosseinabad et al. (2022) also

reported lower ICS mean scores in children aged 4–12 years (mean age = 6.97) with velopharyngeal insufficiency. Moreover in a recent study by McLeod (2020) summarising the use of ICS across 18 international studies, 10 studies reported higher ICS mean scores for typical children compared to children with speech sound disorders, again highlighting the trend of reduced intelligibility in atypical children more generally. McLeod (2020) highlighted those higher total scores were reported by children identified with typical speech than children with atypical speech in cross-cultural validation studies.

Nevertheless, in our sample, the CLP average ICS-SIN mean was notably higher than those reported in McLeod's (2020) summary. This is likely because our sample included an older age range than the children included in other ICS studies. Moreover, in the current study, we excluded participants with syndromes that are known to impact speech, language, and cognitive development. In terms of the ratings across individual ICS-SIN items, the trend in the CLP group was similar to that of the TD group. These children were most intelligible to their parents (84.2%), followed by teachers (78.9%), friends (78.9%), immediate family (76.3%), extended family (68.4%), and acquaintances (68.4%) and strangers (63.2%). A similar trend of most intelligible to mothers and least intelligible to strangers was also reported by Seifert et al. (2021) in CLP children using English as their first language and Hashemi Hosseinabad et al. (2022) in CLP children with velopharyngeal insufficiency using American English.

Psychometric properties of the Sinhala Intelligibility in Context Scale

This study's results support that the ICS-SIN is an appropriate, valid, parent report screening tool to assess speech intelligibility of Sinhala-speaking children in Sri Lanka.

The scale had high internal reliability between items ($\alpha = 0.87$) and moderate-to-high correlations between items, ranging from $\rho = 0.344$ to 0.901 ($p < 0.05$) for both the TD group and for the CLP group ($\alpha = 0.97$) ($\rho = 0.603$ to 0.910 , $p < 0.05$). To assess the consistency of results across items, internal consistency/reliability was examined in 10 published studies to date and found to be very high ($\alpha = 0.91$ – 0.98) (McLeod, 2020). Our study results are in line with those of previous findings, and the internal consistency of ICS-SIN was recorded within this range for the CLP group. However, we found a slightly lower Cronbach's alpha value for the TD group, although this was still at an acceptable level. Similarly, we found slightly lower values than those reported by Hopf et al. (2017) and Lagerberg et al. (2021) who included participants up to 10 years of age. These results are likely to be related to the age range of the children in the current study.

We also examined construct validity of the ICS-SIN. Correlations among the seven ICS-SIN item scores and the total score were found to be highly significant, showing an excellent construct validity of the ICS-SIN. This is in line with most previous ICS validation studies which reported 'moderate to high correlations' for construct validity (McLeod, 2020; Neumann et al., 2017; Pham et al., 2017).

Limitations and future research

This study was part of a larger study investigating quality of life of adolescents with repaired CLP in Sri Lanka. Therefore, the ICS-SIN was tested using a subset of participants and the age range was not typical of other studies validating different language versions of the ICS McLeod's (2020) summary. Moreover, the sample size of the current study was lower than previous studies and the sample was recruited from

one province of Sri Lanka only. Furthermore, this study did not include objective measurements due to the lack of standardised tests in Sri Lanka, nor did it gather demographic information of the participants in order to carry out a comprehensive data analysis. Therefore, although the results support the appropriateness of using ICS-SIN in clinical settings, they should be considered as a preliminary validation of the ICS-SIN. Future studies using the ICS-SIN with younger children and children with a wider range of speech sound disorders is necessary. Hence, a future study of reliability and validity of the ICS-SIN including test-retest reliability is highly recommended with a broader age range. The TD participants were recruited from the Western province of Sri Lanka, covering urban and rural areas, nevertheless, they do not represent a full island-wide sample. The CLP participants were recruited from a leading hospital in the capital, which provides a specialised service to most parts of the country, however this service is not available in other general hospitals in the country and may not reflect speech intelligibility outcomes in all children with CLP born in Sri Lanka. Finally, it would be helpful to record all caregivers' perspectives on their child's intelligibility using the ICS-SIN to determine whether, for example, fathers rate their child's speech intelligibility differently to mothers due to the father-led working, and mother-led childcare culture in Sri Lanka (Kailasapathy & Metz, [2012](#)) which tends to favour higher mother-child interaction.

Conclusion

The study provides the first translation and validation of the ICS into Sinhala. Our pilot validation study results were consistent with that of other studies in that both the typically developing children and children with repaired CLP followed similar trends

in terms of being more readily understood by family, friends, and those they interact with most often. The ICS-SIN was shown to have a good internal consistency, discriminant and construct validity for both the TD and CLP adolescent groups. Hence, the ICS-SIN can be considered an appropriate parent-report screening measure that can be used to describe children and adolescents' intelligibility with different communication partners.

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Ethics statement

The study protocol and ethics applications were approved by the ethics committees of University of Strathclyde, Glasgow, United Kingdom and Lady Ridgeway Hospital for Children, Colombo, Sri Lanka.

Disclosure statement

No potential conflict of interest was reported by the author(s).

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Appendix 2: Abstract CLEFT 2022

An investigation into quality of life of adolescents with repaired cleft lip and palate living in Sri Lanka

Introduction

Cleft Lip and Palate (CLP) incidence in Sri Lanka is estimated at 0.83 in 1000. The key treatment involves surgery to repair the lip and/or palate to improve the child's ability to speak, swallow, and hear normally and to achieve a normal facial appearance. The nature of the lengthy treatment and multiple intervention procedures throughout childhood can result in concerns with physical, mental, emotional and social functioning domains in quality of life (QoL). Therefore, it is vital to investigate the QoL of those children using condition-specific measurements. The Child Oral Health Impact Profile (COHIP) is the most frequently used condition-specific questionnaire to measure QoL in CLP adolescents.

Aims

To translate, culturally adapt and validate COHIP into Sinhala, the principal language spoken in Sri Lanka.

To investigate QoL in adolescents (age 12-15 years) with repaired CLP.

Methods

The COHIP English assessment was translated into Sinhala following the forward - backward - forward method by a bilingual expert panel. Final COHIP – Sinhala (COHIP-S) translation was checked for linguistic and conceptual equivalence to the original before piloting. There were 348 adolescents in total (aged 12-15): 340

typically developing (TD) and 44 with repaired CLP completed the COHIP-S. The PedsQL- Sinhala generic QoL questionnaire was completed by 318 TD and 43 CLP adolescents.

Results

The translation process undertaken will be presented along with the final COHIP-S. The COHIP-S had high reliability with an excellent Cronbach's alpha value of 0.75 for the TD and 0.76 for the CLP group. QoL of the CLP adolescents will be presented compared to the TD adolescents using the PedsQL generic questionnaire data.

Conclusions

QoL in adolescents with CLP was found to be lower than their TD peers. The COHIP-S had good overall psychometric properties and was found to be a more appropriate measure of QoL in CLP adolescents than a generic QoL questionnaire.

Validation of the Intelligibility in Context Scale (ICS) in Sinhala for use with children with Cleft Lip and Palate in Sri Lanka.

Introduction

Speech and language therapists (SLTs) use a range of assessments to measure speech outcomes in children with cleft lip and palate (CLP). The Intelligibility in Context Scale (ICS) is a screening questionnaire that focuses on parents' perceptions of children's speech in different contexts. The original version of the ICS has high internal reliability ($\alpha=0.93$), construct validity and sensitivity (McLeod et al., 2012). It has been translated into 60 languages to date, but not Sinhala, the principal language spoken in Sri Lanka.

Aims

To translate and validate ICS into Sinhala.

To compare the ICS-S ratings of children with repaired CLP and typically developing (TD) children.

Methods

The ICS was translated into Sinhala following Gulimen et al. (1993). This required two forward translations from English to Sinhala; followed by reconciliation and agreement and a backward translation from Sinhala to English. Final forward Sinhala translation was checked for linguistic and conceptual equivalence to the original and then piloted. Fifty parents of typically developing children (aged 12-15)

and 38 parents of children with repaired CLP (aged 12-15) were asked to complete the Sinhala ICS questionnaire.

Results

The ICS - S had high internal consistency for both groups (TD $\alpha = 0.87$, $p < 0.05$, CLP $\alpha = 0.97$, $p < 0.05$). The ICS-S total scores and item scores showed significant correlations, indicating good construct validity. TD participant group's ICS-S average mean scores ($M = 4.88$, $SD = 0.29$) were significantly higher compared to the CLP ICS-S average mean scores ($M = 4.64$, $SD = 0.67$).

Conclusions

A considerable proportion of young children with repaired CLP were found to have reduced intelligibility in their speech. The Sinhala version of the ICS has overall good psychometric properties. Therefore, this tool can be recommended as a parent-rating screening tool for clinical and research purposes in Sri Lanka.

ICPLA 2020: 1st – 4th September 2020

Abstract Submission

Abstract Type:	☒ Poster ☐ Short Oral Presentation

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Oral/Poster abstracts should be 300 words maximum.

Abstract Topic

Cleft palate and craniofacial disorders

Abstract Title:

Validation of the Intelligibility in Context Scale (ICS) in Sinhalese for use in Sri Lanka.

Background:

Cleft lip and/or palate (CL/P) is one of the most common orofacial congenital malformations in live births and the current worldwide incidence is estimated as 1-2/1000. CL/P can affect speech and communication abilities in different ways. Speech and Language Therapists (SLTs) use a range of assessments to understand how well a child understands words as well as how they sound when they speak. The Intelligibility in Context Scale (ICS) is a screening questionnaire that focuses on parents' perceptions of children's speech in different contexts. The original version of the ICS has a high internal reliability ($\alpha=0.93$), construct validity and sensitivity (McLeod et al., 2012) and it has been translated into 60 languages to date, but not in Sinhalese, the principal language spoken in Sri Lanka. The objective of this study was to validate the ICS into Sinhalese.

Methods:

The ICS was translated into Sinhalese following Gulimen et al. (1993). This required two forward translations from English to Sinhalese; followed by reconciliation and agreement and a backward translation from Sinhalese to English. Final forward Sinhalese translation was checked for linguistic and conceptual equivalence to the original and then piloted. 50 parents of typically developing children (aged 12-15) and 30 parents of repaired CL/P children (aged 12-15) were asked to complete the Sinhalese ICS questionnaire.

Results:

Two bilingual SLT's whose mother tongue is Sinhalese and one SLT, whose mother tongue is English, together produced the final Sinhalese translation of ICS. The translation process undertaken will be presented along with the final translations of the ICS questionnaire and the validity of the Sinhalese ICS will be discussed.

Conclusion:

The time taken in preparing and completing the forward-backward-forward translation process should not be underestimated when preparing existing questionnaires for use in other cultural contexts. The translated questionnaire was tested with parents to gather data, statistically analyse and complete the validation process of the ICS Sinhalese translation for use in the Sri Lankan context.

Abstract – ICPF 2019 - Mirihagalla Kankanamalage Inoka, Dr Wendy Cohen, Dr Joanne Cleland

Cross cultural adaptation and validation of a health-related quality of life assessment (COHIP- Child Oral Health Impact Profile) for adolescents with Cleft Lip and Palate in Sri Lanka.

Background - Cleft lip and/or palate (CL/P) is one of the most common orofacial congenital malformations in live births and has varied incidences in different regional populations (Augsornwan & Prngapagatip, 2011). The current worldwide incidence is estimated as 1-2/1000. Treatment processes for CL/P and associated difficulties is a long-term process, usually from birth and lasting until early adulthood, leading to long term quality of life (QOL) implications for these individuals. Measuring QOL in adolescents requires care to ensure that questions are valid and appropriate, particularly where there may be discrete QOL concerns relating specifically to CL/P. Some questionnaires are available in some languages for this population, but not all in Sinhalese, the principal language spoken in Sri Lanka.

The objectives of this study are to culturally adapt and validate an existing QOL assessment for CL/P the “*Child Oral Health Impact Profile (COHIP)*” (Broder., 2017) alongside a measure of speech intelligibility, the “*Intelligibility in Context Scale (ICS)*” (McLeod, Harrison & McCormack, 2012) to Sinhalese. These tools will then be used to measure the QOL of young people with repaired CL/P in Sri Lanka.

Method - The COHIP and ICS were translated into Sinhalese using cross cultural adaptation guidelines (Gulimen et al., 1993). This requires two forward translations

from English to Sinhalese, followed by reconciliation and agreement and a backward translation from Sinhalese to English of the reconciled forward translated questionnaire. Bilingual English and Sinhalese speakers are required for all steps in the process, with three bilingual (Sinhalese and English) speech and language therapists (SLT's) undertaking these tasks.

Results – Two bilingual SLTs whose mother tongue is Sinhalese and one SLT, whose mother tongue is English, together produced the final Sinhalese translation of COHIP and ICS. The forward, reconciliation and backward steps of the translation process were completed leading to a final translation of both the COHIP and ICS ready for future validation in Sri Lanka. The process undertaken will be presented along with the final translations of the two questionnaires.

Discussion – The time taken in preparing and completing the forward-backward-forward translation process should not be underestimated when preparing existing questionnaires for use in other cultural contexts. The next stage in this study will involve trialing the questionnaires with 400 Sri Lankan typically developing adolescents and 30 young people with repaired CL/P, all aged 12-15 years. This will lead to validation of the COHIP and ICS Sinhalese questionnaires for use in the Sri Lankan context.

Appendix 6 : Search String – Web of Science

Search String – Web of Science (2013.01.01-2023.08.31) (239 publications)

Search terms – Quality of life in adolescents or young children with cleft lip and palate

Abualfaraj, R., Daly, B., McDonald, F., & Scambler, S. (2018). Cleft lip and palate in context: Learning from, and adding to, the sociological literature on long-term conditions [Article]. *HEALTH*, 22(4), 372-388. <https://doi.org/10.1177/1363459317693409>

Agnew, C. M., Page, L. F., & Hibbert, S. (2017). Validity and reliability of the COHIP-SF in Australian children with orofacial cleft [Article]. *International journal of paediatric dentistry*, 27(6), 574-582. <https://doi.org/10.1111/ipd.12329>

Ajami, S., Toraby, F., Shavakhi, M., & Eslami, N. (2018). The Impact of Type-D Personality on Oral Health-Related Quality of Life in Cleft Lip and Palate Adolescents [Article]. *Journal of Craniofacial Surgery*, 29(2), 289-292. <https://doi.org/10.1097/SCS.0000000000004093>

Al Anouti, F. (2021). Oral Health among Children and Adolescents in the United Arab Emirates: A Systematic Review of the Past Decade. <https://doi.org/10.17605/OSF.IO/AJMSZ>

Al Anouti, F. (2021). Oral Health among Children and Adolescents in the United Arab Emirates: A Systematic Review of the Past Decade. <https://doi.org/10.17605/OSF.IO/Y7PTZ>

Aleksieva, A., Begnoni, G., Verdonck, A., Laenen, A., Willems, G., & Cadenas de Llano-Perula, M. (2021). Self-Esteem and Oral Health-Related Quality of Life within a Cleft Lip and/or Palate Population: A Prospective Cohort Study [Article]. *International Journal of Environmental Research and Public Health*, 18(11), Article 6078. <https://doi.org/10.3390/ijerph18116078>

Ali, M. A., Abass, S. K., & Nasir, E. F. (2021). A comparative assessment of oral health-related quality of life of children born with orofacial clefts in Sudan and their caregivers' [Article]. *Bmc Oral Health*, 21(1), Article 148. <https://doi.org/10.1186/s12903-021-01514-2>

Ali, M. A., Nasir, A. F., & Abass, S. K. (2021). Oral Health-Related Quality of Life Among Sudanese Children Treated for Cleft Lip and Palate [Article]. *Cleft Palate-Craniofacial Journal*, 58(11), 1405-1411. <https://doi.org/10.1177/1055665620987694>

Alighieri, C., D'Haeseleer, E., Bettens, K., Bonte, K., Vermeersch, H., Vermeire, N., Claeys, M., Sseremba, D., Galiwango, G., & Van Lierde, K. (2022). Sociodemographics and Quality of Life in Dutch-Speaking Adolescents and Adults With and Without a Cleft Lip and/or Palate [Article]. *Cleft Palate-Craniofacial Journal*, 59(4_SUPPL2), S65-S73, Article 10556656211024513. <https://doi.org/10.1177/10556656211024513>

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Antonarakis, G. S., Patel, R. N., & Tompson, B. (2013). Oral health-related quality of life in non-syndromic cleft lip and/or palate patients: a systematic review [Review]. *Community Dental Health*, 30(3), 189-195. https://doi.org/10.1922/CDH_3225Antonarakis07

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WHO Guidelines on Translation

Available at: http://www.who.int/substance_abuse/research_tools/translation/en/

Process of translation and adaptation of instruments

The aim of this process is to achieve different language versions of the English instrument that are conceptually equivalent in each of the target countries/cultures. That is, the instrument should be equally natural and acceptable and should practically perform in the same way. The focus is on cross-cultural and conceptual, rather than on linguistic/literal equivalence. A well-established method to achieve this goal is to use forward-translations and back-translations. This method has been refined in the course of several WHO studies to result in the following guidelines.

Implementation of this method includes the following steps:

- 1 Forward translation
- 2 Expert panel Back-translation
- 3 Pre-testing and cognitive interviewing
- 4 Final version

1. Forward translation

One translator, preferably a health professional, familiar with

terminology of the area covered by the instrument and with interview skills should be given this task. The translator should be knowledgeable of the English-speaking culture but his/her mother tongue should be the primary language of the target culture.

Instructions should be given in the approach to translating, emphasizing conceptual rather than literal translations, as well as the need to use natural and acceptable language for the broadest audience. The following general guidelines should be considered in this process:

Translators should always aim at the conceptual equivalent of a word or phrase, not a word-for-word translation, i.e. not a literal translation. They should consider the definition of the original term and attempt to translate it in the most relevant way.

Translators should strive to be simple, clear and concise in formulating a question. Fewer words are better. Long sentences with many clauses should be avoided.

The target language should aim for the most common audience. Translators should avoid addressing professional audiences such as those in medicine or any other professional group. They should consider the typical respondent for the instrument being translated and what the respondent will understand when s/he hears the question.

Translators should avoid the use of any jargon. For example, they should not use:

technical terms that cannot be understood clearly; and colloquialism, idioms or vernacular terms that cannot be understood by common people in everyday life.

Translators should consider issues of gender and age applicability and avoid any terms that might be considered offensive to the target population.

2. Expert panel

A bilingual (in English and the target language for translation) expert panel should be convened by a designated editor-in-chief. The goal in this step is to identify and resolve the inadequate expressions/concepts of the translation, as well as any discrepancies between the forward translation and the existing or comparable previous versions of the questions if any. The expert panel may question some words or expressions and suggest alternatives. Experts should be given any materials that can help them to be consistent with previous translations. Principal investigators and/or project collaborators will be responsible for providing such materials. The number of experts in the panel may vary. In general, the panel should include the original translator, experts in health, as well as experts with experience in instrument development and translation.

The result of this process will produce a complete translated version of the questionnaire.

3. Back-translation

Using the same approach as that outlined in the first step, the instrument will then be translated back to English by an independent translator, whose mother tongue is English and who has no knowledge of the questionnaire. Back-translation will be limited to selected items that will be identified in two ways. The first will be

items selected by the WHO based on those terms / concepts that are key to the instrument or those that are suspected to be particularly sensitive to translation problems across cultures. These items will be distributed when the English version of the instrument is distributed. The second will consist of other items that are added on as participating countries identify words or phrases that are problematic. These additional items must be submitted to WHO for review and approval.

As in the initial translation, emphasis in the back-translation should be on conceptual and cultural equivalence and not linguistic equivalence. Discrepancies should be discussed with the editor-in-chief and further work (forward translations, discussion by the bilingual expert panel, etc.) should be iterated as many times as needed until a satisfactory version is reached.

Particularly problematic words or phrases that do not completely capture the concept addressed by the original item should be brought to the attention of WHO.

4. Pre-testing and cognitive interviewing

It is necessary to pre-test the instrument on the target population. Each module or section will be fully tested using the methodologies

outlined below.

- a Pre-test respondents should include individuals representative of those who will be administered the questionnaire. For this study, dependent opioid users should be used to test the translated instruments, although such users could be drawn from sources other than those used to recruit study participants – preferably persons who would not otherwise be eligible for the main study.
- b Pre-test respondents should number 10 minimum for each section. They should represent males and females from all age groups (18 years of age and older) and different socioeconomic groups.
- c Pre-test respondents should be administered the instrument and be systematically debriefed. This debriefing should ask respondents what they thought the question was asking, whether they could repeat the question in their own words, what came to their mind when they heard a particular phrase or term. It should also ask them to explain how they choose their answer. These questions should be repeated for each item.
- d The answers to these questions should be compared to the respondent's actual responses to the instrument for consistency.
- e Respondents should also be asked about any word they did not understand as well as any word or expression that they found unacceptable or offensive.
- f Finally, when alternative words or expressions exist for one item or expression, the pre-test respondent should be asked to choose which of the alternatives conforms better to their usual language.
- g This information is best accomplished by in-depth personal interviews although the organization of a focus group may be an alternative.
- h It is very important that these interviews be conducted by an experienced interviewer.

A written report of the pre-testing exercise, together with selected information regarding the participating individuals should also be provided.

5. Final version

The final version of the instrument in the target language should be the result of all the iterations described above. It is important that a

serial number (e.g. 1.0) be given to each version. Instructions for providing the electronic version of the final translated instrument to WHO will be provided.

6. Documentation

All the cultural adaptation procedures should be traceable through the appropriate documents. These include, at the least:

- initial forward version;
- a summary of recommendations by the expert panel;
- the back-translation;
- a summary of problems found during the pre-testing of the instrument and the modifications proposed; and
- the final version.

It is also necessary to describe the samples used in this process (i.e. the composition of the expert panel and the pre-test respondent samples). For the latter, the number of individuals as well as their basic characteristics should be described, as appropriate.

Appendix 8 : Email granting permission by the original author to use COHIP in the study

Re: Requesting COHIP -34/19 questionnaire

Hillary L Broder

Tue 21/08/2018 16:24

To: Inoka Mirihagalla Kankanamalage

Good Day,

Thank you for your interest in the COHIP. I am copying my associate, Ms. Rodriguez, who can send you the requested documents. The COHIP has been validated on ortho, pedo and craniofacial populations and is a reliable OHRQoL measure. Given your interest in CLP, the COHIP has been the most validated, widely used instrument. We have published longitudinal data on this population that include valuable references for your work.

Recent findings indicate that the short form is strongly correlated (ICCs= .094) to the long form from caregiver and youth reports. So if time constraints are salient, I would recommend the COHIP-SF.

Jasmine please send Inoka the long and original COHIP for youth.

Do not hesitate to contact me if you have any additional questions-- now or later.

Best,

Hillary

Hillary L. Broder, PhD, MED

Professor

Cariology and Comprehensive Care

NYU College of Dentistry

Re: Requesting COHIP -34/19 questionnaires

Hillary Broder

Tue 21/08/2018 20:09

To: Inoka Mirihagalla Kankanamalage

Jasmine please be sure to send the COHIP- SF if you have not done so.

Inoka you must seek permission from me-- permission granted. Along the way, you may have some additional queries- fire on.

In summary, you have my permission to use it- definitely follow the rules for cultural sensitivity. No additional collaborative requirements exist. Cheers

Hillary

FW: Intelligibility on Context Scales Translation

Dear Joanne and Inoka

Thanks for your interest in translating the ICS into Sinhalese. I am very sorry for the delay in replying to you (and hope I am not too late).

I encourage you to use forward and back translation (see Pascoe & McLeod, 2016, p. 331), and if possible professional/community checking (see Pascoe & McLeod, 2016, p. 332).

Pascoe, M., & McLeod, S. (2016). Cross-cultural adaptation of the Intelligibility in Context Scale for

South Africa. *Child Language Teaching and Therapy*, 32(3), 327-343.
doi:10.1177/0265659016638395

If she/you would like for the Sinhalese version to be considered to be on the ICS website

(<http://www.csu.edu.au/research/multilingual-speech/ics>) please use the Intelligibility in Context (ICS) translation template for you to use and send back to me when completed, documenting the translation process (How did you use forward and backward translation? How did you use professional and community checking?)

Finally, I have attached a list of journal articles that have used the ICS in their research. I have also attached a copy of two of these papers that our team has published for your interest.

McLeod, S., Harrison, L. J., & McCormack, J. (2012). Intelligibility in Context Scale: Validity and reliability of a subjective rating measure. *Journal of Speech, Language, and Hearing Research*, 55, 648-656. doi:10.1044/1092-4388(2011/10-0130)

McLeod, S., Crowe, K., & Shahaian, A. (2015). Intelligibility in Context Scale: Normative and validation data for English-speaking preschoolers. *Language, Speech, and Hearing Services in Schools*, 46(3), 266-276. doi:10.1044/2015_LSHSS-14-0120

Again, sorry for the delay, and best wishes for your research.

Regards

Sharynne

Appendix 10 : COHIP Sinhala translation (COHIP-S)

Children's Oral Health Impact Profile

COHIP – ශිෂ්‍ය පරිවර්තනය

ආයුබෝවන් !

මෙම ප්‍රශ්නාවලියට පිළිතුරු සැපයීමට එකඟවීම පිළිබඳව ඔබට ස්තූතියි. මෙහි අරමුණ වන්නේ දරුවන්ගේ දත් හා ඔවුන් පිළිබඳව සිතන ආකාරය සම්බන්ධව පැහැදිලි අවබෝධයක් ලබා ගැනීමයි.

පහත දක්වා ඇති ප්‍රකාශන/ ප්‍රශ්න ඉතා හොඳින් කියවන්න. පසුගිය මාස තුනක කාලය ඇතුළත ඔබගේ දත්, කට හා මුහුණ සම්බන්ධව ඔබට දැනුණු ආකාරය ඉතා හොඳින් විස්තර කෙරෙන පිළිතුරු තෝරන්න. මෙහි හරි හෝ වැරදි පිළිතුරු කියා දෙයක් නැත. ඔබට සත්‍ය වශයෙන් ම හැඟුන ආකාරය දැන ගැනීම වැදගත් වේ.

උදාහරණය : පසුගිය මාස තුන ඇතුළත ඔබට ඔබේ දත්, කට හෝ මුහුණ සම්බන්ධව ලැජ්ජා සහිත බවත් දැනන අවස්ථා තිබේ ද ?

ඔබට ලැජ්ජා සහිත බව දැනුනේ ඔබගේ දත්, කට හෝ මුහුණ නිසා බව පමණක් නම් අදාළ පිළිතුර තෝරන්න. ඔබට ලැජ්ජා බව දැනුනේ වෙනත් අමතර හේතු නිසා නම් "එය ඔබට කවදාවත් ගැටළුවක් වූයේ නැත."

පිළිතුරු තෝරන්න.

කවදාවත් ගැටළුවක් වූයේ නැත.	කලාතුරකින් ගැටළුවක් විය	සමහරක් වෙලාවට ගැටළුවක් විය	ගොඩාක් වෙලාවට ගැටළුවක් විය	හැම තිස්සෙම ගැටළුවක් විය

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උපදෙස්

- ප්‍රශ්න සඳහා අවංකව උත්තර සපයන්න.
- ප්‍රශ්න වලට උත්තර සපයන විට අනෙක් අය සමඟ සාකච්ඡා නොකරන්න.
- ප්‍රශ්නයට පිළිතුරු සැපයීමට පෙර , ඔබගෙන් මෙම ප්‍රශ්නය අසන්න.

"මෙය සිදුවූයේ මාගේ දත්, කට සහ මුහුණ නිසාද?"

පසුගිය මාස තුන ඇතුළත ඔබට ඇති වූ තත්ත්වයන් කල්පනා කරමින් පිළිතුරු සපයන්න.

පසුගිය මාස තුන ඇතුළත, කොපමණ වතාවක් පහත ගැටළු ඔබට ඇති වූවේ ද ?	කවදාවත් නැත	කලාතුරකින්	සමහර වෙලාවට	ගොඩක් වෙලාවට	හැම තිස්සේම

1. දත් වල වේදනාව / දත් කැක්කුම.	☐	☐	☐	☐	☐
2. කටෙන් හුස්ම ගැනීමට සිදු වීම / ගෙරවීම.	☐	☐	☐	☐	☐
3. දත් දුර්වර්ණ වීම / දත් වල පැල්ලම් ඇති වීම.	☐	☐	☐	☐	☐
4. දත්වල හැඩය වෙනස් වීම / කැඩීම / දත් අතර හිඬක් ඇති වීම.	☐	☐	☐	☐	☐
5. කට අවට හෝ කට තුළ වේදනාව / ඉදිමුම.	☐	☐	☐	☐	☐
6. හුස්ම පිට කරන විට කට දුභද වීම.	☐	☐	☐	☐	☐
7. විදුරු මගින් ලේ ගැලීම.	☐	☐	☐	☐	☐
8. දත් අතර හෝ දත් තුළ කැම කොටස් සිරවීම.	☐	☐	☐	☐	☐
9. උණු හෝ සීතල ආහාර කෑමේ දී දත්වල වේදනාව හෝ හිරි වැටීම.	☐	☐	☐	☐	☐
10. කට හෝ තොල් වියලීම.	☐	☐	☐	☐	☐
11. සනකම ආහාර වර්ග හැපීමට අපහසුතාවය (ඇපල්,කැරව්,මස් කැබලි)	☐	☐	☐	☐	☐
12. ඔබගේ දත්, කට හා මුහුණ සම්බන්ධව නොසතුට හා කණගාටුව	☐	☐	☐	☐	☐
13. ඔබගේ දත්, කට හා මුහුණ සම්බන්ධ ගැටළු නිසා පාසල් යාමට නොහැකි වීම.	☐	☐	☐	☐	☐
14. ඔබගේ දත්,කට හා මුහුණ සම්බන්ධව සතුදු සිතීම.	☐	☐	☐	☐	☐

පසුගිය මාස තුන ඇතුළත කොපමණ වතාවක් පහත ගැටළු ඔබට ඇති වූවේ ද ?

15. ඔබගේ දත්, කට හා මුහුණ සම්බන්ධ ගැටළු නිසා ඔබ කැමති කෑම කන්නට අපහසුතා ඇති වීම	☐	☐	☐	☐	☐
16. ඔබගේ දත්,කට හා මුහුණ සම්බන්ධව කනගාටුවක්, කරදරයක් දැනීම.	☐	☐	☐	☐	☐
17. ඔබගේ දත්, කට හා මුහුණ පෙනුම නිසා ලැජ්ජා සහගත බවක් හෝ අපහසුතාවයක්	☐	☐	☐	☐	☐

දැනීම

18. ඔබගේ දත්, කට හා මුහුණ සම්බන්ධ ගැටළු නිසා පාසල් වැඩ කටයුතුවලට අවධානය යෙදවීමට නොහැකි වීම	☐	☐	☐	☐	☐
19. ඔබගේ දත්, කට හා මුහුණ සම්බන්ධ ගැටළු නිසා යහළුවන් සමඟ සිතා සීමෙන්නන්/ ශබ්ද නගා සිතාසීමෙන්නන් වැළකීම.	☐	☐	☐	☐	☐
20. ඔබගේ දත්, කට හා මුහුණ සම්බන්ධ ගැටළු නිසා නින්දට බාධා ඇති වීම.	☐	☐	☐	☐	☐
21. ඔබගේ දත්, කට හා මුහුණ සම්බන්ධ ගැටළු නිසා පන්තියේ දී ශබ්ද නගා කථා කිරීමට/ කියවීමට අකමැති වීම.	☐	☐	☐	☐	☐
22. ඔබගේ දත්, කට හා මුහුණ ආශ්‍රිත ගැටළු නිසා අනෙක් ළමයින්ගේ උසුළු වීසුළු වලට ලක් වීම.	☐	☐	☐	☐	☐
23. ඔබගේ දත්, කට හා මුහුණ ආශ්‍රිත ගැටළු නිසා සමහර වචන කීමට අපහසු වීම	☐	☐	☐	☐	☐

පසුගිය මාස තුනක කාලය ඇතුළත කොපමණ වතාවක් පහත ගැටළු ඔබට ඇති වූවේද ?

24. ඔබගේ දත්, කට හා මුහුණ ආශ්‍රිත ගැටළු නිසා ඔබ අනෙක් අයට වඩා පෙනුමෙන් වෙනස් බව හැඟුණේද ?	☐	☐	☐	☐	☐
25. ඔබගේ දත්, කට හා මුහුණ ආශ්‍රිත ගැටළු නිසා ඔබ කියන දෙය තේරුම් ගැනීමට අනෙත් අයට අපහසු වූයේද?	☐	☐	☐	☐	☐
26. ඔබගේ දත්, කට හා මුහුණ පෙනුම නිසා ඔබ අත් අයගෙන් සිත් ඇදගන්නා සුළු බව	☐	☐	☐	☐	☐
27. දත් පිරිසිදුව නොගැනීමට අපහසු වීම.	☐	☐	☐	☐	☐
28. ඔබගේ දත්, කට හා මුහුණ ආශ්‍රිත ගැටළු නිසා ඔබ අනෙත් අය ඔබ ගැන සිතන විදිය ගැන කතාස්සු වීම.	☐	☐	☐	☐	☐
29. ඔබගේ දත්, කට හා මුහුණ සම්බන්ධව අනෙක් අය ඔබගෙන් ප්‍රශ්න කිරීම නිසා අපහසුතාවයට පත් වීම.	☐	☐	☐	☐	☐
30. ඔබගේ දත්, කට හා මුහුණ ආශ්‍රිත ගැටළු නිසා පාසල් යාමට අකමැති වීම.	☐	☐	☐	☐	☐

31. අතින් අය ඔබගේ මුහුණ, කට, දත් ගැන සිතන ආකාරය පිළිබඳව සංවේදීව වැඩිපුර සිතීම. ☐ ☐ ☐ ☐ ☐

පහත සඳහන් ප්‍රකාශ ඔබගේ දත්, කට හා මුහුණ ආශ්‍රිතව හෝ ඔබගේ සාමාන්‍ය සෞඛ්‍ය තත්ත්වය පිළිබඳවය. හොඳින් කියවා ඔබට හැඟෙන ආකාරය ප්‍රකාශ කිරීමට අදාළ පිළිතුර තෝරන්න.

	කඩදාමක් නැත	කලාතුරකින්	සමහර වේලාවට	ගොඩක් වේලාවට	හැම තිත්සෙම
32. මට හොඳ දත් පෙලක් ඇත.	☐	☐	☐	☐	☐
33. මා වයසින් වැඩිවන විට, මම හොඳ දත් පෙලක් ලැබේ යැයි සිතමි.	☐	☐	☐	☐	☐
34. මා වයසින් වැඩිවන විට මට හොඳ සෞඛ්‍ය තත්ත්වයක් ලැබේ යැයි සිතමි.	☐	☐	☐	☐	☐
35. මට මා ගැන සතුටු සිතෙයි. මාගේ ප්‍රතිකාර කටයුතු අවසන් වූ පසුව මාගේ සෞඛ්‍ය තත්ත්වය හොඳ අතට හැරේ යැයි සිතමි.	☐	☐	☐	☐	☐
37. මාගේ දත්, කට හා මුහුණට අවශ්‍ය ප්‍රතිකාර කටයුතු සම්බන්ධව මට බියක් / අපහසුතාවයක් දැනෙයි.	☐	☐	☐	☐	☐

38. සමස්තයක් ලෙස මාගේ සෞඛ්‍ය තත්ත්වය

ඉතා දුර්වලයි	දුර්වලයි	සාමාන්‍යයි	හොඳයි	ඉතා හොඳයි
☐	☐	☐	☐	☐

ස්තූතියි !

මෙම ප්‍රශ්නාවලිය උපුටා ගැනීමට හැක.

ICS ප්‍රශ්නාවලිය [Creative Commons Attribution-Non Commercial – No Derivs 3.0 Unported License](#) යටතේ ලියා පදිංචි කර ඇත.

**අවස්ථානුකූල කථන පැහැදිලිතාව පිළිබඳ
තත්ව මට්ටම : සිංහල**
Intelligibility in Context Scale (ICS): Sinhala
(McLeod, Harrison, & McCormack, 2012)
Translated by: Mirihagalla K. Inoka Sirimanna
University of Strathclyde, UK, 2021

දරුවාගේ නම : _____
දරුවාගේ උපන්දිනය : _____ ස්ත්‍රී / පුරුෂ : _____
කථා කරන භාෂාව/ භාෂා : _____
දිනය : _____ දරුවාගේ වයස : _____
මෙම ප්‍රශ්නාවලිය සම්පූර්ණ කරන්නාගේ නම : _____
දරුවාට ඇති සම්බන්ධතාවය : _____
පහත ප්‍රශ්න ඔබගේ දරුවාගේ කථාව අන් අයට කොතරම් දුරට තේරුම් ගැනීමට හැකිදැයි
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ප්‍රශ්නවලට පිළිතුරු සපයන්න. අදාළ අංකය රවුම් කරන්න.

	සෑමවිට ම	සාමාන්‍යයෙන්	සමහර විට	කලාතුරකි න්	කවදාවත් නැත
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2. ඔබේ පවුලේ ලඟම ඥාතීන්ට ඔබේ දරුවාගේ කථාව තේරෙනවාද?	5	4	3	2	1
3. ඔබේ පවුලේ දුර ඥාතීන්ට ඔබේ දරුවාගේ කථාව තේරෙනවාද?	5	4	3	2	1
4. ඔබේ දරුවාගේ යහළුවන්ට ඔබේ දරුවාගේ කථාව තේරෙනවාද?	5	4	3	2	1
5. වෙනත් හඳුනන අයට ඔබේ දරුවාගේ කථාව තේරෙනවාද?	5	4	3	2	1
6. ඔබේ දරුවාගේ ගුරුවරුන්ට ඔබේ දරුවාගේ කථාව තේරෙනවාද?	5	4	3	2	1
7. අමුත්තන් හට ඔබේ දරුවාගේ කථාව තේරෙනවාද?	5	4	3	2	1
සම්පූර්ණ එකතුව =	/35				

McLeod, S., Harrison, L. J., & McCormack, J. (2012). අවස්ථානුකූල කථන පැහැදිලිතාව පිළිබඳ තත්ව මට්ටම : සිංහල [Intelligibility in Context Scale: Sinhala]. (Mirihagalla, K. Inoka Sirimanna, Trans.). Bathurst, NSW, Australia: Charles Sturt University. Retrieved from <http://www.csu.edu.au/research/multilingual-research/ics>. Published November 2021.

Appendix 12 : Ethics approval confirmation: University of Strathclyde

RE: Ethics application

HaSS PSH Ethics <hass-psh-ethics@strath.ac.uk>

Thu 28/02/2019 14:53

To: Wendy Cohen <wendy.cohen@strath.ac.uk>

Cc: Inoka Mirihagalla Kankanamalage <inoka.mirihagalla-kankanamalage@strath.ac.uk>; Joanne Cleland <joanne.cleland@strath.ac.uk>

Dear Wendy

SEC has reviewed the above application and is happy to approve it with the following amendments and caveats having been addressed:

1. Ethics application form item 7– change start date to 2019 (currently listed as 01/06/2018)
2. SEC assumes you have permission to use and translate the “Intelligibility in Context Scale” into Sinhalese?

Participant information sheets:

3. Remove phrasing on both parent PISs that their participation would be very helpful. This is coercive.
4. Are the researcher’s listed contact details her personal details? It would be safer for the student to NOT provide her personal phone number.
5. Under the subheading “where will data be stored...” add that data will be stored in an online system (Strathcloud).
6. The PIS state that participants can withdraw from the study at any time. However, the consent forms state that participants can withdraw from the project at any time, up until the point that partially anonymised data has been included in the study. This extra information should be included in the PIS.
7. The address for SEC is 40 George Street

Consent forms:

8. The researchers could add a consent item that the parent and the adolescent provide consent for the researcher to contact the school principal if the adolescent’s responses to the QOL questionnaires indicate they could benefit from some support. SEC is concerned about potential ethical issues of sharing this sensitive information with the principal without explicit consent.
9. Remove item that the parent consents to be a participant—this does not appear necessary from the other documents submitted with this application.

Risk assessment form – section 2 is incomplete.

SEC does not require to see the amended documents

Best wishes

Diane

From: Wendy Cohen <wendy.cohen@strath.ac.uk>

Sent: 14 February 2019 14:38

To: HaSS PSH Ethics <hass-psh-ethics@strath.ac.uk>

Cc: Inoka Mirihagalla Kankanamalage <inoka.mirihagalla-kankanamalage@strath.ac.uk>; Joanne Cleland <joanne.cleland@strath.ac.uk>

Subject: Ethics application

Please find attached an ethics application for your consideration,
Best wishes
Wendy

Wendy Cohen PhD, PG Cert, BSc Hons, Reg MRCSLT, SFHEA
Senior Lecturer
Professional and Research Lead (SLT)
School of Psychological Sciences and Health
University of Strathclyde
Room GH549, Graham Hills Building
40 George Street
Glasgow, G1 1QE

SCHOOL OF PSYCHOLOGICAL SCIENCES & HEALTH



Ministry of Health, Nutrition & Indigenous Medicine

Suwasiripaya

No. 385,

Rev. Baddegama Wimalawansa Thero Mawatha.

Colombo 10

Sri Lanka.

For attention of The Sri Lankan Ministry of Health, Nutrition & Indigenous Medicine

Dear Minister of Health, Nutrition & Indigenous Medicine,

Study title: Cross-cultural adaptation and validation of a health related quality of life assessment (COHIP

– Children’s Oral Health Index Profile) for adolescents with Cleft Lip and Palate in Sri Lanka

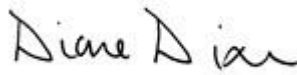
Student: Mrs.Mirihagalla Kankanamalage Inoka Udayangani Sirimanna

Mrs Mirihagalla Kankanamalage Inoka is a current registered PhD student in Speech and Language Therapy at the University of Strathclyde in Scotland. She is completing this project as part of her fulfilment of a PhD degree.

The protocol for her study requires recruitment of 30 Cleft Lip and Palate participants from Sri Lankan hospitals. The study protocol and procedures were reviewed by the University of Strathclyde School Ethics Committee with approval granted on 28th February 2019. Formal permission for this study is also being asked of the Sri Lanka Medical Association Ethics review Committee and Ministry of Education in relation to the typically developing participants.

Please note that this letter is confirmation of the University's usual internal approval procedures for PhD research studies.

Yours Faithfully



Dr Diane Dixon

Reader

Health Psychologist

Chair School of Psychological Sciences and Health Research Ethics Committee

University of Strathclyde

Glasgow

Scotland



Appendix 14 : Ethics Approval confirmation – Lady Ridgeway Children’s Hospital,
Ministry of Health – Sri Lanka

මගේ අංකය } எனது எண் } My No: } ඔබේ අංකය } உமது எண் } Your No: } දෙනෙරු බැනිස්ටර් ද සිල්වා මාලක, කොළඹ 08, කොළඹ 08, කොළඹ 08, මාලක, කොළඹ 08, Dr. Denister De Silva Mw, Colombo 08, Sri Lanka.	 ලීඩ්වේ ආර්ය ළමා රෝහල (ඉගෙනීම) ඒමාද්ද් නිල්වේ ජිහාරා චන්ද්‍රසේන (ආපෝෂක) Lady Ridgeway Hospital for Children (Teaching)	දුරකථන අංකය } தொலைபேசி இல } Telephones } අධ්‍යක්ෂ / இயக்குனர் / Director :011- 2691521 පොදු / பொது / General: 011-2693711-4 ෆැක්ස් / பக்ஸ் / Fax : 011-2686859 විද්‍යුත් තැපෑල / மின்னஞ்சல் / E-mail : dlrh@health.gov.lk දිනය / திகதி / Date: 2019.11.02

Mrs. Mirihagalla Kankanmalage Inoka Sirimanna

(BSc, MSc)

Speech and Language Therapist & PhD Candidate

Speech and Language Therapist Department

University of Strathclyde

Glasgow, United Kingdom

Re: Health Related Quality of Life assessment and Speech Intelligibility rating Scale

Ethical committee sat on 25.10.2019 has granted ethical clearance for the above study. You are Bound to produce a final interim report to the ethical review committee before publishing.

Thanking you,



Dr. Ajith Dantanarayana
Chairman – Ethical Review Committee
Director - LRH

DR. A. DANTANARAYANA
Director
Lady Ridgeway Hospital
Colombo 08.

The following members of the ethical review committee

- Dr. B.A.D. Jayawardene, Consultant Paediatric Surgeon
- Dr. Devan Mendis, Consultant Paediatrician
- Dr. (Mrs) L.A.P. Perera, Consultant Anaesthetist
- Dr. (Mrs) Eresha Jasinge, Chemical Pathologist
- Mr. S.M.S. Jayawardena, Attorney-at-Law
- Mr. S.S. Wanigasekara, Principal, Kannangara Vidyalaya, Borella
- Mrs. M.A.G. Gunarathne, Chief Matron

Appendix 15 : User agreement with Mapi Research Trust to use PedsQL questionnaire in the study.

User agreement

Special Terms

Mapi Research Trust, a non-for-profit organisation subject to the terms of the French law of 1st July 1901, registered in Carpentras under number 453 979 346, whose business address is 27 rue de la Villette, 69003 Lyon, France, hereafter referred to as “MRT” and the User, as defined herein, (each referred to singularly as a “Party” and/or collectively as the “Parties”), do hereby agree to the following User Agreement Special and General Terms:

Mapi Research Trust

PROVIDE™

27 rue de la Villette

69003 Lyon

France

Phone: +33 (0)4 72 13 66 66

Recitals

The User acknowledges that it is subject to these Special Terms and to the General Terms of the Agreement, which are included in Appendix 1 to these Special Terms and fully incorporated herein by reference. Under the Agreement, the Questionnaire referenced herein is licensed, not sold, to the User by MRT for use only in accordance

with the terms and conditions defined herein. MRT reserves all rights not expressly granted to the User.

The Parties, in these Special Terms, intend to detail the special conditions of their partnership.

The Parties intend that all capitalized terms in the Special Terms have the same definitions as those given in article 1 of the General Terms included in Appendix 1.

In this respect, the Parties have agreed as follows:

Article 1. Conditions Specific to the User

Section 1.01 Identification of the User

User Name	Inoka Mirihagalla
Legal Form	Student
Address	50, George Street Glasgow - Scotland G11 1QE Glasgow
Country	United Kingdom
Email address	inoka.mirihagalla-kankanamalage@strath.ac.uk
Telephone number	07492813791

Section 1.02 Identification of the Questionnaire

Title	Pediatric Quality of Life Inventory™ (PedsQL™)
Author(s)	Varni JW
Owner	Varni James W, PhD
Copyright	Copyright © 1998 JW Varni, Ph.D. All rights reserved

Original bibliographic references	See Appendix 2

Article 2. Rights to Use

Section 2.01 Context of the Use of the Questionnaire

The User undertakes to only use the Questionnaire in the context of the Study as defined hereafter.

Context of Use	Other project
Title	Mrs
Disease or condition	Cleft Lip and Palate
Start	01/2018
End	12/2021
Description of the project	PhD study - Measuring quality of life in adolescents with cleft lip and palate -Sri Lanka
Presentation format of project	Thesis

Section 2.02 Conditions for Use

The User undertakes to use the Questionnaire in accordance with the conditions for use defined hereafter.

(a) Rights transferred

Acting in the Owner's name, MRT transfers the following limited, non-exclusive rights, to the User (the "Limited Rights") (i) to use the Questionnaire, only as part of the Study; this right is made up exclusively of the right to communicate it to

the Beneficiaries only, free of charge, by any means of communication and by any means of remote distribution known or unknown to date, subject to respecting the conditions for use described hereafter; and

to reproduce the Questionnaire, only as part of the Study; this right is made up exclusively of the right to physically establish the Questionnaire or to have it physically established, on any paper, electronic, analog or digital medium, and in particular documents, articles, studies, observations, publications, websites whether or not protected by restricted access, CD, DVD, CD-ROM, hard disk, USB flash drive, for the Beneficiaries only and subject to respecting the conditions for use described hereafter; and

Should the Questionnaire not already have been translated into the language requested, the User is entitled to translate the Questionnaire or have it translated in this language, subject to informing MRT of the same beforehand by the signature of a Translation Agreement indicating the terms of it and to providing a copy of the translation thus obtained as soon as possible to MRT.

The User acknowledges and accepts that it is not entitled to amend, modify, condense, adapt, reorganise the Questionnaire on any medium whatsoever, in any way whatsoever, even minor, without MRT's prior specific written consent. (b) Specific conditions for the Owner

The Owner has intended to transfer a part of the copyright on the Questionnaire and/or the Documentation to MRT in order to enable MRT to make it available to the User for the purpose of the Study, subject to the User respecting the following conditions:

User shall not modify, abridge, condense, translate, adapt, recast or transform the Questionnaire in any manner or form, including but not limited to any minor or significant change in wordings or organisation in the Questionnaire, without the prior written agreement of the Owner. If permission is granted, any improvements, modifications, or enhancements to the Questionnaire which may be conceived or developed, including translations and modules, shall become the property of the Owner.

The User therefore undertakes to respect these special terms.

(c) Specific conditions for the Questionnaire

- Use in Individual clinical practice or Research study / project

The User undertakes never to duplicate, transfer or publish the Questionnaire without indicating the Copyright Notice.

In the case of use of an electronic version of the Questionnaire in academic studies, the User undertakes to respect the following special obligations:

In case of use of an IT Company (e-vendor), User shall check with Mapi Research Trust that IT Company has

signed the necessary License Agreement with Mapi Research Trust before developing the electronic version of the Questionnaire - Not modify the questionnaire (items and response scales, including the response scale numbers from 0-4) - Cite the reference publications

Insert the Owner's copyright notice on all pages/screens on which the Questionnaire will be presented and insert the Trademark information: PedsQL™, Copyright © 1998 JW Varni, Ph.D. All rights reserved.

Mention the following information: "PedsQL™ contact information and permission to use: Mapi Research Trust,

Lyon, France–Internet: <https://eprovide.mapi-trust.org> and www.pedsql.org/index.html ”

Submit the screenshots of all the Pages where the Questionnaire appears to Dr James W. Varni before release for approval and to check that the above-mentioned requirements have been respected.

In the case of use of an electronic version of the Questionnaire in commercial studies / projects, the User undertakes to respect the following special obligations:

User shall:

In case of use of an IT Company (e-vendor), User shall check with Mapi Research Trust that IT Company has

signed the necessary License Agreement with Mapi Research Trust before developing the electronic version of the Questionnaire - Not modify the questionnaire (items and response scales, including the response scale numbers from 0-4) - Cite the reference publications

Insert the Owner's copyright notice on all pages/screens on which the Questionnaire will be presented and insert the Trademark information: PedsQL™, Copyright © 1998 JW Varni, Ph.D. All rights reserved.

Mention the following information: “PedsQL™ contact information and permission to use: Mapi Research Trust, Lyon, France – Internet: <https://eprovide.mapi-trust.org> and www.pedsql.org/index.html”

For the first migration of the Questionnaire (generally the original version) into a specific electronic device - Review of screenshots:

After implementation of the Questionnaire into the device, the user/IT Company will generate screen captures (screenshots) of the original questionnaire as displayed in the device. These will be reviewed by Mapi to check that they are consistent with the original paper version in terms of presentation, content and completion except for specific instructions related to the electronic administration. Corrections that may be needed will be reported to the user/IT Company. In this case, screenshots after correction will be generated for another round of review by Mapi until all screenshots are approved.

Dr James W. Varni will review all approved screenshots for a final validation.

Usability testing:

Usability testing is a methodology which aims to examine whether respondents are able to use a device and associated software as intended. Major issues of concern in usability testing typically include device complexity, navigation and response selection for example.

The objective of this investigation is to ensure that the electronic version of the questionnaire as included in the device meets usability criteria, focusing on functional aspects and respondents’ understanding of instructions. Usability testing consists in interviews with patients where patients will complete the electronic version of the

Questionnaire on the device and comment on their understanding of the instructions, ease of use and handiness of the device. A Usability testing report presenting results will be produced. If any changes are recommended, these will be implemented by the user/IT Company. If issues raised by respondents are rated as major, the user/IT Company may need to perform additional developments and another round of interviews may be needed.

Dr James W. Varni will review the changes suggested, if any, following the interviews.

The review of screenshots is mandatory. The usability testing is highly recommended by Mapi, however should the User and/or IT Company decide not to perform this step, Mapi Research Trust shall not be held responsible for any consequence and expense associated with this decision which shall remain the User and/or IT Company's sole liability.

The review of screenshots and usability testing, when and if performed, shall be performed exclusively by Mapi and shall be sponsored by the User.

The performance of the review of screenshots and usability testing will result in a certification of the electronic device original version of the Questionnaires by Mapi for future licenses.

For the migration of other language versions of the Questionnaire on an existing certified specific electronic device

Update version

After the electronic device original version of the Questionnaire is fully ready, the Questionnaire's language versions developed for paper administration will be updated

to reflect the changes in wording of instructions implemented in the electronic device original version of the questionnaire.

Native speakers of the languages will reflect the changes made to the electronic device original version of the Questionnaire and will provide English equivalents of all changes made for Mapi's quality control.

Review of screenshots:

After implementation of the Questionnaire into the device, the user/IT Company will generate screen captures (screenshots) of the original questionnaire as displayed in the device. These will be reviewed by Mapi to check that they are consistent with the original paper version in terms of presentation, content and completion except for specific instructions related to the electronic administration. Corrections that may be needed will be reported to the user/IT Company. In this case, screenshots after correction will be generated for another round of review by Mapi until all screenshots are approved.

The update of version and review of screenshots are mandatory. These steps shall be performed exclusively by Mapi and shall be sponsored by the User.

The performance of the update of version and review of screenshots will result in a certification of the electronic device language version of the Questionnaires by Mapi for future licenses.

Use in a publication:

In the case of a publication, article, study or observation on paper or electronic format of the Questionnaire, the User undertakes to respect the following special obligations:

not to include any full copy of the Questionnaire, but a version with the indication “sample copy, do not use without permission”

to indicate the name and copyright notice of the Owner (PedsQL™, Copyright © 1998 JW Varni, Ph.D. All rights reserved)

to include the reference publications of the Questionnaire

to indicate the details of MRT for any information on the Questionnaire as follows:

"PedsQL™ contact information and permission to use: Mapi Research Trust, Lyon, France. – Internet: <https://eprovide.mapi-trust.org> and www.pedsql.org "- to provide MRT, as soon as possible, with a copy of any publication regarding the Questionnaire, for information purposes

to submit the screenshots of all the Pages where the Questionnaire appears to MRT before release to check that the above-mentioned requirements have been respected.

Use for dissemination or marketing:

In the case of use in a dissemination/marketing context:

On a website with unrestricted access:

The publication of a copy of the PedsQL™ on a website with unrestricted access is not permitted.

On a website with restricted access:

In the case of publication on a website with restricted access, the User may include a version of the Questionnaire that may be amended, subject to this version being protected by a sufficiently secure access to only allow the Beneficiaries to access it.

Article 3. Term

MRT transfers the Limited Rights to use the Questionnaire as from the date of delivery of the Questionnaire to the User and for the whole period of the Study.

Article 4. Beneficiaries

The Parties agree that the User may communicate the Questionnaire in accordance with the conditions defined above to the Beneficiaries involved in the Study only, in relation to the Study defined in section 2.01.

Article 5. Territories and Languages

MRT transfers the Limited Rights to use the Questionnaire on the following territories and in the languages indicated in the table below:

Questionnaire	Language
PedsQL™ Generic Core Scales	English for the UK

Article 6. Price and Payment Terms

The User undertakes in relation to MRT to pay the price owed in return for the availability of the Questionnaire, according to the prices set out below, depending on the languages requested and the costs of using the Questionnaire, in accordance with the terms and conditions described in section 6.02 of the General Terms included in Appendix 1.

Access to the Questionnaire in non-funded academic research and individual clinical practice is free of charge.

Agreed and acknowledged by

Inoka Mirihagalla

03-Sep-2018

RE: PedsQL Sinhalese translation (Sri Lanka)

Lavenir, Valerie

Mon 06/05/2019 15:05

To: Inoka Mirihagalla Kankanamalage

Cc: Edieux, Marie Sidonie

Dear Inoka,

The available Sinhalese versions of the PedsQL Generic Core Scales are now available for download through our online process. We kindly ask you to please try the process again, making sure that you select **“Sinhalese for Sri Lanka”**.

Guidelines are available [here](#).

Best regards,

Valérie Lavenir

Client Services Assoc. II, PCS



How does quality of life in young people with cleft lip and palate compare to other young people.

Participant information sheet – Parents of typically developing adolescents

Introduction

My name is Mrs. Mirihagalla Kankanamalage Inoka Udayangani Sirimanna. I used to be a speech and language therapist at Colombo North Teaching Hospital- Ragama and I am now a doctoral student at the University of Strathclyde, Glasgow, United Kingdom. I am contacting you because your child's school principal thinks you and your child might be able to help with my study to check the suitability of some questionnaires I have translated for using in Sri Lanka.

Please read this information carefully before deciding whether or not you would like your child to participate in the study.

Your help is greatly appreciated!

What is the purpose of the research?

This study aims to translate a Health-Related Quality of Life Questionnaire From English to Sinhalese and to use this new version to find out how quality of life might be different in children with repaired Cleft Lip and Palate compared to same age children without Cleft Lip and Palate. Your child has been invited to take part as they are developing as expected for a child at their age and are in a similar age group to the children with cleft lip and palate who will also be invited to take part.

Does my child have to take part?

No. Participation is voluntary, and it is completely up to you and your child if you want to take part. However, it will be really helpful if you and your child can take part in this study by completing the questionnaires. If you and your child decide not to participate in this study, or if you decide to take part and then change your mind, there will be no impact on any aspect of your child's learning at school.

What will happen if my child takes part in the study?

As parents you will be asked to complete the enclosed questionnaire and consent form, name code sheet and send these back to the school with your child. This will tell us that you give your permission for your child to take part in the study. If you give permission for your child to participate in this study, he or she will then be asked to

complete two questionnaires at school, which will take approximately 15-20 minutes. Example questions in the questionnaire are:-

In the last three months, have you; Had pain in your teeth/ toothache?

In the last three months, have you; Had bad breath?

In the last three months, have you; Had difficulty paying attention in school because of your teeth, mouth or face?

We expect to be completing the questionnaires in school sometime between the dates of 10.07.2019 to 15.07.2019. All children who have permission from their parents will be asked to fill in the questionnaires at the same time in their classroom, at a time that will be agreed with the class teacher. Your child will be getting a pen as a thank you gesture for filling in the questionnaires.

Why has your child been invited to take part?

Part of this study is to check the suitability of these questionnaires in Sri Lanka. It is understood that your child may not have any speech or quality of life concerns, but the study will be asking up to 400 typically developing young people so that their experiences can be compared to the children with cleft lip and palate. As part of the study, I am hoping to find whether the quality of life of children with cleft lip and palate is the same as similar aged typically developing children or not.

What is the potential risk to you in taking part?

The risks of filling in the questionnaires are very minimal. There is a chance that your child may find some of the questions in the questionnaire a little upsetting. All children will have the study explained to them and given details about what they are expected to do before they start to fill in the questionnaire. They will also be advised that if they do not want to complete the questionnaire, they can stop at any time. I will be available when they fill the questionnaire, so they can raise any questions or ask any clarifications while they complete it.

What information is being collected in the project?

The Researcher will allocate a number to your child's name. This has been sent to you in this pack. Your child's name will not be written on the questionnaire. They will be asked to write their number code on top of the questionnaire. The names and number codes will be kept confidential. In the unlikely event that a young person's answers to the questionnaire might suggest they could benefit from some support, this will allow us to identify that young person to the school principal.

Who will have access to the information?

You and your child's confidentiality will be maintained at all times. Only the researcher (Me) and my two supervisors at the University of Strathclyde will be able to see the completed questionnaires. If your child raises any quality of life concerns as identified by the answers, I will share it with the school principal.

Where will the information be stored and how long it will be kept for?

The completed questionnaires will be transported back to the UK securely with me for analysis. The questionnaires will be stored in a secure, locked cupboard in the University of Strathclyde for ten years.

What will happen to the results of the research study?

The findings will be analysed and discussed in my doctoral thesis. Findings also will be prepared for presentations at conferences and a written report that might be published. No names or identifying information will be used in any of these. Translated copies of the questionnaires will be available in Sri Lanka in the future.

What if there is a problem?

If you have any concerns or need to ask any questions about this project before deciding to take part, please contact me using the below number as I am in Sri Lanka now. You can also contact the school principal or your child's class teacher if you need any other information.

If you have any problems or questions about the project, you can raise these with my supervisor:

Dr. Wendy Cohen
Speech and Language Therapy department
Graham Hills Building
50, George Street
Glasgow
G1 1QE
UK
E-mail-
Tel –

If you would rather talk to someone who is not involved in the project please contact:

Dr. Dianne Dixon
Chair of the School Ethics Committee
School of the Psychological Science and Health
Graham Hills Building
50, George Street
Glasgow.
G1 1QE
E-mail-

My contact Details

Telephone (Sri Lanka)

E-mail-

Address (UK) – Speech and Language Therapy Department

Graham Hills Building

University of Strathclyde

50, George Street

Glasgow

G1 1QE

UK

This research study has been reviewed approved by the University of Strathclyde School of Psychological and Social Sciences Ethics committee, the Provincial Director of the Sri Lanka Department of Education and the Medical Council of Sri Lanka.



How does quality of life in young people with cleft lip and palate compare to other young people.

Participant information sheet –Typically developing adolescents

Introduction

My name is Mrs. Mirihagalla Kankanamalage Inoka Udayangani Sirimanna. I used to be a speech and language therapist at Colombo North Teaching Hospital- Ragama and I am now a doctoral student at the University of Strathclyde – Glasgow- United Kingdom. I am contacting you because your school principal thinks you might be able to help with my study to check the suitability of some questionnaires, I have translated for using in Sri Lanka.

Please read this carefully before deciding whether or not you would like to take part in the study. Your parents will also be informed and their permission is needed along with yours.

Your help is greatly appreciated!

What is the purpose of the research?

This study aims to translate a Health Related Quality of Life Questionnaire from English to Sinhalese and find out how suitable this new version is in Sri Lanka. I also want to find out how quality of life might be different in young people with repaired Cleft Lip and Palate.

For this study, I am asking Sri Lankan typically developing children aged 12-15 years to take part. I am also asking young people with Cleft Lip and Palate to complete the questionnaires.

Do you have to take part?

No, you can decide if you want to take part or not. Also, even if you initially decide to take part and then change your mind, you can leave the study at any time.

What will happen if I decide to take part in the study?

If your parents have given their permission for you to participate in the study and you are also willing to participate, you will be asked to complete two questionnaires at school. It is very valuable to gather your own answers to the questionnaire, so please try to complete these by yourself. It will take about 15 minutes to do this. You will be asked to fill these in during class sometimes between the 10.07.2019 to 15.07.2019.

As a thank you for taking part you will get a pen that you can use to fill out the questionnaire.

Why have you been invited to take part?

This study is trying out these questionnaires with up to 400 adolescents in Sri Lanka. While you might not have any speech or quality of life concerns, that is not important as all the information is valuable and will help us compare the wellbeing of children with and without Cleft Lip and Palate.

What is the potential risk to you in taking part?

Although it is unlikely, there is a small chance that you may find some of the questions in the questionnaires a little upsetting. If you feel that you cannot complete the questionnaires, you can stop at any time and speak to an adult you trust, such as your teacher. I will be around when you fill the questionnaire, so you can raise any questions or ask any clarifications while you complete it.

What information is being collected in the project?

I will give you a number and ask you to write that number on the top of the questionnaires you fill in. This will mean that your name is not on the questionnaires. I will make sure that I keep your name and number confidential. After you have finished completing the questionnaire, I will take this away with me and look at everyone's responses. In the unlikely event that any of your answers to the questionnaires suggest that you might need some help at school, then I will let the school principal know so they can talk to you about that.

Who will have access to the information?

Your confidentiality will be maintained at all times. Only the researcher (Me) and my two supervisors at the University of Strathclyde will be able to see the completed questionnaires. If you come up with any quality of life concerns as identified by the answers, I will share it with your school principal.

Where will the information be stored and how long it will be kept for?

The completed questionnaires will be transported back to the UK securely with me for analysis. The questionnaires will be stored in a secure, locked cupboard in the University of Strathclyde for ten years.

What will happen to the results of the research study?

The findings will be analysed and discussed in my doctoral thesis. Findings also will be prepared for presentations at conferences and a written report that might be published. I will not use your name or any identifying information in any of these. Translated copies of the questionnaires will be available in Sri Lanka in the future.

What if there is a problem?

If you have any concerns or need to ask any questions about this project before deciding to take part, please contact me using the below number as I am in Sri Lanka now. You can also contact the school principal or your class teacher if you need any other information.

If you have any problems or questions about the project you can raise these with my supervisor:

Dr. Wendy Cohen

Speech and Language Therapy department

Graham Hills Building

50, George Street

Glasgow

G1 1QE

UK

E-mail-

Tel –

If you would rather talk to someone who is not involved in the project please contact:

Dr. Dianne Dixon

Chair of the School Ethics Committee

School of the Psychological Science and Health

Graham Hills Building

50, George Street

Glasgow.

G1 1QE

E-mail-

My contact Details

Telephone (Sri Lanka)

E-mail-

Address (UK) – Speech and Language Therapy Department

Graham Hills Building

University of Strathclyde

50, George Street

Glasgow

G1 1QE,

UK

This research has been reviewed and approved by the University of Strathclyde School of Psychological and Social Sciences ethics committee, the Provincial Director of the Sri Lanka Department of Education and the Medical Council of Sri Lanka.



Consent Form for parents – Typically Developing Children

Name of the department: School of Psychological Sciences and Health- Speech and Language Therapy

Title of the study: How does quality of life in young people with cleft lip and palate compare to other young people.

Child's name code-.....

- I confirm that I have read and understood the participant information sheet for the above project and the researcher has answered any queries to my satisfaction.
- I understand me and my child's participation is voluntary and that I and my child are free to withdraw from the project at any time, up to the point of completion, without having to give a reason and without any consequences.
- I understand that partially anonymised data cannot be withdrawn once they have been included in the study.
- I understand that any information recorded during the investigation will remain confidential and no information that identifies me or my child will be made publicly available.
- I consent to being a participant in the project.
- I give my consent for my child to participate in the project.

Print name of the parent

.....
.....

Signature of the parent

Date

.....
.....



Assent Form – Typically Developing Children

Name of the department: School of Psychological Sciences and Health- Speech and Language Therapy

Title of the study: How does quality of life in young people with cleft lip and palate compare to other young people.

Name code.....

- I confirm that I have read and understood the participant information sheet for the above project and the researcher has answered any queries to my satisfaction.
- I understand that my participation is voluntary and that I am free to withdraw from the project at any time, up to the point of completion, without having to give a reason and without any consequences.
- I understand that partially anonymised data cannot be withdrawn once they have been included in the study.
- I understand that any information recorded during the investigation will remain confidential and no information that identifies me will be made publicly available.
- I consent to being a participant in the project .

Print name of the child

.....

Signature of the child

Date

Appendix 21 : Sample letter to given out to parents of young children with Cleft Lip and Palate by the local speech and language therapist

Sample letter to send out to parents of young children with Cleft Lip and Palate by the local speech and language therapist with the questionnaires, consent sheet and information leaflet (This will be typed in Sinhalese on a local hospital headed notepaper)

Speech and Language Therapy Clinic
Teaching Hospital

.....

Date.....

Dear Parents,

Please find enclosed some information about a research study that you and your child might be interested in taking part in. If you have any questions about this study, please contact Inoka on

Thank you very much for your kind co-operation.

Yours,

Faithfully,

.....

Speech and language therapist



How does quality of life in young people with cleft lip and palate compare to other young people.

Participant information sheet – Parents of adolescents with repaired Cleft Lip and Palate

Introduction

My name is Mrs. Mirihagalla Kankanamalage Inoka Udayangani Sirimanna. I used to be a speech and language therapist at Colombo North Teaching Hospital- Ragama and I am now a doctoral student at the University of Strathclyde , Glasgow, United Kingdom.

I am contacting you because your child's speech and language therapist at the Speech and Language Therapy clinic, Teaching Hospital-..... (location) thinks you and your child might be able to help with my study on how your child's health, including cleft lip and/or palate, affects his/her wellbeing.

Please read this information carefully before deciding whether or not you would like your child to participate in the study.

Your help is greatly appreciated!

What is the purpose of the research?

This study aims to translate a Health-Related Quality of Life Questionnaire from English to Sinhalese and to use this new version to find out about quality of life in young people with repaired Cleft Lip and Palate.

For this study, I am asking Sri Lankan children aged 12-15 years, with a repaired Cleft Lip and Palate to take part. I am also asking Sri Lankan children of the same age range without Cleft Lip and Palate to take part so I can see if there is a difference in quality of life in young people with repaired Cleft Lip and Palate.

Does my child have to take part?

No. Participation is voluntary and it is completely up to you and your child if you want to take part. However, it will be really helpful if you and your child can participate in this study by completing the questionnaires. Declining to take part will have no impact on any aspect of your child's speech and language therapy or further hospital treatments. Further, even if you initially decide to take part in this study, you or your

child completely have the right to withdraw from the study at any time without affecting your child's current care.

What will happen if my child takes part in the study?

As parents you will be asked to complete the enclosed questionnaire and consent form. Your child will be asked to complete the enclosed consent sheet and fill two questionnaires attached to it. Please understand we greatly value the child's own views and responses so would ask that you do not help them with answering the questions. Please post back all completed forms with the name code sheet in the provided stamped, addressed envelope to your child's Speech and Language Therapy clinic.

Why has your child been invited to take part?

It is understood that your child may not have severe or any speech understanding problems, or quality of life concerns. Part of this study is to check the suitability of these questionnaires in Sri Lanka, therefore I am gathering responses from young people with repaired Cleft Lip and Palate along with young people who do not have Cleft Lip and Palate. Responses will help me to find out the quality of life of children with Cleft Lip and Palate is the same in typically developing children.

What is the potential risk to my child in taking part?

The risks of filling the questionnaires are very minimal. There is a chance that your child may find some of the questions in the questionnaire a little upsetting. Your child has received an information sheet including the study explained to them and details about what they are expected to do before they start to fill in the questionnaire. They have also advised that if they do not want to complete the questionnaire, they can stop at any time. They can contact me if they have any questions about the study or the questionnaires on the number noted below.

What information is being collected in the project?

Your child has been allocated a number, this has been sent in a separate sheet and written on the top of the questionnaires. This means that the questionnaire responses are anonymous but will allow us to follow up any concerns that might be raised in the questionnaires with your child's speech and language therapist.

Who will have access to the information?

You and your child's confidentiality will be maintained at all times. Only the researcher (Me) and my two supervisors at the University of Strathclyde will be able to see the completed questionnaires. If your child comes up with any quality of life concerns as identified by the answers, I will share it with your child's speech and language therapist.

Where will the information be stored and how long it will be kept for?

The completed questionnaires will be transported back to the UK very securely with me for analysis. The questionnaires will be stored in a secure, locked cupboard in the University of Strathclyde for ten years.

What will happen to the results of the research study?

The findings will be analysed and discussed in my doctoral thesis. Findings also will be prepared for presentations at conferences and a written report that might be published. No names or identifying information will be used in any of these. Translated copies of the questionnaires will be available in Sri Lanka in the future.

What if there is a problem?

If you have any concerns or need to ask any questions about this project before deciding to take part, please contact me using the below number as I am in Sri Lanka now. You can also your speech and language therapist if you need any other information.

If you have any problems or questions about the project, you can raise these with my supervisor:

Dr. Wendy Cohen

Speech and Language Therapy department

Graham Hills Building

50, George Street

Glasgow

G1 1QE

UK

E-mail-

Tel

If you would rather talk to someone who is not involved in the project please contact:

Dr. Dianne Dixon

Chair of the School Ethics Committee

School of the Psychological Science and Health

Graham Hills Building

50, George Street

Glasgow.

G1 1QE

My contact Details

Address (UK) – Speech and Language Therapy Department

Graham Hills Building

University of Strathclyde

50, George Street

Glasgow

G1 1QE

UK

This research has been reviewed and approved by the University of Strathclyde School of Psychological and Social Sciences Ethics committee, the provincial director of the Sri Lanka Department of Education and the Medical Council of Sri Lanka.



How does quality of life in young people with cleft lip and palate compare to other young people.

Participant information sheet –Young people with repaired Cleft Lip and Palate

Introduction

My name is Mrs. Mirihagalla Kankanamalage Inoka Udayangani Sirimanna. I used to be a speech and language therapist at Colombo North Teaching Hospital- Ragama and I am now a doctoral student at the University of Strathclyde, Glasgow, United Kingdom. I am contacting you because your speech and language therapist at the Speech and Language Therapy clinic, Teaching Hospital-..... (location) thinks you might be able to help with my study on how your health, including your cleft lip and/or palate, affects your wellbeing.

Please read this carefully before deciding whether or not you would like to take part in the study. Your parents will also be informed, and their permission is needed along with yours.

Your help is greatly appreciated!

Introduction

What is the purpose of the research?

This study aims to translate a Health-Related Quality of Life Questionnaire from English to Sinhalese and to use this new version to find out about quality of life in young people with repaired Cleft Lip and Palate.

For this study, I am asking Sri Lankan children aged 12-15 years, with a repaired Cleft Lip and Palate to take part. I am also asking young people without Cleft Lip and Palate so I can see if there is any difference in quality of life between people with and without Cleft Lip and Palate.

Do you have to take part?

No, you can decide if you want to take part or not. If you decide not to take part, it will not affect your speech and language therapy or any future hospital treatments. Also, even if you initially decide to take part and then change your mind, you can leave the study at any time without affecting any of your current care.

What will you have to do?

If your parents give their permission for you to participate in the study and you are also willing to participate, please sign the enclosed consent form, write your name code and complete the two questionnaires attached. You can then put these and small sheet containing your name code in the stamped envelope with the papers from your parents to post back to the Speech and Language Therapy clinic. It is very valuable to gather your own answers to the questionnaire, so please try to complete them by yourself without any help. You can use the pen you've been sent with this information pack to fill in the questionnaires and you can keep this as a thank you.

Why have you been invited to take part?

Part of this study is to check if the questionnaires work in the Sinhalese language, so it is important that we check them with children who have a history of Cleft Lip and Palate and have had surgeries for this. You might have not any speech problems, or quality of life concerns. This does not matter as all the information is valuable and will help us compare the wellbeing of children with and without Cleft Lip and Palate.

What is the potential risk to you in taking part?

Although it is unlikely, there is a small chance that you may find some of the questions in the questionnaires a little upsetting. If you feel that you cannot complete the questionnaires, you can stop at any time and speak to an adult you trust, such as your parent or a teacher. You can contact me if you have any questions about the study or the questionnaires on the number noted below.

What information is being collected in the project?

You have been allocated a unique number and this has been sent to you and written on the top of the questionnaires. This means that questionnaires responses are anonymous, but will allow me to follow up any concerns that might be raised in the questionnaires with your speech and language therapist.

Who will have access to the information?

Your confidentiality will be maintained at all times. Only the researcher (Me) and my two supervisors at the University of Strathclyde will be able to see the completed questionnaires. If you come up with any quality of life concerns as identified by the answers, I will share it with your speech and language therapist.

Where will the information be stored and how long it will be kept for?

The completed questionnaires will be transported back to the UK very securely with me for the analysis. The questionnaires will be stored in a secure, locked cupboard in the University of Strathclyde for ten years.

What will happen to the results of the research study?

The findings will be analysed and discussed in my doctoral thesis. Findings also will be prepared for presentations at conferences and a written report that might be published. Your name will not be used in any of these. Translated copies of the questionnaires will be available in Sri Lanka in the future.

What if there is a problem?

If you have any concerns or need to ask any questions about this project before deciding to take part, please contact me using the below number as I am in Sri Lanka now. You can also contact your speech and language therapist if you need any other information.

If you have any problems or questions about the project you can raise these with my supervisor:

Dr. Wendy Cohen

Speech and Language Therapy department

Graham Hills Building

50, George Street

Glasgow

G1 1QE

UK

E-mail-

Tel –

If you would rather talk to someone who is not involved in the project please contact:

Dr. Dianne Dixon

Chair of the School Ethics Committee

School of the Psychological Science and Health

Graham Hills Building

50, George Street

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G1 1QE

E-mail-

My contact Details

Telephone (Sri Lanka)

E-mail-

Address (UK) – Speech and Language Therapy Department

Graham Hills Building

University of Strathclyde

50, George Street

Glasgow

G1 1QE

UK

This research has been reviewed and approved by the University of Strathclyde School of Psychological and Social Sciences ethics committee, the Provincial Director of the Sri Lanka Department of Education and the Medical Council of Sri Lanka.



Consent Form for parents – Children with Repaired Cleft Lip and Palate

Name of the department: School of Psychological Sciences and Health- Speech and Language Therapy

Title of the study: How does quality of life in young people with cleft lip and palate compare to other young people.

Child's name code-

- I confirm that I have read and understood the participant information sheet for the above project and the researcher has answered any queries to my satisfaction.
- I understand me and my child's participation is voluntary and that I and my child are free to withdraw from the project at any time, up to the point of completion, without having to give a reason and without any consequences.
- I understand that partially anonymised data cannot be withdrawn once they have been included in the study.
- I understand that any information recorded during the investigation will remain confidential and no information that identifies me or my child will be made publicly available.
- I consent to being a participant in the project.
- I give my consent for my child to participate in the project.

Print name of the parent

.....
.....

Signature of the parent

Date

.....
.....



Assent Form – Children with repaired Cleft Lip and Palate

Name of the department: School of Psychological Sciences and Health- Speech and Language Therapy

Title of the study: How does quality of life in young people with cleft lip and palate compare to other young people.

Name code-.....

- I confirm that I have read and understood the participant information sheet for the above project and the researcher has answered any queries to my satisfaction.
- I understand that my participation is voluntary and that I am free to withdraw from the project at any time, up to the point of completion, without having to give a reason and without any consequences.
- I understand that partially anonymised data cannot be withdrawn once they have been included in the study.
- I understand that any information recorded during the investigation will remain confidential and no information that identifies me will be made publicly available.
- I consent to being a participant in the project.

Print name of the child

.....

.....

Signature of the child

Date

Appendix 26 : Key code document for anonymisation – TD

Parents- Typically developing children.

Dear Parents,

Please find the key code that I allocated to your child's name. You or your child's name must not be written on any of these documents. Please write this key code on the questionnaires, consent and assent sheet.

Your child's key code.....

Please keep hold of this in case you need contact me after completing and send me the questionnaire if you and your child wish to withdraw from the study.

Please answer the following questions and send this document back to me.

1. Does your child have any longstanding medical conditions? Yes/No

If Yes, please

state.....
.....

2. Do you think that your child needs any help with reading and writing?

Yes/No

If Yes, Please
explain.....
.....

Yours sincerely

Inoka

My contact Details Telephone (Sri Lanka)

Appendix 27 : Key code document for anonymisation – CLP

Parents- Young children with repaired Cleft Lip and Palate

Dear Parents,

Please find the key code that I allocated to your child's name. You or your child's name must not be written on any of these documents. Please write this key code on the questionnaires, consent and assent sheet.

Your child's key code.....

Please keep hold of this in case you need contact me after completing and send me the questionnaire if you and your child wish to withdraw from the study.

Please answer the following questions and send this document back to me.

1. Does your child have any longstanding medical conditions? Yes/No

If Yes, please

state.....
.....

2. Do you think that your child needs any help with reading and writing? Yes/No

If Yes, Please

explain.....

Yours sincerely

Inoka

My contact Details Telephone (Sri Lanka)

Appendix 28 : IPA Sinhala

		Labial	Dental	Alveolar	Retroflex	Palatal	Velar	Glottal
Stops	Voiceless	p	t		ʈ		k	
	Voiced	b	d		ɖ		g	
Affricates	Voiceless					c		
	Voiced					ɟ		
Prenasalized Voiced stops		ḃ	ḍ		ɖ̣		ḡ	
Nasals		m		n		ɲ	ŋ	
Trill				r				
Lateral				l				
Fricatives		f	s			ʃ		h
Semi-vowels		v				j		

Ethics Application Form



Please answer all questions

1. Title of the investigation

Cross cultural adaptation and validation of a health related quality of life assessment (COHIP- Children's Oral Health Index Profile) for adolescents with Cleft Lip and Palate in Sri Lanka.

Please state the title on the PIS and Consent Form, if different:
How does quality of life in young people with cleft lip and palate compare to other young people.

2. Chief Investigator (must be at least a Grade 7 member of staff or equivalent)

Name: Dr. Wendy Cohen

☐ Professor

☐ Reader

☒ Senior Lecturer

☐ Lecturer

☐ Senior Teaching Fellow

☐ Teaching Fellow

Department: Speech and language Therapy

Telephone:

E-mail:

3. Other Strathclyde investigator(s)

Name: Dr. Joanne Cleland

Status : Senior Lecturer

Department: Speech and Language Therapy

Telephone:

E-mail:

Name: Mrs. Mirihagalla Kankanamalage Inoka

Status : PhD student Researcher

Department: Speech and Language Therapy
Telephone:
E-mail:

4. Non-Strathclyde collaborating investigator(s) (where applicable)

Name:
Status (e.g. lecturer, post-/undergraduate):
Department/Institution:
If student(s), name of supervisor:
Telephone:
E-mail:
Please provide details for all investigators involved in the study:

5. Overseas Supervisor(s) (where applicable)

Name(s):
Status:
Department/Institution:
Telephone:
Email:
I can confirm that the local supervisor has obtained a copy of the Code of Practice: Yes
☐ No ☐
Please provide details for all supervisors involved in the study:

6. Location of the investigation

At what place(s) will the investigation be conducted

University of Strathclyde- UK

Data Collection – Typically developing adolescents will be recruited from three mainstream mixed schools in Gampaha and Colombo District, Sri Lanka. Adolescents with repaired Cleft Lip and Palate will be identified and recruited from Speech and Language Therapy clinic records in three teaching hospitals in Sri Lanka;

- Lady Ridgeway Children's Hospital, Colombo
- Teaching Hospital, Karapitiya
- Teaching Hospital, Kandy

If this is not on University of Strathclyde premises, how have you satisfied yourself that adequate Health and Safety arrangements are in place to prevent injury or harm?

Researcher- Sri Lanka is my home country and I am therefore familiar with travelling and safety and I will also be travelling with a travel insurance.

Typically developing adolescents - I will be seeking permission to recruit participants from relevant authorities and consent will be taken from parents and children prior to the study to approach participants in their school settings. All data consists of questionnaires which will be completed by the typically developing adolescents in school settings where the local health and safety arrangements are in place.

Adolescents with repaired cleft lip and palate - All data is questionnaires which will be completed by the adolescents with cleft lip and palate at home and posted back to the researcher.

7. Duration of the investigation

Duration(years/months) : 18 months

Start date (expected): 01 / 06 / 2018
/ 12 / 2020

Completion date (expected): 31

8. Sponsor

Please note that this is not the funder; refer to Section C and Annexes 1 and 3 of the Code of Practice for a definition and the key responsibilities of the sponsor.

Will the sponsor be the University of Strathclyde: Yes ☒ No ☐

If not, please specify who is the sponsor:

9. Funding body or proposed funding body (if applicable)

Name of funding body:

Status of proposal – if seeking funding (please click appropriate box):

☐ In preparation☐ Submitted☐ AcceptedDate of submission of proposal: / /
/ /

Date of start of funding:

10. Ethical issues

Describe the main ethical issues and how you propose to address them:

While there are minimal ethical concerns with completing a questionnaire study of this nature, it is possible that some of the typically developing children may give responses in the quality of life questionnaire that indicate where they might benefit from further general support. For this reason, the questionnaire responses will be pseudo anonymised, so that follow on support can be arranged via their school. This process is explained fully in the participant information leaflet.

Furthermore, some of the typically developing children might feel that aspects of the Oral Health Related Quality of Life Questionnaire are not relevant to them, but they will be reassured during completion of the questionnaire that while some questions might seem personally unrelated to them, all questions should be answered, so that the questionnaires can be validated into the Sinhalese Language and compared to the children with repaired Cleft Lip and Palate.

Adolescents with repaired Cleft Lip and Palate might find it difficult to answer openly as they will be filling in the questionnaire at home and parents may be able to access their child's answers. The investigator will advise parents in the information sheet that young people should complete the questionnaires independently to get the child's own views on their quality of life.

11. Objectives of investigation (including the academic rationale and justification for the investigation) Please use plain English

Cleft lip and/or Palate (CL/P) is the fourth most common birth defect (Munz et al., 2011) and the most common congenital abnormality in the world (Augsornwan & Prngapagatip, 2011). The prevalence of cleft lip and/or palate is approximately one in every 700 newborn babies globally, however, the incidence varies from 1 in 1000 to 2.69 in 1000 births depending on location and ethnicity (Goodacre & Swan,

2011). For example, in the UK the prevalence of CL/ P is 1 per 1000 births, 0.3 per 1000 in African and American population, 2.1 per 1000 in Japanese (Goodacre, 2011) and 0.83 per 1000 in Sri Lankan populations.

CL/P can occur mainly in three variations, as isolated cleft lip (CL), isolated cleft palate (CP) and cleft lip and palate (CLP). It can be unilateral or bilateral with unilateral clefts nine times more prevalent than bilateral clefts (Goodcare, 2011).

This condition affects on individual's speech and language development, hearing, facial appearance (affected by facial disfigurement) and dentition, and which can lead to long lasting complications throughout life. Cleft in the secondary palate can lead to hypernasality and speech intelligibility disorders, ear infections, hearing loss and nasal regurgitation. Furthermore, cleft in the primary palate, including lip and alveolus, is associated with facial disfigurements, dental anomalies and learning disabilities (Broder, 2012). Apart from these common visible effects, there can be an impact on many psychological and social health dimensions such as anxiety, depression, inhibition, low self-esteem, reduced cognitive function and low achievement in school children (Bos & Prahl, 2011). These impacts can continue throughout life and result in social inhibition, low social competence and overall low quality of life.

According to the World Health Organisation (1997), quality of life (QOL) is an individual's perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns. It is a broad ranging concept affected in a complex way by the person's physical health, psychological state, level of independence, social relationships, personal beliefs and their relationship to salient features of their environment. Health related quality of life is evaluated, by adding personal judgements of a person's health and disease to quality of life and a multidimensional assessment of a person's satisfaction with life, and includes domains related to physical, mental, emotional, and social functioning (<https://www.who.int/healthinfo/survey/whogol-qualityoflife/en/>).

Although not life threatening, cleft lip and/or palate is a chronic condition that affects QOL, because numerous intervention procedures are often necessary to reconstruct, rehabilitate and improve outcomes. Early surgical intervention, speech and language therapy, dental treatments and other supportive treatments such as counselling, support from Ear, Nose and Throat specialists and dieticians can minimise the impacts of cleft conditions' effects on an individual's life, thus QOL may not be adversely effected in every individual depending on the severity and other conditions associated with the cleft. Even though a possible best outcome is achieved with early surgical treatment and speech and language therapy, it is still questionable whether an optimal health related quality of life in children can be achieved when social competence and aesthetic physical appearance are included. To date, there is no definitive answer to this question and previous studies conducted to evaluate the quality of life in cleft lip and palate in children and adolescents have given varying results, with some studies reporting lower, other similar and again others higher, health related quality of life when compared to non-cleft controls.

Correa de Queiroz Herkrath et al. (2015:157), highlighted that *"In the recent literature, it is apparent that quality of life measures have been used as indicators to evaluate the effectiveness, efficiency and impact of distinct treatments for*

different diseases or health disorders”. Numerous different generic and specific health related and oral health related quality of life outcome measures have been used in published studies so far, nonetheless there remains no condition specific health related quality of life assessment available for measuring the domains of health related QOL in adolescents with CL/P as pointed out by Klassen et al. (2013) and Eckstein et al. (2011).

Specific Oral health questionnaires such as COHIP (Child Oral Health Impact Profile), COHQoL (Child Oral Health Quality of life) have been used in many studies and the COHIP appears to be the most frequently used questionnaire in the CL/P adolescent population (Broder et al., 2017). The COHIP scale shows good reliability and is identified as a sensitive outcome measure (Aravena, 2017, Bos & Prahl, 2011, Broder et al., 2017). Further, the COHIP scale is recognised as an appropriate measure of oral health related QOL (OHRQOL) for younger and older children with CLP and it's one of the two OHRQOL measures that has been sufficiently validated according to guidelines (Antonarakis, 2013 & Broder, 2017). Equally it is important to identify the determinants of QOL outcome of CLP patients, along with a condition specific QOL measuring instrument. The most explored demographic determinants are age, gender and cleft type. Speech understandability is also identified as a determinant associated with QOL. The findings of this are widely different depending on geographic and sample differences. It has been argued the cleft type has a significant impact on the QOL outcome depending on the severity, with larger samples required to explore this further (Bos & Prahl, 2011). In addition to the demographic determinants, socioeconomic factors are also considerably associated with the QOL outcome. Spencer et al. (2006) and Houben-Van Herten et al. (2015) studied the relationship of these factors in typical adolescents and reported a number of demographic, socioeconomic and family environmental determinants contribute to the child's health related QOL. Dak-Alab et al. (2013), Broder et al. (2017), Wehby et al. (2010), found that the socioeconomic status can negatively affect QOL of CL/P patients, with those from lower socioeconomic backgrounds more prone to develop emotional and social problems. Further, it has been argued that speech understandability has also directly affected the quality of life in this client group. Therefore, it is vitally important to identify which factors are mostly associated with QOL outcomes in this adolescent population in Sri Lanka.

In Sri Lanka, only two generic health related quality of life assessments (PedsQL & KINDL^R) are validated in Sinhalese at present. This study will use the PedsQL Sinhalese assessment to gather generic QOL from the typical and CL/P adolescent populations. This will be the first study to attempt to validate a Health Related assessment specifically for Cleft Lip and Palate adolescents, the COHIP, in Sri Lanka. Moreover, this will be the first study to address the literature gap of finding QOL in Cleft Lip and Palate adolescent population as a comparative study and contributing factors for the variation of quality of life outcomes. Additionally, this study will produce a translated and validated speech intelligibility measure for Sri Lanka.

The proposed study objectives are as follows :

- Translate and culturally adapt COHIP (Child Oral Health Impact Profile) oral health related quality of life assessment into Sinhalese.

- Determine the validity and reliability of the Sinhalese version of COHIP for a typical adolescent population (12-15 years old) and for adolescents with repaired cleft lip and palate (12-15 years old).
- Translate and validate the “Intelligibility in Context Scale” (McLeod, Harrison & McCormack, 2012) speech intelligibility rating scale to Sinhalese.
- Compare the health-related quality of life findings using PedsQoL of typical adolescent population with repaired cleft lip and palate adolescent population.
- Determine whether the quality of life findings varies according to speech intelligibility, gender and type of cleft in Cleft Lip and Palate adolescent group.

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12. Participants

Please detail the nature of the participants:

- Typically developing adolescents
- Adolescents with repaired Cleft Lip and Palate (CL/P)

Summarise the number and age (range) of each group of participants:

<u>Number</u>	<u>Age (range)</u>
400 typically developing adolescents	12-15 years old
30 adolescents with repaired Cleft Lip and Palate	12-15 years old.

Please detail any inclusion/exclusion criteria and any further screening procedures to be used:

Inclusion criteria- typically developing adolescents

- Healthy adolescents without any reported chronic medical conditions or known syndromes
- Aged between 12-15 years
- Studying in a mainstream school
- Speakers/readers of Sinhalese

Exclusion criteria – typically developing adolescents

- Children with long term medical conditions or disability
- Identified or diagnosed as having co-ordination, reading or writing difficulties (Dyslexia/ Dyspraxia) or any syndromic conditions.

Inclusion criteria- CL/P

- Aged between 12-15 years
- Adolescents who underwent surgical interventions at within the standard time periods to repair cleft lip and/or palate
- Adolescents who have adequate language skills to understand and answer the questionnaire
- Speakers/readers of Sinhalese

Exclusion criteria- CL/P

- Adolescents who have genetic syndromes associated with cleft lip and palate
- Adolescents who underwent surgical interventions outside of the recommended time periods , eg- Primary surgery completed at a later age

- Adolescents who are also diagnosed with Dyslexia or Dyspraxia along with CLP

13. Nature of the participants

Please note that investigations governed by the Code of Practice that involve any of the types of participants listed in B1(b) must be submitted to the University Ethics Committee (UEC) rather than DEC/SEC for approval.

Do any of the participants fall into a category listed in Section B1(b) (participant considerations) applicable in this investigation?: Yes ☐ No ☒
If yes, please detail which category (and submit this application to the UEC):

14. Method of recruitment

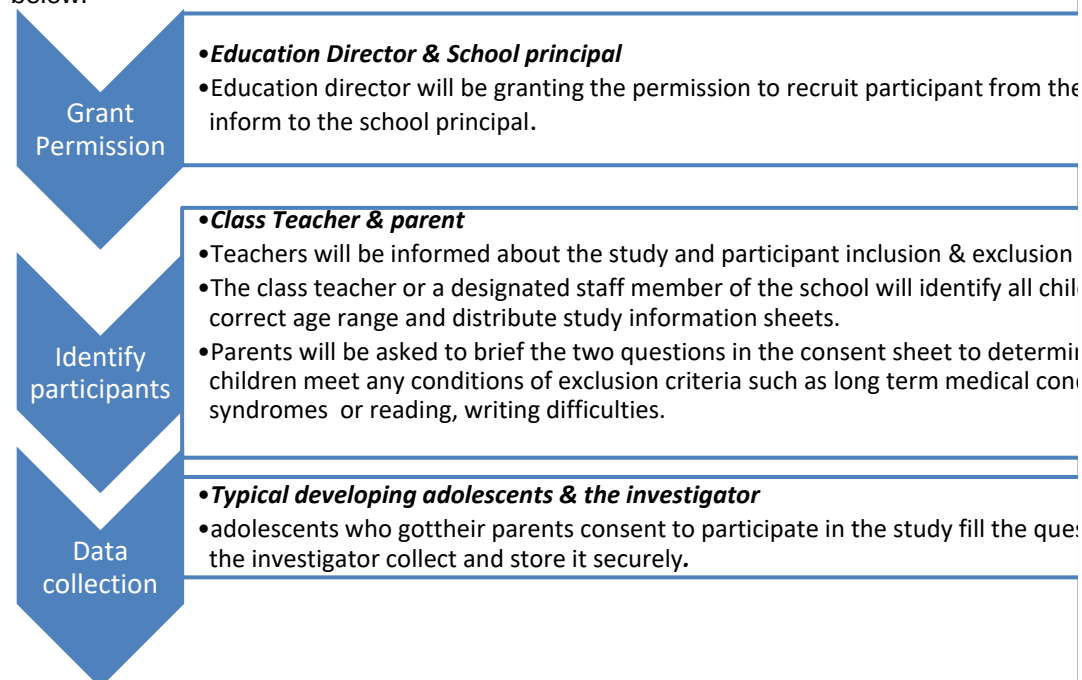
Describe the method of recruitment (see section B4 of the Code of Practice), providing information on any payments, expenses or other incentives.

Methods of recruitment

Typically developing adolescents.

Typically developing adolescents aged between 12-15 years will be recruited from three mainstream mixed schools in Sri Lanka. From each school about 150 participants, studying in three grades will be invited to participate in the study. The three schools participating in this study will be recruited according convenience sampling in order to recruit 150 students from each school. The sample will be recruited from a combination of urban and non-urban schools. Children who participate in the study will be given a piece of stationary as an incentive.

Stages of obtaining permission and identify typically developing adolescents are detailed below.

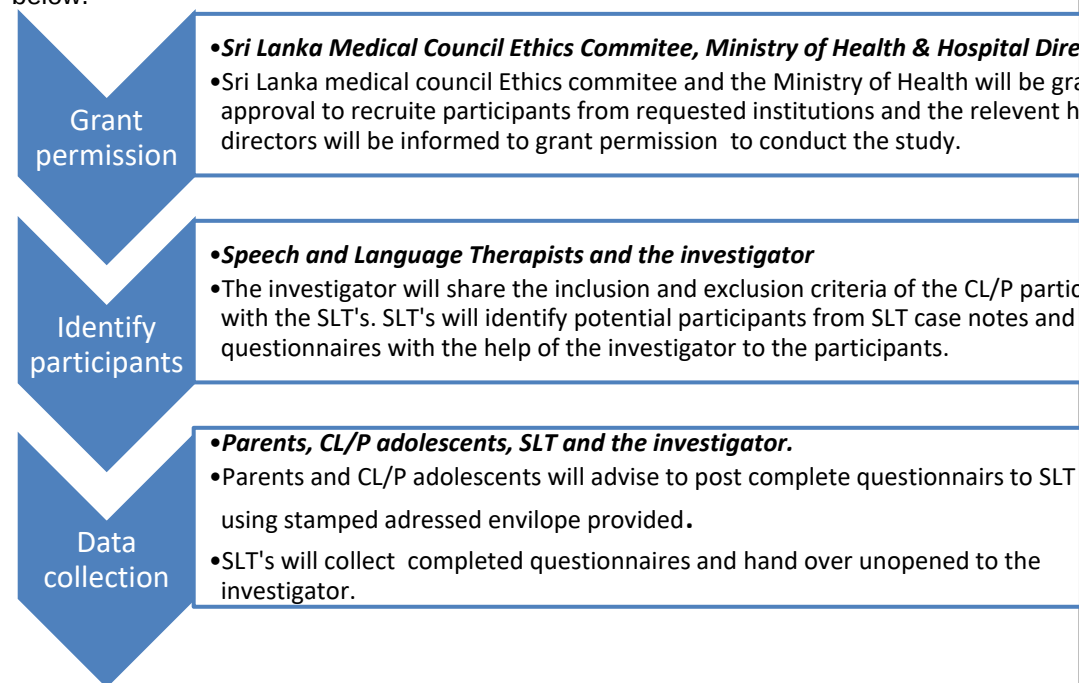


Adolescents with Cleft lip and palate

Adolescents with CL/P aged between 12-15 years will be recruited for the study from three teaching hospitals in Sri Lanka. Adolescents attending speech and language therapy clinics will be invited to participate in the study, using the available lists of young people

who continue to attend the service. Local speech and language therapists will identify thirty participants from three hospitals. The three main hospitals provide services to the biggest cleft lip and palate surgical units and multidisciplinary teams in Sri Lanka, the sample size is therefore realistic.

Stages of obtaining permission and identify cleft lip and palate adolescents are detailed below.



15. Participant consent

Please state the groups from whom consent/assent will be sought (please refer to the Guidance Document). The PIS and Consent Form(s) to be used should be attached to this application form.

Typical adolescents-The study proposal will be submitted to the Ministry of Education Sri Lanka and permission will be obtained to conduct this study in the school settings. The procedure for this requires that provincial educational directors are notified. They will then contact the school principals and grant permission, dependant on the principals' willingness to conduct the study in school and allocation of school time to fill the questionnaire. The researcher will explain the details of the study to the principal of each school and request their cooperation. If school permission is granted, details of the study and consent forms will be distributed to the parents via children and the children who return the consent forms from their parents will be enrolled into the study. Children are free to leave the study at any time by not completing the questionnaire. Children will be advised If they want to leave within the completing questionnaire stage, to raise their hand and let the researcher know, so the researcher will discard the questionnaires and remove the code from the list. If a child wants to leave from the study once they complete questionnaires and researcher collected data, they will be advised to e-mail the researcher about their decision with their name or code, so the researcher will check their name with the code and remove questionnaires from data.

CL/P adolescents-The Researcher will submit the project proposal and all the necessary documents, including information sheets, consent forms, ethics application and the university ethics approval to the Sri Lanka Medical Council (SLMC) research ethics committee and request approval to conduct the study in Sri Lanka. On successful approval from the SLMC ethics committee, the researcher will submit the SLMC ethics approval

letter to the Ministry of Health Sri Lanka and request permission to access the hospital clinics and recruit participants. The Ministry of Health will inform the hospital directors and the hospital director will inform the Speech and Language Therapy clinic to assist with the study. The Sinhala versions of COHIP, PedsQL and Intelligibility in Context Scale will be posted with the study information, name code and consent sheets for parents and assent forms for adolescents. If a child wants to leave from the study once they complete questionnaires and sent back to the clinics, they will be advised to e-mail the researcher about their decision with their code, so the researcher will check their code and remove questionnaires from data.

All participant information sheets, consent and assent forms will be provided in Sinhalese. Samples are provided for this application in English language. These will be translated for use at the recruitment stage. Part of the Sri Lanka permissions procedure requires checking of these documents by the Sri Lanka Medical Council and the Ministry of Education in Sri Lanka.

16. Methodology

Investigations governed by the Code of Practice which involve any of the types of projects listed in B1(a) must be submitted to the University Ethics Committee rather than DEC/SEC for approval.

Are any of the categories mentioned in the Code of Practice Section B1(a) (project considerations) applicable in this investigation? ☐ Yes ☒ No

If 'yes' please detail:

Describe the research methodology and procedure, providing a timeline of activities where possible. Please use plain English.

Assessment translation and validation

The original authors of the COHIP (Broader, 2007) and Intelligibility in Context Scales (MacLeod et al., 2012) will be informed about the nature of the study and the status of the investigator so that a collaboration agreement can be set up to translate and validate the assessments. Thereafter, the procedure follows the stages outlined below;

Stage one : Translation and cultural adaptation of the COHIP and the Intelligibility in Context Scales.

This process will follow the international cross-cultural translation guidelines recommended by Guillemin et al., (1993), using a Forward-Backward- Forward technique.

- The published English language assessment will be translated into Sinhalese by two independent translators (01 & 02), both qualified speech and language therapists (one will be the investigator) whose mother tongue is Sinhalese.
- Reconciliation step: the two translators will review two forward translations (01&02) and create a respective reconciled forward final translation, meeting all demands of conceptual equivalence with the original English language draft.

- The reconciled forward translation, will be translated back into English by a bilingual English-Sinhalese speech and language therapist (translator 03) whose native language is English.
- Finally, all translators (01,02, 03) review the forward and respective backward translations and generate a final forward Sinhalese translation of the QOL assessment

Stage two : Pilot testing

- There will be a pre-testing pilot study with the translated Sinhalese assessments with 5 typical adolescents and 5 repaired Cleft Lip and Palate adolescents, after which further necessary language and cultural adaptations will be made.
- The probe technique will check face validity and confirm the questions are acceptable and understandable.

The PedsQL, quality of life assessment is already translated and validated into Sinhalese.

Stage three: Typical adolescent population data gathering

- School principals will send information sheets, name code and consent forms to all eligible participants.
- Parents will be invited to read the information sheets with their child and then complete consent form and the “Intelligibility in Context Scale” and return back to school.
- At an agreed time with the school principal and class teachers, the translated COHIP and PedsQL questionnaires will be distributed to those children who have agreed to participate in the study and they will be asked to fill in during a designated class. This should take approximately 15-20 minutes.
- Children will be asked to fill the questionnaire on their own without discussing answers with others in order to minimise the bias of the responses.

Stage four : CL/P adolescent population data gathering

- Speech and language therapists (SLTs) from the three hospitals will be asked to identify participants.
- The SLTs will post on to all potential participants the participant information sheet, name code sheet, consent and assent forms along with the Sinhalese version of COHIP, PedsQL and Intelligibility in Context Scale for the parents to rate their child’s speech.
- The investigator’s contact details will be posted with the questionnaires and parents will be advised to contact if they need any clarification or further details.

- Questionnaires will be posted to the parents with a returned stamped envelope and instructions to post back to the Speech and Language therapy clinics from where the investigator will collect completed questionnaires from SLT's.

Activity	Feb 201 9	Mar 201 9	Apr 1 June 201 9	July 201 9	Aug 201 9	Sept 201 9	Oct 201 9	Nov - Dec 201 9	Jan- Dec 202 0
School Ethics Committee approval	*								
University Ethics Committee approval if necessary		*							
Finalise Questionnaire Translations	*	*							
Medical Council Sri Lanka Ethics Committee approval			*						
Education Ministry /School permissions Sri Lanka			*						
Preparation of necessary documents to conduct the study Eg- Questionnaires, advice/information sheets, consent and assent forms		*	*						
Investigator travel to Sri Lanka			*						
Piloting the translated questionnaires and do the minor cultural adjustments			*						

Identify the Cleft Lip and Palate participant group from Hospital SLT clinics and post the questionnaires			*	*					
Data collection in schools and CLP adolescents				*	*				
Data uploaded to Strath Cloud and prepare to transport to UK					*				
Data analysis					*	*	*	*	
Write a data analysis draft chapter and submit for supervisor reviews							*	*	
Writing - Thesis									*
Preparation for conference presentation									*
Preparation for publications									*

What specific techniques will be employed and what exactly is asked of the participants? Please identify any non-validated scale or measure and include any scale and measures charts as an Appendix to this application. Please include questionnaires, interview schedules or any other non-standardised method of data collection as appendices to this application.

Copies of all questionnaires that will be used in the study are appended to this application. These include

COHIP (Long Version) (Broader, 2007)

Intelligibility in Context Scale (MacLeod et al., 2012)

PedsQL (James W. Varni, 1998-2019)

Where an independent reviewer is not used, then the UEC, DEC or SEC reserves the right to scrutinise the methodology. Has this methodology been subject to independent scrutiny? Yes ☐ No ☒

If yes, please provide the name and contact details of the independent reviewer:

17. Previous experience of the investigator(s) with the procedures involved.
Experience should demonstrate an ability to carry out the proposed research in accordance with the written methodology.

Mirihagalla Kankanamalage Inoka Udayangani Sirimanna is an experienced speech and language therapist who has worked at a Sri Lankan leading hospital for nearly ten years. She has experience with working with CL/P children/adolescents, parents, other professionals and also administering assessments and recording data. Further Inoka conducted her research study for her BSc under the supervision of a consultant paediatrician about family impacts of having a child with feeding difficulties. She also conducted another research study for her master's degree investigating the speech understandability and speech acceptability longitudinally in repaired cleft lip and palate children using previously recorded data. Inoka has the experience of conducting research studies with vulnerable groups, good understanding about ethical aspects of a study and good knowledge about research methodology and analysing and interpreting data. Inoka's supervisors are Dr. Wendy Cohen and Dr. Joanne Cleland, both are senior academics in the Speech and Language Therapy Department with a range of experience in both qualitative and quantitative research analysis including past and current research into cleft lip and palate.

18. Data collection, storage and security

How and where are data handled? Please specify whether it will be fully anonymous (i.e. the identity unknown even to the researchers) or pseudo-anonymised (i.e. the raw data is anonymised and given a code name, with the key for code names being stored in a separate location from the raw data) - if neither please justify.

The Investigator will travel to Sri Lanka for data collection purpose. After the typical adolescents and cleft lip and palate adolescents complete the questionnaire, the investigator will collect all the originals and make sure that there are no copies left in the clinics or schools.

Data will be pseudo-anonymised by the investigator in order to identify any child with QOL issues and refer to necessary services via their school principal. A key code will be allocated for every CL/P adolescents identified from the register and researcher will keep a record of names and key codes. Key codes for the names will be separately stored in a different location. A small sheet with the child's name and a key code will be posted with the questionnaires to let them know their key code and asked to send it back when they return completed questionnaires. The Researcher will destroy this sheet of paper containing the key code once all information is received and recorded. A key code will be allocated for every school child's name and a sheet of paper containing code details will be sent out with the information and consent sheets to the parents. Children will be instructed to return the name code details sheet with their parents' consent sheets and children who returned the consent from their parents and who signed the assent forms will be asked to write key code on the questionnaire when they complete it. The researcher will destroy small sheets at the end of data collection from schools and Key codes for the names will be separately stored in a different location.

Explain how and where it will be stored, who has access to it, how long it will be stored and whether it will be securely destroyed after use:

Raw data (paper files) will be stored separately and the investigator will scan all the originals and upload to Strath-cloud before return to the UK. Original paper copies will be safely transported to the UK in a locked hand luggage carried with the investigator. Original questionnaires will then be stored in a university department locked filing cabinet. Data will be entered into SPSS files and saved into the investigator's university home drive. Paper and electronic data will be stored in the university pure system and with the principal investigator for ten years. Data will be destroyed after ten years by shredding and securely deleting electronic files.

Will anyone other than the named investigators have access to the data? Yes ☐ No ☒
 If 'yes' please explain:

19. Potential risks or hazards

Briefly describe the potential Occupational Health and Safety (OHS) hazards and risks associated with the investigation:
 Participation in this study presents minimal risk to participants and researchers. There will be a slight risk as data is not fully anonymised but this will only be used in the rare event that a typical adolescent highlights quality of life issues which may not have been identified within the schools. This is in order to safeguard these children so they can be directed to the necessary services via their school.

There may be mild psychological distress associated with completing the questionnaire at home for the CL/P adolescents.

No other risks or hazards have been identified.

Please attach a completed OHS Risk Assessment (S20) for the research. Further Guidance on Risk Assessment and Form can be obtained on [Occupational Health, Safety and Wellbeing's webpages](#)

20. What method will you use to communicate the outcomes and any additional relevant details of the study to the participants?

Participants will be updated via the schools and Speech and Language Therapy Clinics and a summary of the findings will be prepared and sent to the involved schools and SLT clinics.

21. How will the outcomes of the study be disseminated (e.g. will you seek to publish the results and, if relevant, how will you protect the identities of your participants in said dissemination)?

PhD thesis, presentations at relevant conferences and publication in a peer reviewed journal

Data will be pseudo anonymised only for the purpose of identifying children with QOL issues and refer them to relevant services, so there will be no identities published in any written documents.

Checklist	Enclosed	N/A
Participant Information Sheet(s)	☒	☐
Consent Form(s)	☒	☐
Sample questionnaire(s)	☒	☐
Sample interview format(s)	☐	☐
Sample advertisement(s)	☐	☐
OHS Risk Assessment (S20)	☒	
Any other documents (please specify below)	☒	☐
Permission to use COHIP	☒	☐
Permission to use PedsQL	☒	☐
Sample cover letter from Sri Lanka SLT to parents of CLP	☒	☐
Key code documents (typical and CLP) for pseudo-anonymisation	☒	☐

22. Chief Investigator and Head of Department Declaration

Please note that unsigned applications will not be accepted and both signatures are required

I have read the University's Code of Practice on Investigations involving Human Beings and have completed this application accordingly. By signing below, I acknowledge that I am aware of and accept my responsibilities as Chief Investigator under Clauses 3.11 – 3.13 of the [Research Governance Framework](#) and that this investigation cannot proceed before all approvals required have been obtained.

Signature of Chief Investigator

Please also type name here:

Wendy Cohen

I confirm I have read this application, I am happy that the study is consistent with departmental strategy, that the staff and/or students involved have the appropriate expertise to undertake the study and that adequate arrangements are in place to supervise any students that might be acting as investigators, that the study has access to the resources needed to conduct the proposed research successfully, and that there are no other departmental-specific issues relating to the study of which I am aware.

Signature of Head of Department

Please also type name here

Date:

/ /

23. Only for University sponsored projects under the remit of the DEC/SEC, with no external funding and no NHS involvement

Head of Department statement on Sponsorship

This application requires the University to sponsor the investigation. This is done by the Head of Department for all DEC applications with exception of those that are externally funded and those which are connected to the NHS (those exceptions should be submitted to R&KES). I am aware of the implications of University sponsorship of the investigation and have assessed this investigation with respect to sponsorship and management risk. As this particular investigation is within the remit of the DEC and has no external funding and no NHS involvement, I agree on behalf of the University that the University is the appropriate sponsor of the investigation and there are no management risks posed by the investigation.

If not applicable, tick here ☐

Date: / /

For applications to the University Ethics Committee, the completed form should be sent to ethics@strath.ac.uk with the relevant electronic signatures.

The questionnaire below must be completed and included in your submission to the UEC/DEC/SEC:

Is the proposed research an investigation or series of investigations conducted on any person for a Medicinal Purpose? Medicinal Purpose means: ▪ treating or preventing disease or diagnosing disease or ▪ ascertaining the existence degree of or extent of a physiological condition or ▪ assisting with or altering in any way the process of conception or ▪ investigating or participating in methods of contraception or ▪ inducing anaesthesia or ▪ otherwise preventing or interfering with the normal operation of a physiological function or ▪ altering the administration of prescribed medication.	Yes / No

If **“Yes”** please go to **Section A (Clinical Trials)** – all questions must be completed
If **“No”** please go to **Section B (Public Liability)** – all questions must be completed

Section A (Clinical Trials)

Does the proposed research involve subjects who are either:	Yes / No
i. under the age of 5 years at the time of the trial; ii. known to be pregnant at the time of the trial	

If "Yes" the UEC should refer to Finance

Is the proposed research limited to: iii. Questionnaires, interviews, psychological activity including CBT; iv. Venepuncture (withdrawal of blood); v. Muscle biopsy; vi. Measurements or monitoring of physiological processes including scanning; vii. Collections of body secretions by non-invasive methods; viii. Intake of foods or nutrients or variation of diet (excluding administration of drugs).	Yes / No

If "No" the UEC should refer to Finance

Will the proposed research take place within the UK?	Yes / No

If "No" the UEC should refer to Finance

Title of Research	
Chief Investigator	
Sponsoring Organisation	
Does the proposed research involve:	
a) investigating or participating in methods of contraception?	Yes / No
b) assisting with or altering the process of conception?	Yes / No
c) the use of drugs?	Yes / No
d) the use of surgery (other than biopsy)?	Yes / No
e) genetic engineering?	Yes / No
f) participants under 5 years of age (other than activities i-vi above)?	Yes / No
g) participants known to be pregnant (other than activities i-vi above)?	Yes / No
h) pharmaceutical product/appliance designed or manufactured by the institution?	Yes / No
i) work outside the United Kingdom?	Yes / No

If **“YES”** to **any** of the questions a-i please also complete the **Employee Activity Form** (attached).

If **“YES”** to **any** of the questions a-i, and this is a follow-on phase, please provide details of SUSARs on a separate sheet.

If **“Yes”** to any of the questions a-i then the UEC/DEC/SEC should refer to Finance (insurance-services@strath.ac.uk).

Section B (Public Liability)	
Does the proposed research involve :	
a) aircraft or any aerial device	~~Yes~~ / No
b) hovercraft or any water borne craft	~~Yes~~ / No
c) ionising radiation	~~Yes~~ / No
d) asbestos	<u>Yes</u> / No
e) participants under 5 years of age	~~Yes~~ / No
f) participants known to be pregnant	~~Yes~~ / No
g) pharmaceutical product/appliance designed or manufactured by the institution?	~~Yes~~ / No
h) work outside the United Kingdom?	~~Yes~~ / No

If **“YES”** to any of the questions the UEC/DEC/SEC should refer to Finance (insurance-services@strath.ac.uk).

For NHS applications only - Employee Activity Form

Has NHS Indemnity been provided?	Yes / No
Are Medical Practitioners involved in the project?	Yes / No
If YES, will Medical Practitioners be covered by the MDU or other body?	Yes / No

This section aims to identify the staff involved, their employment contract and the extent of their involvement in the research (in some cases it may be more appropriate to refer to a group of persons rather than individuals).

Chief Investigator		
Name	Employer	NHS Contract? Honorary
		Yes / No
Others		
Name	Employer	NHS Contract? Honorary
		Yes / No
		Yes / No
		Yes / No
		Yes / No

Please provide any further relevant information here: