

Cleft lip and palate feeding intervention: a scoping review

by
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DECLARATION

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Abstract

Background: Infants with cleft lip and palate (CLP) often suffer from feeding difficulties before surgical intervention. Speech therapists can provide different types of feeding intervention for this population. A scoping review was suggested to determine the evidence-based practice for feeding intervention in the CLP population. The research question for this scoping review was: What management strategies and associated outcomes are described in the research literature for feeding difficulties in the CLP population? Objectives: To summarize available literature on CLP feeding management strategies and their associated outcomes, as well as to identify gaps in the evidence base of feeding intervention in the CLP population. Methods: Arksey and O'Malley's (2005) scoping review methodological framework was utilized and included all six stages of the framework. Inclusion criteria: Only articles published between 1990 and 2018 were included. The studies needed to be either published or translated into English or Afrikaans. The age range of the research participants was from newborn to six years of age. The primary diagnosis had to be cleft lip, cleft palate or CLP, which was not related to other syndromes. The articles had to include feeding intervention as well as an outcome for that intervention. Only primary research was included in this scoping review. Search strategy: The following Boolean search string was used to search through 5 databases: ("cleft lip and palate" OR "cleft lip" OR "cleft palate" OR craniofacial) AND (feeding OR swallowing OR breastfeeding OR dysphagia OR eating OR deglutition) AND (manage* OR rehabilitation OR treatment OR intervention OR therapy). Extraction of data: Screening measures first included the titles of the articles, then the abstracts, and finally, full-text reviews. The charting of the final selection of articles was grouped according to the following categories: title, authors, year of publication, location of the study, design, participants, timing of intervention, feeding intervention and associated outcomes. After the data was extracted from the articles, interviews were held with experienced speech therapists to determine their perceptions on the studied subject. Analysis of results: Thirty-one articles were included in this scoping review. The main feeding intervention themes included: caregiver training (43%), use of feeding utensils (40%), use of prostheses (14%) and alternative feeding (3%). The use of various modified bottles and teaching caregivers feeding strategies were some of the commonly reported strategies in the articles. Generally, positive outcomes were reported in the articles, such as weight gain. The interviewed speech therapists, however, prefer to use other interventions in their clinical practice compared to the feeding interventions reported in the research. Their clinical contexts had an influence on the type of feeding intervention prescribed for their patients. Conclusions:

The results from the research and the perceptions of the therapists indicated a need for more evidence-based research within the South African and other low- and middle-income countries' contexts, as most of the available research is from high-income countries. A recommendation for speech therapists in low- and middle-income countries is that they need to rely more on their clinical experience than the available research to provide evidence-based practice.

Keywords: Cleft lip and/or palate (CLP); scoping review; feeding intervention; outcomes

Opsomming

Agtergrond: Babas met gesplete lip en verhemelte (GLV) het dikwels voedingsprobleme voor chirurgie plaasvind. Spraakterapeute kan verskillende tipes voedingsintervensies vir hierdie teikengroep bied. 'n Omvangsbepaling was voorgestel om die bewysgebaseerde praktyk vir voedingsintervensie in die GLV populasie te ondersoek. Die navorsingsvraag vir hierdie omvangsbepaling was: Watter behandelingstrategieë en gepaardgaande uitkomstes word in die navorsingsliteratuur oor voedingsprobleme in die GLV populasie beskryf? Doelwitte: Om die beskikbare literatuur rondom GLV voedingsbehandeling in terme van die intervensie strategieë en hul gepaardgaande uitkomstes op te soek om leemtes in bewysgebaseerde navorsing van voedingsintervensies met die GLV populasie te identifiseer. Metode: 'n Omvangsbepalings-raamwerk van Arksey en O'Malley (2005) was gebruik wat al ses stadiums van die omvangsbepalings-raamwerk insluit. Insluitingskriteria: Net artikels tussen die jare 1990 en 2018, is ingesluit. Die studies moes in Afrikaans of Engels of vertaal in Afrikaans of Engels wees. Die ouderdom van deelnemers kon tussen pasgebore tot ses jaar oud wees. Die primêre diagnose van die deelnemers moes gesplete lip, gesplete verhemelte of GLV, wat nie verwant is aan ander sindrome nie, insluit. Die artikels moes 'n voedingsintervensie insluit asook 'n uitkomste verwant aan die intervensie. Net primêre navorsing was in die omvangsbepaling ingesluit. Soekstrategieë: Die volgende Boolean soekstring was gebruik om deur vyf databasisse navorsing te doen: ("cleft lip and palate" OR "cleft lip" OR "cleft palate" OR craniofacial) AND (feeding OR swallowing OR breastfeeding OR dysphagia OR eating OR deglutition) AND (manage* OR rehabilitation OR treatment OR intervention OR therapy). Uittreksel vanuit data: Die titels van die artikels was eerste gesif en daarna die opsommings. Die hele artikel was met die finale sifting deurgegaan. Die finale keuse van artikels was volgens die volgende kategorieë gekarteer: titel, outeur, jaar van publikasie, plek van die studie,

studie ontwerp, deelnemers, tyd van intervensie, voedingsintervensies en gepaardgaande uitkomstes. Na afloop van die uittreksel van die data vanuit die artikels, was onderhoude met ervare spraakterapeute gehou om te bepaal wat hulle persepsies rondom die onderwerp van hierdie studie is. Analise van resultate: Een-en-dertig artikels was in hierdie omvangsbepaling ingesluit. Die hoofemas rondom voedingsintervensie was versorger opleiding (43%), voeding gereedskap (40%), prostese (14%) en alternatiewe voeding (3%). Die gebruik van verskeie aangepaste bottels en opleiding van versorgers om verskillende voedingstrategieë toe te pas, was van die intervensies wat die meeste in die artikels voorgekom het. Positiewe uitkomstes, soos gewig toename, was oor die algemeen gerapporteer. Die spraakterapeute het egter ander voedingsintervensies verkies in hulle kliniese praktyk teenoor die voedingsintervensies wat in die navorsing berig was. Hulle kliniese konteks het 'n groot invloed op watter tipe voedingsintervensies vir hulle pasiënte voorgeskryf word. Gevolgtrekking: Die resultate van die navorsing en die persepsies van die spraakterapeute dui 'n behoefte aan vir meer bewysgebaseerde navorsing binne die konteks van Suid-Afrika en ander ontwikkelende lande, omdat meeste navorsing vanaf hoë inkomste lande kom. Die aanbeveling vir spraakterapeute in lae en gemiddelde inkomste lande is dat hul meer op hul kliniese ervaring moet staatmaak as die beskikbare navorsing om sodoende bewysgebaseerde praktyk te verskaf.

Sleutelwoorde: Gesplete lip en verhemelte; omvangsbepaling; voedingsintervensie; uitkomstes

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CHAPTER 1: Introduction

Cleft lip and palate (CLP) is classified as a congenital anomaly of the craniofacial structures (Arvedson & Brodsky, 2002). During the 4th to 8th weeks of pregnancy, the craniofacial structures of the embryo develop separately, where after the subsequent fusion of these structures occurs (Chigurupati, 2012). The process of fusion calls for accurate timing. Disruptions during this intricate phase of orofacial development may lead to CLP, in the event that the orofacial structures do not fuse successfully (Yu, Serrano, Miguel, Ruest, & Svoboda, 2009).

Feeding difficulties are common in infants with CLP. De Vries et al. (2014) reported that 67% of infants with cleft palate suffered from feeding difficulties and 86% were not able to breastfeed. Patients with CLP experience feeding difficulties due to the incomplete development and fusion of the orofacial structures (Zajac, David & Vallino, 2017). Feeding difficulties in the infant with CLP can lead to poor weight gain and failure to thrive (Beaumont, 2008). The provision of feeding interventions for these infants is therefore essential.

Speech therapists have a central role in the provision of evidence based management of patients with feeding and swallowing disorders (Groher & Crary, 2010). Having research as the foundation of clinical practice is considered to be the gold standard, as opposed to basing management on practice, experience and intuition (Mccurtin & Roddam, 2012). A scoping review is a recommended research method for the researcher to encapsulate a large range of research in the evidence base of that field (Smith, Williams, & Bryan, 2016). By performing a scoping review, the best external evidence can be obtained to contribute to evidence-based practice. For this study, a scoping review was chosen to investigate possible gaps in the research as well as to report on the research that is informing the practice in the field (The Joanna Briggs Institute, 2015).

A scoping review design entails looking at the population, concept and context to define the background of the study (The Joanna Briggs Institute, 2015). For the purpose of this study, the population is defined as patients with CLP who have feeding difficulties. The concept of this study will focus on the feeding intervention for the CLP population only. In terms of context, a global perspective will be taken into account, while discussing the South African context alongside the included studies.

CHAPTER 2: Literature review

The World Health Organisation (2016a) stated that the incidence of CLP is one per 500-700 births, which varies across ethnicities, gender and countries. Males are more likely to be born with CLP and females with isolated cleft palate (Mossey, Little, Munger, Dixon, & Shaw, 2009). Across racial groups, cases of CLP have been reported most frequent in Asian populations, whereas the African populations had the least number of reported cases (Peterson-Falzone, Hardin-Jones, & Karnell, 2010). Nearly 20% of recorded congenital disorders in South Africa, between 2006 and 2014, were cases of CLP (Lebese, Aldous, & Malherbe, 2016). The intensity of disability that CLP places on the person as well as their family, is a reason why it is classified by the World Health Organisation (2016b) as one of the seven priority oral disorders in the world. The severity of the disability depends on the classification of the craniofacial structures affected by the cleft.

Clefts are generally categorised according to the facial structures affected, with the most frequently occurring being isolated cleft palate, as well as a cleft lip which can occur with or without a cleft palate (Mossey et al., 2009; Watkins, Meyer, Strauss, & Aylsworth, 2014). A cleft palate can vary from a mere gap at the back of the soft palate, which is an incomplete cleft, to an almost entire separation of the roof of the mouth, which is classified as a complete cleft (McCorkell, McCarron, Blair, & Coates, 2012). In literature, CLP is frequently referred to as syndromic when the CLP is a feature of a syndrome or a disorder e.g. Pierre Robin Sequence or Stickler Syndrome, or nonsyndromic (Peterson-Falzone et al., 2010; Zajac et al., 2017). According to Jugessur, Farlie and Kilpatrick (2009), approximately 50% of cleft palate cases and 70% of CLP cases are nonsyndromic (as cited in Hadidi et al., 2017). It is important to know the classification of the cleft as it influences the patient's feeding physiology.

Feeding requires complete and well-functioning oral structures such as the lips, tongue, hard and soft palates, and teeth, as well as the pharyngeal wall. The coordination of these oral structures is required to develop a synchronized suck-swallow-breath pattern for effective feeding and swallowing (Groher & Crary, 2010). The oral structures of an infant with CLP make this sophisticated pattern of swallowing difficult to develop in the oral phase. Infants produce suction by sealing the oral cavity from the nasal cavity, which generates intraoral pressure (Reid, Reilly, & Kilpatrick, 2007). Clefts of the palate cause an inability to separate

the oral and nasal cavities to achieve the complete closure required for negative intraoral pressure build-up (Peterson-Falzone, Trost-Cardamone, Karnell, & Hardin-Jones, 2006). A complete seal cannot be obtained as air flows from the nasal cavity through the cleft palate to the oral cavity (Burca, Gephart, Miller, & Cote, 2016). Furthermore, infants with a cleft lip struggle to seal their lips around the breast or nipple to produce intraoral pressure needed for sucking, which results in feeding difficulties (Burca et al., 2016).

Inadequate suction during feeding, as result of the orofacial cleft, can lead to unsatisfactory milk intake, fatigue and excessive air consumption (Zajac et al., 2017). Clefts in the palate can lead to liquids spilling out of the nasal cavity (Devi, Sai Sankar, Manoj Kumar, & Sujatha, 2012). Feeding problems can also lead to poor weight gain and slower growth patterns. During the first six months, infants with CLP have poorer growth in terms of weight and height, compared to infants without clefts, due to their feeding difficulties (Zarate et al., 2010). Maintaining a nutritious diet is thus essential to facilitate development and growth, in preparation for craniofacial surgery (Amstalden-Mendes, Magna, & Gil-da-Silva-Lopes, 2007).

Surgical intervention for each infant with CLP is dependent on age, nature of the problem and social circumstances (Murthy, 2009). For instance, the availability of healthcare specialists to perform craniofacial surgery and follow up care can be a factor in determining when the craniofacial surgery occurs. Every patient with CLP will, therefore, receive treatment specifically adapted to repair and treat the problems with which they present. The main objectives for cleft palate surgery are to create closure of the cleft, to produce a mechanism for normal feeding and speech development, as well as to decrease abnormal maxillary growth and dento-alveolar disturbances (Agrawal, 2009).

Surgical intervention can reduce feeding difficulties by repairing the orofacial clefts. At the age of 3 months, the cleft lip can be surgically repaired (Zajac et al., 2017). The cleft palate is typically repaired at age 6 to 12 months, which is important for feeding (Agrawal, 2009). The quality of life improves for patients with CLP and their families after surgical correction of the associated craniofacial malformations (Beluci & Genaro, 2016). Successful early surgery for infants with CLP will produce better physical results and diminish difficulties with social integration that they may have faced later in life (Mossey & Little, 2009). However, timely surgery for patients with CLP in low- and middle-income countries is not always possible.

The World Bank classifies countries into four categories, according to their gross national income (GNI) per capita: low-income, lower-middle-income, upper-middle income and high-income (Fantom & Serajuddin, 2016). South Africa is classified as an upper-middle-income country as the GNI per capita is between \$3,956 and \$12,235 (The World Bank, 2019a). In Africa, 41% of the population live in extreme poverty and 413 million people are classified as poor (The World Bank, 2019b). In 2015, 59,7% of poor South Africans lived in rural areas and 18,8% of South Africans lived below the poverty line of 1,9 US dollar per day (The World Bank, 2018). In the context of an upper-middle-income economy, healthcare services in South Africa are affected.

In low- and middle-income countries, paediatric surgical services for cases such as congenital malformations have been seen as too costly and, as such, not a critical service for children (Bickler & Rode, 2002). A global study conducted in low and middle income countries by Carlson et al. (2016), calculated that 2000 patients with CLP in South Africa, and more than 600 000 cases of CLP in all the low- and middle-income countries, were left untreated due to limited healthcare services for craniofacial surgery. Several non-governmental organisations conduct surgery outreaches in low- and middle-income countries, attempting to decrease the backlog of untreated patients with CLP. These organisations attempt to relieve the burden of disease but are not always sustainable for long-term follow-up of patients (Shrime, Sleemi, & Ravilla, 2015). This phenomenon leads to untreated infants with CLP and prolonged feeding difficulties.

In most cases of CLP feeding difficulties, the emphasis of intervention is placed on compensatory feeding strategies, such as positioning during mealtimes, as well as the use of alternative feeding bottles (Kumar Jindal & Khan, 2013). Feeding utensils and alternatives for the infant with CLP, as an alternative to standard breastfeeding or bottle-feeding practices, include: various modified bottles, cups, spoons, a feeding obturator and nasogastric tube feeding (Ize-Iyamu & Saheeb, 2011). Regardless of the feeding utensil or alternative feeding method used, in all cases the correct positioning of the infant with CLP while feeding is essential.

Providing support for the head and body of the infant with CLP while breastfeeding can lead to more efficient feeding (Groher & Crary, 2010). Positioning the infant, especially with a

cleft palate, upright while feeding, does not change the feeding difficulties in creating intraoral pressure build-up, however, can prevent the milk from entering the airway, which could possibly cause aspiration (Kumar Jindal & Khan, 2013). The infant with CLP should be positioned in a semi-upright position while feeding. This enables burping and will reduce nasal regurgitation of liquids (Burca et al., 2016). Furthermore, it is important to position the breast or feeding utensil in relation to the infant's mouth so that it provides a steady flow of liquids, so as to not impede their swallowing and breathing cycle (Cooper-Brown et al., 2008). Efficient feeding can be achieved with breastfeeding and the correct positioning.

Breastfeeding is beneficial for newborn babies as the breast milk lowers their risk for infections, such as otitis media and pneumonia (Burca et al., 2016). Babies with a cleft lip are more likely to breastfeed than babies with a cleft palate or CLP (Reilly et al., 2013). Babies with a cleft lip can easily be supported while breastfeeding by placing the baby directly facing the mother's breast and the mother providing support for the baby's cheek. The width of the cleft could then be decreased and better lip closure can be achieved for feeding (Kumar Jindal & Khan, 2013). The use of adapted feeding bottles can be recommended, as an alternative to breastfeeding, for the infant with cleft palate and CLP to overcome suction difficulties (Groher & Crary, 2010).

Various bottles are available for feeding intervention, which include adapted teats and squeezable bottles (Cooper-Brown et al., 2008). For instance, the Haberman feeder has a one-way valve that allows the milk to fill the teat. Once filled, the milk cannot flow back into the bottle, and the infant can attempt to extract the milk from the teat only, giving the infant more control over the volume and rate of the flow (Turner et al., 2001). While the infant with CLP cannot create suction, extraction of milk can take place with compression, using the jaw to push the milk out of the teat (Groher & Crary, 2010). The bottle can be squeezed by the caregiver as well, in the event that supplementary milk is required (Glass & Wolf, 1999). Various adapted and specialized feeding bottles are available to purchase for parents and healthcare institutions.

Unfortunately, specialised feeding bottles for infants with CLP, such as a Haberman bottle, carry a considerably higher cost than standard feeding bottles (Zajac et al., 2017). Moreover, the hygiene and care for feeding bottles in general are important to prevent the spread of disease, which might be problematic in low- and middle-income countries as well. In Sub Saharan Africa, 319 million people do not have access to running water (WHO, 2015). In South

Africa, 83.5% of households have access to running water and 90.3% have access to electricity but only 46,4% have access to piped water in their homes (Statistics South Africa, 2016). This means that more than half of South African households do not have direct access to water, making the cleaning of bottles and teats difficult. The use of bottles with infants increases the risk for diarrhea, because of the care and hygiene required to keep the bottles clean; whereas exclusive breastfeeding and early initiation of breastfeeding have shown decreased risk for diarrhea in Sub-Saharan African countries (Ogbo et al., 2017). Cup feeding has been a recommended alternative to bottle feeding and breastfeeding in low- and middle-income countries, as well as high-income countries (Dowling, Meier, DiFiore, Blatz, & Martin, 2002).

There are many benefits to cup feeding for infants with CLP, such as the fact that the infant can regulate their own feeding, rate of intake, and the volume of milk. It is an easy method which both parents can use. Cup feeding provides the infant tactile and olfactory stimulation, and has shown to sustain oxygen saturation (Flint, New, & Davies, 2016). It is a recommended supplemental feeding method for premature infants who struggle to breastfeed as well (Yilmaz, Caylan, Karacan, Bodur, & Gokcay, 2014). Therefore, in low- and middle-income countries especially, cup feeding is a recommended feeding method for infants with CLP (Flint et al., 2016). Cleaning and hygiene of cups are easier to maintain than bottles in low- and middle-income countries.

The Baby-Friendly Hospital Initiative (BFHI) is an international campaign, that was launched by the WHO and UNICEF in 1990, with the goal of instigating practices that will support, protect and promote breastfeeding (WHO & UNICEF, 2009). In South Africa, the BFHI is known as the Mother Baby Friendly Initiative (MBFI) (du Plessis, Peer, Honikman, & English, 2016). In the Western Cape province of South Africa, 94% of public healthcare facilities are using MBFI guidelines with their patients (du Plessis et al., 2016). Specific policies regarding breastfeeding and other feeding practices are part of the MBFI guidelines.

MBFI accredited facilities do not allow artificial bottles (WHO & UNICEF, 2009), which have been one of the recommendations for feeding interventions in the infant with CLP (Redford-Badwal, Mabry, & Frassinelli, 2003). This poses another barrier to the accessibility of healthcare for the patient with CLP, as adapted bottles are one of the most commonly used practices in the intervention of feeding difficulties for cleft palate specifically. Although MBFI is a positive campaign which promotes breastfeeding for the typically developing infant, the

guidelines of implementation pose a threat for the feeding intervention of the infant with CLP. When neither breastfeeding nor bottle feeding is an option, cup feeding can still be recommended. The context in which the infant with CLP is being treated can, therefore, have an influence on their feeding intervention. For older children living with untreated CLP, different feeding strategies and utensils need to be considered.

In low- and middle-income countries, the role of the speech therapist in feeding intervention is slightly different to speech therapists practicing in high-income countries, as the infants might live with untreated clefts for longer. Typically developing infants are introduced to solid foods from 6 months onwards, as their nutritional needs change (Cichero, 2016). The infant left with an unrepaired CLP is required to start with solid foods at the appropriate age as well. The feeding intervention shifts to different feeding utensils that can be used to eat solid foods, such as a spoon. Eating solid foods, compared to only drinking liquids, poses new challenges, such as food being left behind in the nasal cavity after meals, which commonly occurs (Kasten et al., 2008). Speech therapists can educate parents on the importance of oral hygiene and how to maintain oral hygiene with an infant with CLP, who is more susceptible to oral health issues such as dental caries (Lockhart, 2003). When feeding orally is not possible, alternative feeding methods can be considered.

Nasogastric tube feeding is a possible alternative feeding method. Parents are advised, however, to use this option only when the oral structures are too severely affected for oral feeding (Peterson-Falzone et al., 2006). Nasogastric tube feeding is typically recommended as temporary alternative to oral feeding (Groher & Crary, 2010). Extended use of nasogastric tube feeding results in decreased stimulation in the oral cavity and reduces the stimulation of a suckle response. The development of a suckle reflex should be stimulated and encouraged in the early stages of the neonate's life, even though infants with CLP cannot produce a suck-swallow feeding pattern (Peterson-Falzone et al., 2010). When the cleft has been repaired, the infant needs to develop a normal feeding pattern. Before the cleft palate is repaired, a palatal obturator could be a temporary option to close the cleft for feeding purposes.

A palatal obturator is an oral prosthetic that can be recommended for use with a specialised bottle to close the cleft (Goyal, Chopra, Bansal, & Marwaha, 2014; Karayazgan, Gunay, Gurbuzer, Erkan, & Atay, 2009). It improves feeding in the oral phase by allowing the tongue to create intraoral pressure against the teat of the bottle required to suck fluid from the bottle

(Hansen, Cook, & Ahmad, 2016). However, some studies have argued that the use of maxillofacial orthopaedics for feeding purposes in infants with CLP do not result in better outcomes than feeding without an obturator, in terms of weight and growth (Prahl, Kuijpers-Jagtman, Van't Hof, & Prahl-Andersen, 2005; Masarei, Wade, Mars, Sommerlad, & Sell, 2007b). Although limited, some success has been reported in combination with other intervention methods (Turner et al., 2001). The feeding intervention will change over time as the infant grows and the cleft is repaired.

Once the oral structures have been surgically repaired, it is expected that the child will be able to feed with less difficulty. Feeding ability immediately post-operatively can be different to that experienced in the weeks following the surgery. Feeding with a spoon, syringe or medicine dropper have been reported as standard protocol for post-operative feeding of cleft lip repair (Darzi, Chowdri, & Bhat, 1996). With palatoplasty, bottle feeding for the first month after surgery is strictly prohibited at certain healthcare institutions, to prevent bottle contact with the surgical site (Duarte, Ramos, & Cardoso, 2016). Varying policies at healthcare institutions can influence the use of bottle feeding with infants with CLP.

The World Health Organisation developed the International Classification of Functioning, Disability and Health (ICF) to provide a framework for the description of health and health-related domains (WHO, 2007). In the field of speech and language therapy, it is a valuable tool for designing holistic management plans for the patients, as it includes functioning and disability as well as contextual factors influencing the patient's health (ASHA, 2016). Neumann and Romonath (2012) applied the ICF to children diagnosed with CLP to aid craniofacial teams in planning assessment, counselling and therapy for this population. The contextual factors of the ICF Framework will be discussed to illustrate the context of CLP intervention in South Africa.

Contextual factors are further divided into environmental factors and personal factors. Environmental factors refer to the physical, attitudinal and social factors that could possibly influence the assessment and management of a patient with CLP (WHO, 2007). When looking at the physical environment, the topic of healthcare services in low- and middle-income countries versus high-income countries is of importance. For instance, if there are any speech therapy services in low- and middle-income countries, it might only be available in capital cities (Wylie, McAllister, Davidson, & Marshall, 2013). This necessitates that patients travel

far distances to access healthcare services, making the follow-up of these patients difficult to manage. The availability of speech therapists at cleft clinics and patients' access to such services could influence the intervention for patients with CLP.

In a study considering the health professionals forming part of the cleft care team in African countries, speech therapists were represented in only 18.2% of the cleft care teams, even though it is rated as a high priority service (Adetayo & Martin, 2012; Akinmoladun, Obimakinde, & Okoje, 2013). Speech therapy services are a scarce healthcare service in South Africa. In South Africa, 5216 health professionals were registered under Speech Language and Hearing professions in 2017, which included audiologists (HPCSA, 2017). Considering the estimated 55.6 million people living in South Africa (Statistics South Africa, 2016), these statistics would suggest that there is approximately one speech therapist for every 10660 people in South Africa.

Availability of healthcare services in South Africa is an environmental factor that needs to be included in the ICF framework when assessing the context of CLP feeding intervention. In South Africa and other low- and middle-income countries, certain barriers to cleft surgery and other essential cleft healthcare services, such as feeding intervention, exist. These barriers can include poverty, scarcity of specialized medical services, limited awareness of the accessibility of care, cultural and social influences, as well as the age of the patient. The age at which individuals with CLP arrive for primary treatment can vary from a few days to well over forty years (Murthy, 2009). An international study on barriers to cleft surgery found the lack of funds, poor patient awareness, and cost of travel to be common barriers to cleft surgery. In African countries, a patient follow-up rate of less than 50% was found (Massenburg et al., 2016). The post-operative follow-up and intervention is often missed by speech therapy and audiology services due to barriers in low- and middle-income countries (Furr et al., 2011).

The attitudes of family members and community members, further environmental factors, can pose a barrier when they are not accepting of the child with CLP (Neumann & Romonath, 2012). Teasing and bullying of children with CLP has been reported, due to their facial appearance or speech (Hunt, Burden, Hepper, Stevenson, & Johnston, 2006). For mothers with infants with CLP, it can be very stressful and emotional having a child with feeding difficulties (Owens, 2008). The families of children with CLP need support and reassurance from the healthcare professionals involved in the feeding process, such as speech therapists. Different

cultures have different expectations and beliefs within their communities, which healthcare professionals should bear in mind.

Cultural barriers also exist when providing CLP medical intervention in low- and middle-income countries. Stigmas surrounding CLP can influence the treatment of these patients, especially in Africa. Traditional healers in South Africa believe that CLP has a supernatural aetiology, such as ancestral spirits (Dagher & Ross, 2004). Some traditional Hindu and Muslim healers have superstitious beliefs about the aetiology of CLP as well, such as karma or that pregnant woman handling a sharp knife during an eclipse can cause their child to be born with CLP (Ross, 2007). Such stigmas and beliefs could result in decreased support, from the family or community, provided to the mother and her infant with CLP. Families might approach a traditional healer rather than seeking medical attention or advice at a healthcare facility. These cultural beliefs regarding CLP can delay surgery and prolong the patients' feeding difficulties.

Another environmental factor that could potentially impact the healthcare service provision is language. Difference in languages between patient and healthcare provider can influence the effectiveness of speech therapy services for patients with CLP, both in low- and middle-income countries and high-income countries. In low- and middle-income countries, with patients who do not speak the official language(s) of the country, translation services are often difficult to access. The majority of speech therapists working in low- and middle-income countries are from a high-income country, English speaking and know perhaps some of the local language (Wylie et al., 2013). In South Africa, there are 11 official languages (Brock-Utne & Holmarsdottir, 2004). If the speech therapist is unable to provide healthcare services in a language that the patient can communicate in, it can become a service delivery barrier which influences the care of the patient. For example, if a parent of an infant with CLP did not understand the instructions for feeding their infant, as per the speech therapist's recommendation, the feeding difficulties will not resolve. The context of the feeding intervention is thus important to consider when deciding on an intervention plan, alongside the available evidence-based research on the chosen intervention.

Evidence-based management integrates the following components: the clinical expertise of the therapist, the best external evidence for the chosen therapy, and the patient's values and expectations of the treatment (McCurrtin & Roddam, 2012). According to Dodd (2007), the advantages to evidence-based practice are that it increases confidence for clinical decision

making, encourages the practitioner to think about the outcomes of the chosen treatment, promotes lifelong learning, and advocates for continuing professional education which will result in the best research being put into practice faster. Utilizing the latest evidence-based practice informs the patients and other stakeholders of the effectiveness of your chosen treatment to their diagnosis. However, conflicting evidence as well as the small quantity of research evidence have been some of the complaints from speech therapists on the difficulties of implementing evidence-based practice (Mccurtin & Roddam, 2012).

In a systematic review by Reid, (2004), most intervention strategies were only supported by clinical experience and expert opinions while little randomized controlled trials have been performed to support the evidence base in this field. A review on randomised controlled trials in CLP intervention found only 4 articles on feeding and/or speech therapy intervention in the last 10 years (Hardwicke, Nassimizadeh, & Richard, 2017). Evidence-based intervention strategies, as well as associated positive outcomes for breastfeeding practices, specifically in the CLP population, have been identified as insufficient for clinicians (Reilly, Reid, & Skeat, 2007). The lack of articles to support clinical practice as well as a lack of randomized controlled trials found in these reviews motivated the need for a scoping study.

Access to research, in order to provide intervention to patients that is evidence-based, is vital for all speech therapists. To investigate the evidence-based practice for the intervention of feeding difficulties in the CLP population, a scoping review is suggested. This review will aid in identifying interventions that are being used in practice; identifying those interventions that have been found to be effective in the management of feeding difficulties in patients with CLP; and in identifying research gaps in the evidence base for future research recommendations. Therefore, the research question for this study is: What management strategies and associated outcomes are described in the research literature for feeding difficulties in the CLP population?

The objectives of this study are:

- To summarize available literature on CLP feeding management related to intervention strategies.
- To summarize available literature on CLP feeding management related to the outcomes associated with the intervention.

- To identify research gaps in the evidence base of feeding management in the CLP population.

CHAPTER 3: Methodology

3.1 Research design

The research was conducted by means of a scoping study design proposed by Arksey and O'Malley's (2005) framework and enhanced by Levac, Colquhoun and O'Brien (2010). Scoping reviews are performed for various reasons: to investigate the scope of research activity in a specific field, to determine the benefit of a full systematic review, to review and consolidate the research with stakeholders and clinicians in that field, and to identify shortcomings in the existing literature (Arksey & O'Malley, 2005; Levac et al., 2010). A scoping review has been chosen for this study to investigate possible gaps in the research as well as to report on the type of research informing the practice in the field (The Joanna Briggs Institute, 2015).

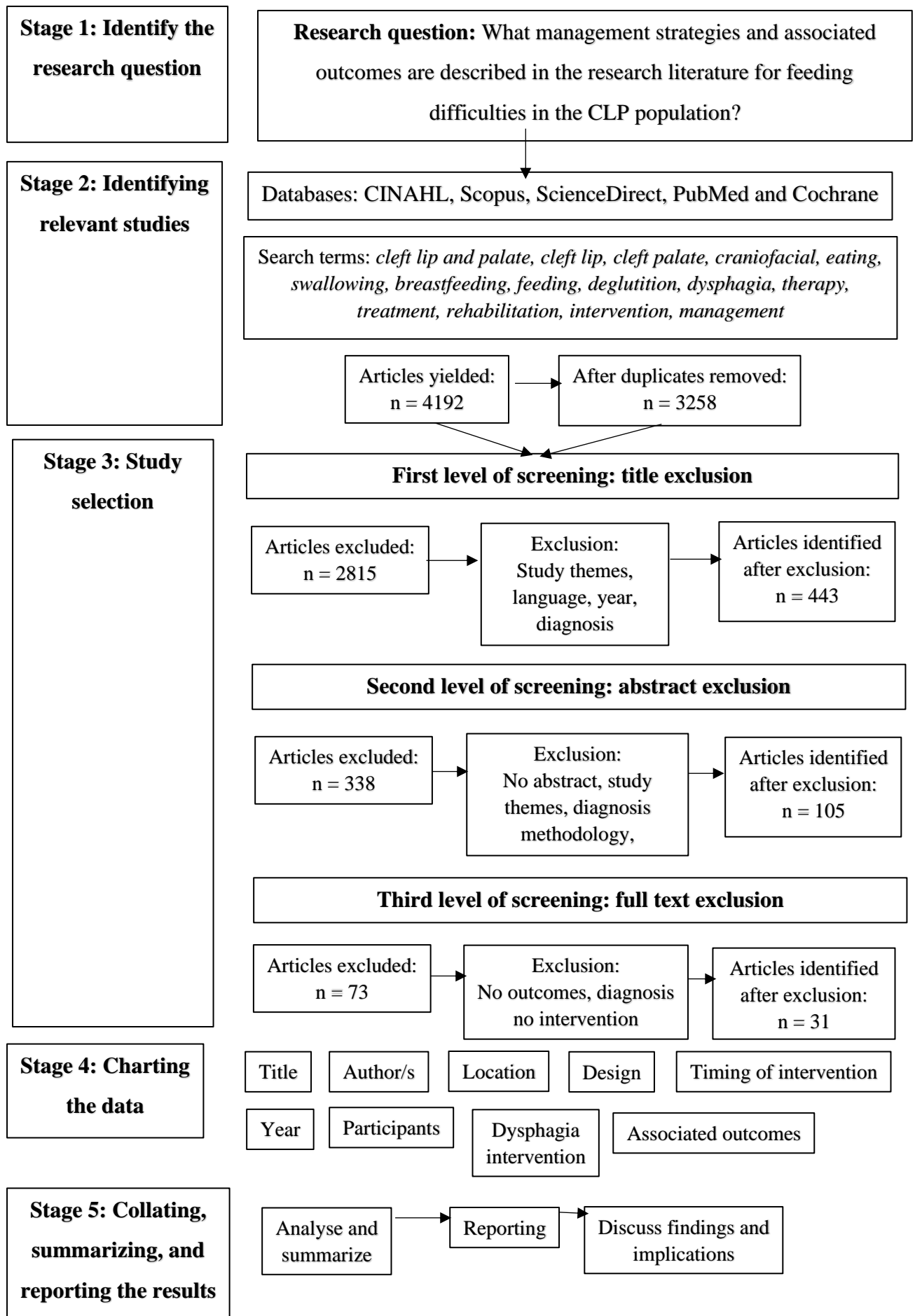
Scoping reviews have grown in popularity in recent years, especially in the health sciences. Peterson, Pearce, Ferguson and Langford (2017) found that between 2000 and 2015, 500 scoping reviews were available on medical databases PubMed and CINAHL. Where only one report was published in 2000, 151 reports were published in 2015 alone on these databases.

Colquhoun et al. (2014) proposes that "scoping reviews have the potential to advance healthcare practice, research and policy" (p. 1292). A scoping review is fitting for the aim of this study because a need exists for more research on evidence-based practice in speech- and language therapy (Marshall, Goldbart, Pickstone, & Roulstone, 2011). Having research that clarifies the management and associated outcomes, especially with the management of feeding difficulties in CLP, can aid in differentiating effective from ineffective management to ensure a safe, rather than a negative outcome (McCurrtin & Roddam, 2012).

An advantage of the scoping review methodology is that the scoping study can include research with different designs making it different from a systematic review (Arksey & O'Malley, 2005). It is not limited to a single research design and can therefore include a wider scope of research in the specific field. Systematic reviews, which regard randomized control trials as the highest valued research design, do not give a fair depiction of the available research in speech therapy. Randomized control trials are not always feasible in the field of speech therapy as the patients are often heterogeneous (Dodd, 2007). The scoping review will therefore be comprehensive of existing research by including literature with different methodologies.

A potential limitation in the methodology of scoping reviews is that the scoping review does not evaluate the quality of the research included in the study (Arksey & O'Malley, 2005). Specific inclusion and exclusion criteria were used to select the articles for this scoping review.

The methodological framework of Arksey and O'Malley (2005) will be explained step by step in the next section. Figure 1 outlines the stages of the scoping review methodological framework relating to this scoping study.



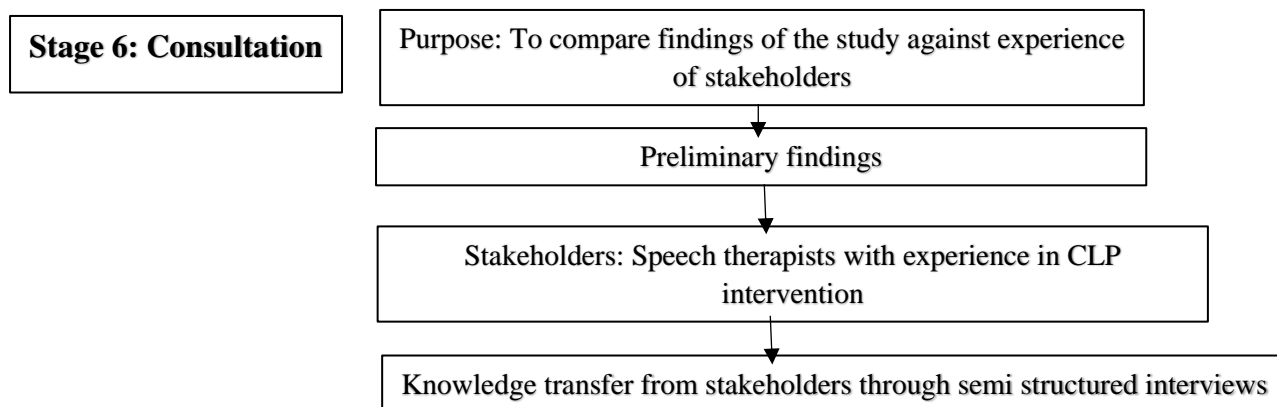


Figure 1: Methodological Framework of Scoping Review

Methodological framework

3.2 Identifying the research question

The research question is important for all the stages in the methodological framework as it determines the focus of the study. Consequently, it should be clearly defined (Colquhoun et al., 2014). When formulating a research question for a scoping review, the following areas were considered: population, concept and context (The Joanna Briggs Institute, 2015). For this study, the population refers to patients with CLP and the concept refers to the management and associated outcomes of feeding difficulties. The context was not specified in the research question with the purpose of including a wide range of studies.

The research question for this study is: What management strategies and associated outcomes are described in the research literature for feeding difficulties in the CLP population?

3.3 Identifying relevant studies

Articles were identified through a systematic search of electronic databases that were more likely to contain articles related to health sciences and rehabilitation. In consultation with a health sciences faculty librarian, databases were chosen based on their potential to yield the most articles in the field of health sciences. The following databases were used: PubMed, Scopus, CINAHL, ScienceDirect and Cochrane.

To conduct the systematic search within the databases selected, certain keywords and phrases were used to identify articles that suit the theme of the scoping study. It was important to use synonyms of the key words in the search string in order to identify articles with the same

content, for example the words “intervention” and “management” can refer to the same aspect. Different combinations of the following words were used in search strings:

Population	Concept	Management
<i>cleft lip and palate</i>	<i>eating</i>	<i>therapy</i>
<i>cleft lip</i>	<i>swallowing</i>	<i>management</i>
<i>cleft palate</i>	<i>feeding</i>	<i>rehabilitation</i>
<i>craniofacial</i>	<i>dysphagia</i>	<i>treatment</i>
	<i>deglutition</i>	<i>intervention</i>
	<i>breastfeeding</i>	

A search string was created by using all the key words. A Boolean search strategy was used to create the search string. By using the modifier “OR” between synonyms or alternative words, the search string detected all the possible terms. The modifier “AND” limits the search to include all the concepts in the search string. The initial search string included the following:

(“cleft lip and palate” OR “cleft lip” OR “cleft palate” OR craniofacial) AND (feeding OR swallowing OR breastfeeding OR dysphagia OR eating OR deglutition) AND (manage* OR rehabilitation OR treatment OR intervention OR therapy)

The search string varied slightly for each database search. Different combinations of the three categories identified in Table 1 were used in order to include all applicable studies. The population was used in all the search strings; however, the concept and management aspects were not used in all the search strings. This was done to include a larger range of articles as the search string searches for key words in the titles and abstracts of the articles. Search alerts were created on the chosen electronic databases to ensure that if new articles were published during the timeframe of the scoping review, and fit with the topic of this research study, that these articles could be included in the study as well.

A scoping review can result in a considerable body of research which can be difficult to organise effectively and efficiently for the reviewing process. To aid the process of the scoping study, reference management software is recommended (Peters, 2017). Mendeley software was

used to save the articles, remove duplicate articles as well as screen the titles, abstracts and full texts of the articles. Mendeley could suggest articles with the same themes as the ones saved by the researcher. These articles were included in the scoping review as well.

3.4 Study selection

Three stages of screening the selected articles were implemented to exclude irrelevant articles for this study. The screening determined if the articles were able to meet the aims of the research. For the screening process, two reviewers are recommended to independently review the articles for inclusion in the scoping review (Levac et al., 2010). A third reviewer was consulted when the two reviewers disagreed on inclusion of studies (Colquhoun et al., 2014).

	Inclusion criteria	Exclusion criteria
Publication year	1990 till 2018	Older than 1990
Language	English, Afrikaans and English translation	Other languages
Participants age	Children (0-6)	Older children (7+) and adults
Diagnosis	Cleft lip Cleft palate Cleft lip and palate	Other craniofacial syndromes e.g. Pierre Robin Sequence
Type of sources	Primary research	Systematic reviews, grey literature, books, letters
Intervention	Feeding management	Craniofacial corrective surgery Speech therapy for pronunciation Dental management
Outcomes	Any type of feedback included to indicate an outcome for the intervention used, e.g. statistical information, commentary.	No feedback on outcome

The scoping review's study selection was not rigid and was refined during the selection of articles when the researcher became more familiar with the available literature (Levac et al.,

2010). The study yielded 4192 articles in total. After duplicate articles were removed, 3258 articles remained. Inclusion and exclusion criteria for the study were applied during the database searches, as well as in the study selection screening levels.

All peer reviewed articles published since 1990 that described management or intervention, and/or outcomes, for feeding difficulties in the CLP population were included in the initial study selection. This was done to ensure that the latest research is included in this review. The year parameter was set in the electronic databases, with the appropriate search string, to only obtain articles published since 1 January 1990 and onwards.

Only articles published in Afrikaans and English, or translated to English, were included as the researcher was not able to review academic articles in other languages. The language of publication could not always be controlled with the electronic database search parameters. This resulted in many articles entering the first level of screening, and even the second level of screening, as the titles were English but the abstract and text in another language.

An age range was included for the participants of the studies. Cleft feeding issues appear in infancy when corrective surgery has not occurred yet. However, in third world countries where specialized medical services such as maxillofacial surgery are scarce, the clefts are often left untreated for longer resulting in prolonged feeding issues. The participants of the included studies were required to have been between 0 and 6 years of age. Thus, studies related to children older than 6 and adult participants were excluded from the study.

Systematic reviews were not included in the scoping review. However, the reference lists of the systematic reviews identified throughout the scoping review were searched for relevant articles that would fit this study's criteria. Any other type of review articles, such as a literature review article, were not included in this study. The articles needed to have an original research study and not merely give a summary on the available research.

Studies on other craniofacial syndromes, for example Pierre Robin sequence, were not included in the study as the clinical pictures of feeding difficulties vary in different craniofacial syndromes. This study focused specifically on feeding intervention for patients with cleft lip and/or palate only.

The studies included needed to be on a type of feeding intervention for patients with CLP that a speech therapist could perform. Other medical interventions which patients with CLP undergo, were excluded, such as surgical intervention, speech therapy for speech production issues, and dental management.

As the outcome of the intervention was one of the objectives of this study, all included studies needed to have feedback on the intervention mentioned in the article. Statistics, commentary and any other means were accepted. Articles were only excluded if there was no feedback on the outcome of the feeding intervention.

It was decided that only articles that were available through Stellenbosch University's library services would be included in the study. Only five articles could not be obtained by the faculty librarian. Access to the full texts of the studies was difficult to obtain as they were published in journals that the university library did not have access to, or because no electronic version was available. The names of the articles that could not be accessed can be found in Appendix A.

The first level of screening involved reviewing the titles of the articles. Both the researcher and the second reviewer reviewed the titles of the articles independently. The second reviewer was given the inclusion and exclusion criteria as stated in Table 2, to be able to perform the article reviews. This process was carried out with Mendeley software for easy access of the articles and secure online storage of the data.

If the title included only a part of the study subject, it was still included in the subsequent screening levels. For instance, five articles were named "cleft lip and palate" and they were included as they could still have information in the abstract and full text on feeding intervention. Articles about cleft repair surgery, such as palatoplasty, were excluded. The number of articles excluded after the first level of screening was 2815 articles and only 443 articles remained.

The second level of screening required the researcher to screen all the abstracts of the articles left after the first level of screening. Both the researcher and the second reviewer reviewed the abstracts of the articles independently. Four articles did not have abstracts but only a full text article. These articles were excluded as they did not have abstracts to screen and may not have

been academically appropriate for a scoping review. They were mostly letters to the editor or a table of content for an academic journal. Several articles were excluded in this level due to the methodology of the studies, such as reviews.

If the abstracts were fitting with research question and aims, then those articles were included for the final stage of screening. The emerging themes of articles that were not appropriate for the topic of research were: CLP surgery, classification of CLP, orthodontic management, and feeding intervention with populations other than CLP such premature babies. A total of 338 articles were excluded after the second level of screening, leaving a total of 105 articles for full-text screening.

The last level of screening involved reviewing the full texts of the remaining articles, to determine if they meet the inclusion criteria for this study. The full texts were reviewed independently by the researcher and the second reviewer. The researcher read through the entire articles twice to determine the suitability for this study. The inclusion and exclusion criteria for the final selection of articles guided the researcher to select appropriate articles for this scoping review. Many of the full texts described the literature and did not report on the results from a research study with outcomes and were therefore excluded. After the third level of screening, 31 articles were deemed suitable for this study and included in this scoping review. The references for each included article are attached as Appendix B. Their content will be reported on in the results section.

3.5 Charting the data

The fourth stage in the methodological framework of a scoping study requires the researcher to extract the data from the selected articles. The content of the data was analysed utilizing a qualitative approach (Colquhoun et al., 2014). Arksey and O'Malley (2005) suggest a data charting form consisting of the following categories: author, year of publication, study location, study population, methodology, interventions, outcomes and other important findings. The data charting form for this study was based on these categories. The form was adjusted iteratively during the data collection process whilst the researcher become familiar with the data (Levac et al., 2010).

A category that was added during the charting was the timing of the intervention. This refers to when the feeding intervention occurred in relation to cleft lip and/or palate repair surgeries.

For instance, some articles specifically looked at feeding post palatal surgery for patients with cleft palate in order to not damage the surgical site during recovery. The distinction between pre- and postsurgical feeding intervention is thus important.

3.6 Collating, summarizing and reporting results

The fifth stage in the scoping review process is the collating, summarizing and reporting of the results. Arksey and O'Malley (2005) suggest that the data collected be analysed numerically as well as thematically. The numerical analysis shows the amount of studies, date of publications, countries and continents represented, type of studies reviewed, and the timing of the interventions reported in the studies.

Content analysis was applied to extract themes from the data (Bless, Higson-Smith, & Sithole, 2013). The emerging intervention strategies from the data were categorised into different themes. Intervention strategies had broader themes (e.g. feeding utensils and parent training). Under these themes, different management strategies were grouped, such as different bottles and cups were grouped under feeding utensils, whereas teaching feeding strategies and positioning were grouped under parent training.

While analysing the outcomes of intervention, overarching themes were identified in the articles. Positive and negative outcomes were identified. These were grouped according to the outcomes, such as weight gain, improved intake, ease of feeding, and no improvement in feeding.

3.7 Consultation

The final stage in Arksey and O'Malley's (2005) methodological framework is consultation with practitioners from the field in which the study is conducted. Although this stage is optional, it is argued by Levac et al. (2010) to be required because of the value it adds to the scoping study. Existing evidence-based research can then be compared with experience from the field.

Speech therapists working in South Africa might have different approaches to the feeding management of patients with CLP compared to speech therapists working in high-income countries. This consultation sought to aid in the application of the results of the scoping review to the South African context of healthcare.

A. Research question

For the final stage of this scoping study, the researcher aimed to answer this question: what is the perception of speech therapists, working within the craniofacial field, regarding intervention strategies and the associated outcomes for feeding difficulties in patient with CLP?

B. Aim

The key aim of the final stage of the scoping study was to determine the perceptions of speech therapists, specifically with regards to their own clinical experience with patients with CLP, on the intervention of feeding difficulties in the CLP population and the associated outcomes thereof.

Objectives

- To determine speech therapists' current practice in the intervention of feeding problems and the associated outcomes for the patient with CLP.
- To make a comparison between the scoping review results and the current practice of speech therapists in terms of feeding intervention and associated outcomes for the patient with CLP.
- To determine speech therapists' opinion on what research is lacking in terms of feeding intervention for the patient with CLP.

C. Research design

A qualitative research design was followed in the final stage in Arksey and O'Malley's (2005) methodological framework for scoping review. This design was chosen to be able to record and to describe the perceptions of speech therapists regarding their lived experiences with feeding intervention for patients with CLP and the associated outcomes thereof (Bless et al., 2013).

D. Methods

The qualitative data was collected through individual interviews with experienced speech therapists in the field of feeding intervention for patients with CLP. A semi-structured interview utilized to gather the information for the study. It incorporated the broad questions from an unstructured interview with probe questions found in a structured interview (Bless et al., 2013). This method was beneficial for this study as the researcher wished to compare the opinions of the participants with the results from the scoping study.

E. Sampling

Purposive sampling was used to select the participants according to specific criteria which were important for the study (Bless et al., 2013). Different tertiary hospitals were contacted telephonically to enquire if they have speech therapy staff working with patients with CLP on a regular basis. These speech therapists were contacted via email with the information leaflet and the consent form. Additionally, the speech therapists who were interviewed first were asked if they could recommend any other colleagues who would be appropriate for the interview. The number of participants that the researcher was planning to interview, was between 5 and 15 or when data saturation has been reached. It should be noted that this is a small section of a main study protocol and therefore a maximum of five speech therapists was interviewed. Furthermore, speech therapists working with the CLP population in South Africa are scarce. Therefore, the researcher decided that the sample size is representative of the population being interviewed (Bless et al., 2013).

The participants who were invited to participate in the interviews needed to meet the following inclusion and exclusion criteria. Participant needed to be speech therapists who have experience with working with patients with CLP. It was essential for the speech therapists to have at least two years' experience in the craniofacial field, to compare their lived experience with the results from the study. The setting of their work experience could have been in a clinic, tertiary hospital, rural outreach, or private practice. Having participants from different work settings is representative of the South African clinical context.

F. Materials and instrumentation

An interview schedule was prepared by the researcher to use for the semi-structured interviews. Firstly, the researcher provided a short introduction to orientate the participants as to what the interview was about. The questions for the participant then followed. The questions were open ended, with the goal of attaining perceptions and beliefs from the participants (Creswell, 2009). Stewart and Shamdasani (1990) suggest that the initial questions should be broad and develop towards more specific questions during the interview (as cited in Gill, Stewart, Treasure, & Chadwick, 2008). Each of the questions had prompts for the participants to give more detail on their opinions and expand on their answers (Creswell, 2009). The interview schedule can be found in Appendix D.

The central themes for the questions were based on the objectives of the study. The intervention strategies used by the participants and their opinions on the effectiveness of their chosen intervention were discussed. Trends identified in the academic articles, such as the use of specialized bottles and feeding obturators, were discussed to see if the scoping review results aligned with their clinical experience. The participants were asked about their opinions on the available research on the topic of feeding intervention in the patient with CLP.

G. Procedure

The participants were contacted and invited to participate in the study with an information leaflet that explained the procedure of the interview to them. If they wished to participate, they had to read and sign an informed consent form and return the consent form to the researcher. An additional consent form was given to the participants for their permission to complete an audio recording of the interview. The researcher arranged a date, time and place which was convenient for the participant as well as for the researcher to conduct the interview. If the participants could not attend an interview in person, a Skype interview was arranged. All interviews were audio recorded to ensure that the participants' responses were accurately depicted for the data analysis. The interviews lasted for up to 75 minutes per interview. The location for the interview had to be in a quiet room as the researcher needed to record the audio from the interview for transcription purposes. The informed consent form can be found in Appendix F.

H. Data coding and analysis

The data obtained from the interviews (the transcripts) were analysed by using a qualitative data analysis approach: thematic content analysis. This process involves a series of steps to summarize the breadth of data obtained in the study by identifying themes and categories in the data (Burnard, Gill, Stewart, Treasure, & Chadwick, 2008). The analysis was manually. Braun and Clarke's (2008) six phases of thematic analysis were used to analyse the data.

The first step involves becoming familiar with the data (Braun & Clarke, 2008). The researcher conducted the interviews and transcribed the recordings of the interviews independently. These processes familiarized the researcher with the data.

The second step was to generate initial coding (Braun & Clarke, 2008). The researcher read through all the transcripts from the interviews and grouped phrases together that share the same theme (Burnard et al., 2008).

The third step was to search for themes in the coding (Braun & Clarke, 2008). This required the researcher to search through the coded phrases for similar ideas to further summarize the data. Similar codes were grouped into themes.

The fourth step was to revisit the themes identified in the previous step (Braun & Clarke, 2008). The researcher compared the themes with the initial coding to ensure that the themes encapsulated the data obtained from the interviews.

The fifth step was to further define and to name the themes (Braun & Clarke, 2008). The name and definition of the themes were clearly defined by the researcher to be able to explain the process of coding to others (Bless et al., 2013).

The final step was the production of the report (Braun & Clarke, 2008). The identified themes were then used to analyse and report the data from the interviews. When the data was written up, it was added and discussed with the results from the first 5 stages of the scoping study.

I. Trustworthiness

Within a qualitative research study, the data analysis and interpretation are usually more subjective than in a quantitative study (Burnard et al., 2008). It is thus important to ensure trustworthiness of the analysis and interpretation of data (Bless et al., 2013). To ensure trustworthiness of the data collection process, reflexivity was applied. Reflexivity in qualitative research refers to how the researcher reflects and analyses their own influence on the research process (Finlay, 2002). The researcher reflected after each interview on how they could have influenced the participant's responses, for example in the manner the questions were asked or how much time was given to answer each question. The interview process was adapted accordingly. Another way of increasing trustworthiness in the data interpretation was to add quotations from the study to the results. In this study, the direct quotations were then compared to the interpreted data (Bless et al., 2013). Interviewer bias was considered as the researcher designed the questions for the interview schedule. To ensure objectivity, another speech

therapist with no affiliation towards the study conducted the interviews on behalf of the researcher.

J. Ethical considerations

A scoping review usually has little or no ethical considerations. The only human participation in this study was with the semi-structured interviews during the consultation stage. Ethical clearance was obtained from the Health Research Ethics Committee at Stellenbosch University to perform the interviews (8106). The approval letter from the Health Research Ethics Committee can be found in Appendix E.

The participants received a letter of informed consent where it was explained that participation was voluntary. The reason for the interview and the contribution that they could make to the study by participating was explained. Written consent was obtained from the participating speech therapists. Their personal details were kept confidential by the researcher and not distributed to the public. The consent forms with their personal details were kept in a locked drawer.

When transcribing the voice recordings, the researcher kept the participant's names and the name of their hospitals anonymous. To protect the anonymity of the participants, it was decided to not include the full transcripts as an appendix in this study as the transcripts included considerable identifiable information. The transcription of the voice recordings was kept secure on an external hard drive in a locked drawer. The results of the study, after analysing the data from the interviews, was made available to the participants, if desired.

CHAPTER 4: Results

The scoping review included thirty-one articles. A numerical analysis was applied to all the studies to summarize the information as a collective. Content analysis was applied to report on the different interventions and associated outcomes from the included studies. The results will be presented according to the key findings within the categories used to summarize the articles in the data charting table. A descriptive summary using numerical data of the general information of the articles will be presented first, followed by the specific content on intervention and outcomes. Lastly, the results from the consultation stage will be presented using content analysis.

4.1 Numerical analysis

The articles were summarized in the predetermined data charting table based on the categories recommended by the Joanna Briggs Institute (2015) and adjusted according to the information obtained in the articles. The categories were the following: title, authors, year of publication, location of the study, design, participants, timing of intervention, feeding intervention, and associated outcomes. The data charting table can be found in Appendix C.

Within the period of 1990 until 2018, thirty-one articles met the inclusion criteria for this study. Ten (32%) of these articles were published between 2010 and 2014 and seven (22%) were published between 1995 and 1999. Thirteen articles were published between 1990 and 2004 compared to eighteen articles between 2005 and 2018. Only three articles were published on this topic since 2015. The dates of publication of all the articles are illustrated in Figure 2.

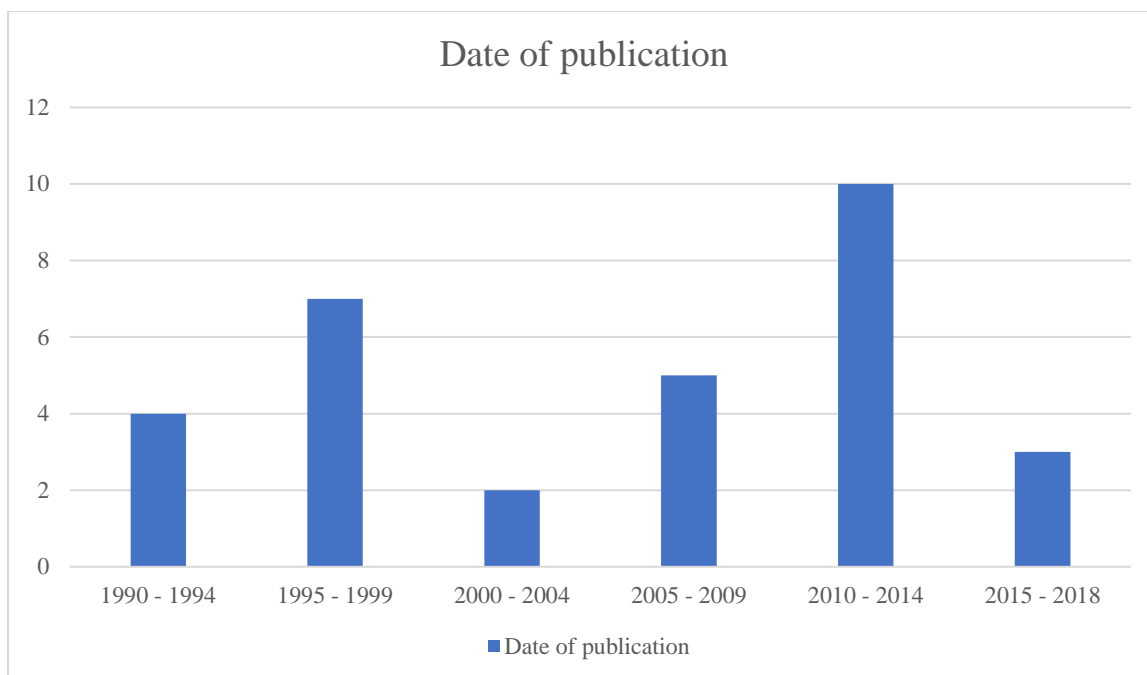


Figure 2: Date of publication

Fifteen different countries were represented in the publication of the included articles. India had conducted seven articles (23%) and the USA five articles (16%). Ten of the countries only published one article each, including South Africa. Eight countries are classified as high-income countries, four as upper-middle-income countries and three as lower-middle-income countries. Seventeen articles (55%) were published in high-income countries and fourteen articles (45%) in low- or middle-income countries. Table 3 summarises further information on the countries of publication.

Location	Number of articles	Percentage of articles	Income classification
India	7	23%	Lower-middle
USA	5	16%	High
UK	4	13%	High
Japan	3	10%	High
Turkey	2	6%	Upper-middle
Australia	1	3%	High
Bangladesh	1	3%	Lower-middle
Brazil	1	3%	Upper-middle
Czech Republic	1	3%	High
Germany	1	3%	High
Netherlands	1	3%	High
Nigeria	1	3%	Lower-middle
South Africa	1	3%	Upper-middle
South Korea	1	3%	High
Thailand	1	3%	Upper-middle

When examining the continents represented in publication of the studies, researchers from Asian and European countries published the most articles with thirteen (42%) and nine (29%) respectively. African countries only published two articles included in this scoping review. This data is represented in Figure 3.

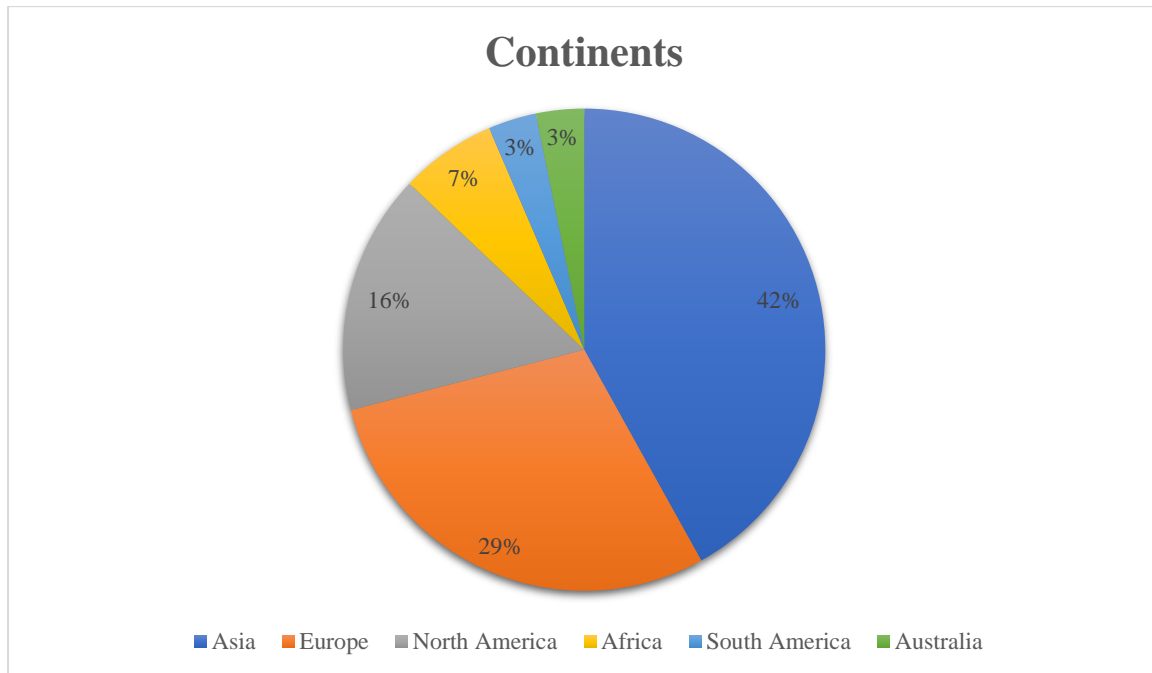


Figure 3: Continents

Seven different methodologies were utilized in the included studies. The most frequently used were randomized control trials, with twelve (39%) articles, and single case studies, with nine (29%) articles. All methodologies are illustrated in Figure 4.

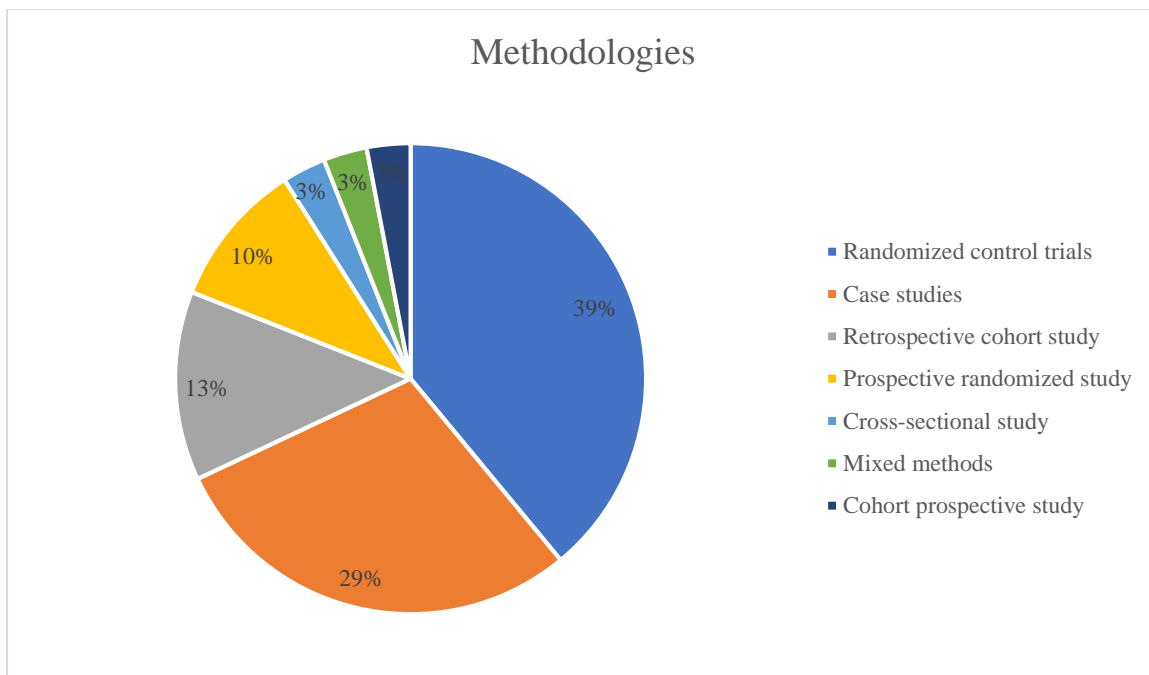


Figure 4: Methodologies

The timing of feeding intervention, in relation to corrective craniofacial surgery, were referenced in the scoping review articles. The majority (61%) of the interventions occurred before corrective surgery. Some articles included longitudinal studies where feeding intervention was studied before and after surgery. The results are presented in Figure 5.

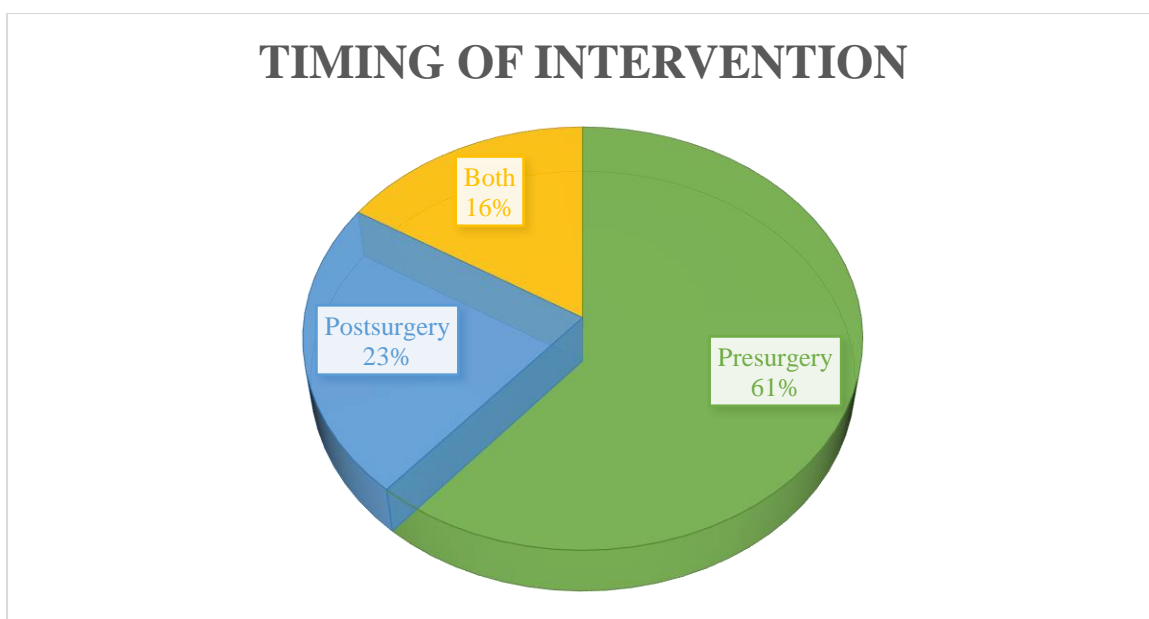


Figure 5: Timing of Intervention

4.2 Content analysis

Ninety-one references to feeding intervention were made in the articles. Some studies compared different methods of feeding intervention when more than one reference was recorded. Most studies combined different types of feeding intervention.

Firstly, the interventions referenced in the articles were coded individually. The codes were then summarized and grouped into themes according to similar types of intervention. Four categories were formulated from the content of the articles, namely: feeding utensils, parent/caregiver training, prosthesis, and alternative feeding. Table 4 summarises the type of intervention and frequency of the intervention recorded.

Type of interventions	Frequency reported (%)	Outcomes
Parent/caregiver training	43%	Feeding efficiency Not enough intake No improvement
Feeding utensils	40%	Feeding efficiency Comparing interventions Improved intake Weight gain No improvement
Prosthesis	14%	Feeding efficiency Improved intake Weight gain Ease of feeding Less feeding fatigue No improvement Not enough intake
Alternative feeding	3%	Comparing interventions Ease of feeding

Parent or caregiver training included any type of instruction or training given to the parent on how to feed their baby, such as breastfeeding education, oral hygiene, feeding strategies, and positioning of the baby during feeding. Parent or caregiver training accounted for thirty-nine (43%) of the codes. Training in the use of feeding strategies were represented in sixteen (46%) of the codes and breastfeeding education in nine (23%), which represented the most codes within the parent or caregiver training category. Positioning of the baby during feeding only accounted for nine (23%) of the codes within this category. Figure 6 demonstrates the distribution of codes in this category.

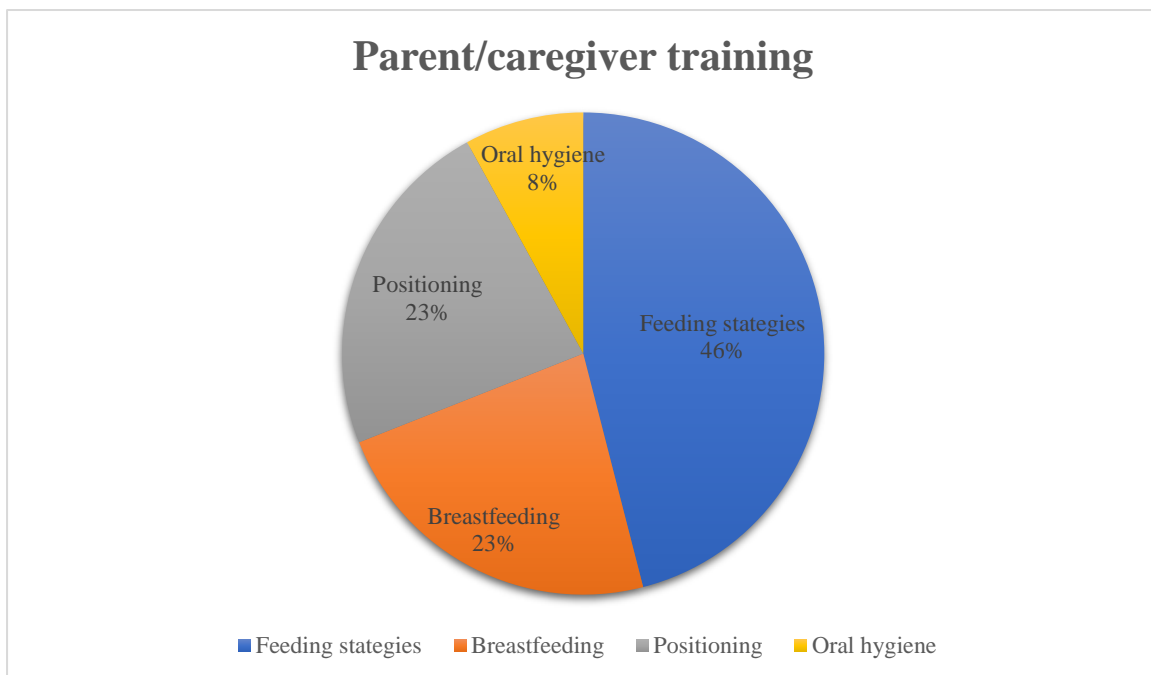


Figure 6: Parent/caregiver training

Feeding utensils included any type of external utensil given to the patient to improve their feeding. This included bottles, modified bottles, cups, spoons, and syringes. Feeding utensils had the second most codes with thirty-six (40%). Modified bottles were coded twelve (33%) times and regular bottles ten (28%) times, accounting for two-thirds of the codes under feeding utensils when combined. Using a spoon was coded six (17%) times. The use of a cup was only referenced five (14%) times. Figure 7 demonstrates the distribution of codes in this category.

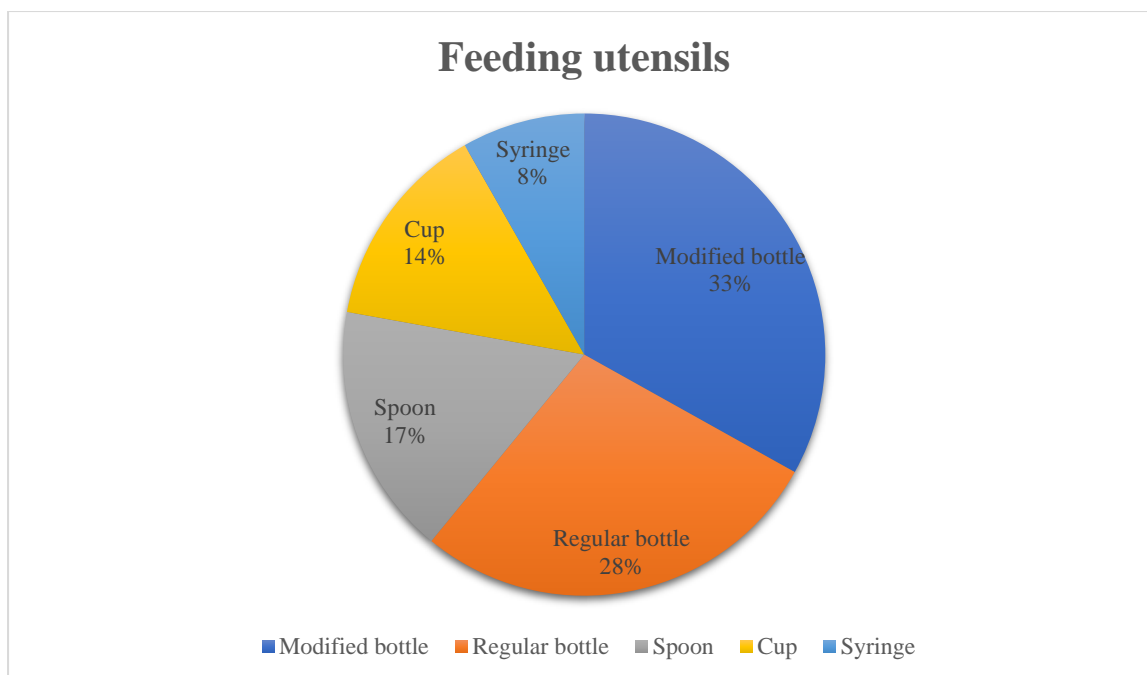


Figure 7: Feeding utensils

The use of a palatal obturator to overcome feeding difficulties was grouped under prosthesis, as it is the only prosthetic-type device mentioned in the studies. Prosthesis use covered thirteen (14%) of the total codes for intervention. Prosthesis use as an intervention method is the only referenced intervention that had seven different types of outcomes across the studies. Most studies said that the use of a palatal obturator showed improvement in feeding efficiency, but three studies made reference to either no improvement or not enough intake.

The use of a nasogastric tube for feeding was categorised as alternative feeding because it is an alternative method to typical oral feeding methods. Three (3%) of the total codes for intervention were for alternative feeding. Comparing interventions and ease of feeding were the only two outcomes referenced in the studies.

Forty-nine references were made to associated outcomes within the texts. The classification of the outcomes was created by the common themes referenced in the texts of the articles. The specific outcomes were coded in the same way in which the interventions were coded. For the studies comparing different interventions, the preference of intervention was the outcome and the outcome type was coded under comparing interventions. For the other studies looking at a specific intervention, each outcome referenced had their specific category related to either a positive outcome or a negative outcome. The specific outcomes which were positive included

“improved intake”, “improved feeding efficiency”, “weight gain”, “ease of feeding” and “less feeding fatigue”. “No improvement” and “not enough intake” were the only specific negative outcomes. Table 5 details the specific outcomes that were either positive or negative and their related intervention themes.

Specific outcomes	Examples from text	Intervention themes
Feeding efficiency	<ul style="list-style-type: none"> - Improved sucking - Effective feeding - Safe to feed - Decreased feeding duration 	Feeding utensils Parent/caregiver training Prosthesis
Improved Intake	<ul style="list-style-type: none"> - Less spillage - Less coughing - Increased volume of intake 	Prosthesis Feeding utensils
Weight gain	<ul style="list-style-type: none"> - Improved weight gain 	Prosthesis Feeding utensils
Ease of feeding	<ul style="list-style-type: none"> - Easier for parents - Easier for infant 	Prosthesis Feeding utensils Alternative feeding
Less feeding fatigue	<ul style="list-style-type: none"> - Less fatigue during and after feeds 	Prosthesis
No improvement	<ul style="list-style-type: none"> - No difference in weight gain 	Prosthesis Parent/caregiver training Feeding utensils
Not enough intake	<ul style="list-style-type: none"> - Need supplemental feeds 	Prosthesis Parent/caregiver training

Better feeding efficiency was referenced fifteen (31%) times in the articles. This included any type of commentary referring to more efficient feeding, such as improved sucking or safe feeding. The different intervention themes that had better feeding efficiency as an outcome were different feeding utensils, parent or caregiver training, and prosthesis.

Improved intake was covered in six (13%) of the total codes for outcomes. The type of references grouped under improved intake were less spillage, less coughing, and increased volume of intake. Weight gain was covered in five (11%) of the total codes for outcomes. This outcome referred to infants gaining weight after using the chosen feeding intervention. Ease of feeding referred to the method of feeding being easier for the parent or for the infant with CLP. Four (8%) codes were recorded under ease of feeding. One (2%) reference was made to less feeding fatigue.

Negative outcomes reported in the articles were either no improvement or not enough intake of fluids. No improvement was coded four (8%) times and not enough intake two (4%) times.

Most types of intervention referenced at least two of the abovementioned outcomes as a result of their feeding intervention. The use of a prosthesis had seven listed outcomes and only 14% of references were made to a prosthesis as type of feeding intervention in the CLP population. Figure 8 details the frequency of the different outcomes referred to in the studies.

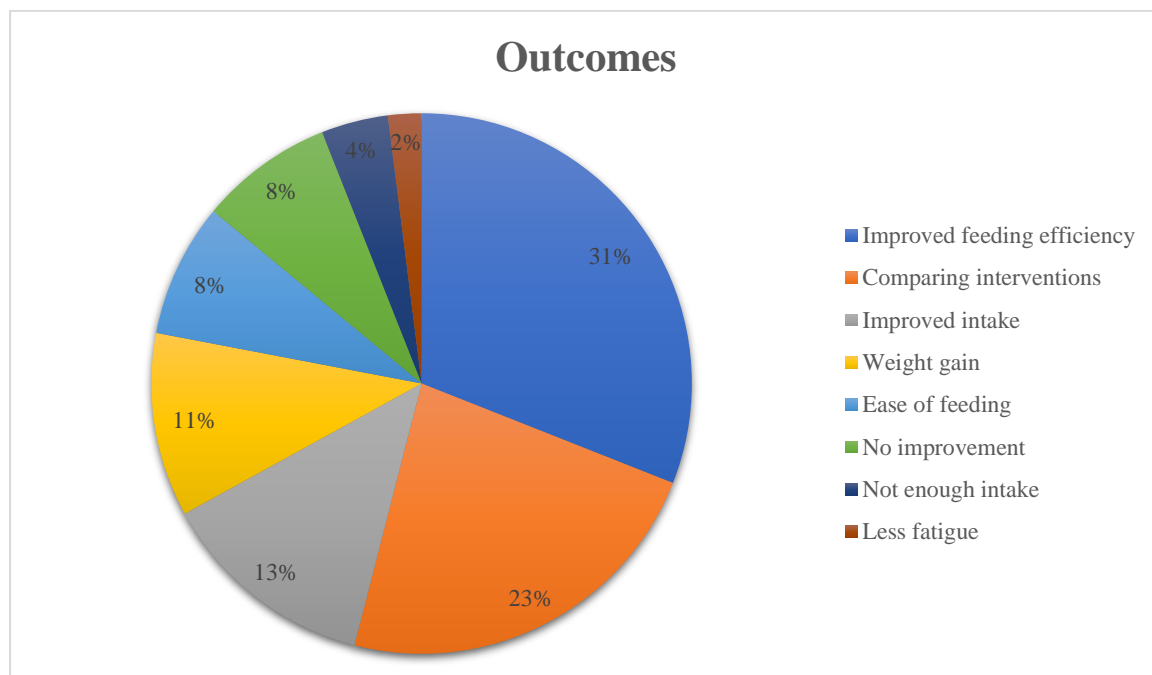


Figure 8: Outcomes

The comparison of different feeding utensils or different feeding methods was coded eleven (23%) times, representing the second most frequently referenced outcome. This category included any study that referred to comparison between two or more feeding utensils or methods which stated that one had more favourable outcomes than the other. These mainly included different types of bottles or teats and other utensils, such as a cup or a spoon. Some studies revealed the same outcomes between the different feeding utensils, such as different specialized bottles. However, other studies comparing bottles indicated a preference, such as the squeezable bottle over a rigid bottle. Caregiver training in the use of feeding strategies had a more preferable outcome than having only a specialized bottle for feeding without training. Feeding with a syringe was favoured in one study but in another study it was not. Each study that compared two or more feeding interventions are presented in Table 6.

Table 6: Comparing interventions outcomes	
Comparing interventions	Outcome preference
Different squeezable bottles	Same outcomes
Squeezable bottle versus rigid bottle	Squeezable bottle
Breastfeeding versus spoon feeding	Breastfeeding
Squeezable bottle with long, narrow nipple versus bottle with cross-cut nipple	Same outcomes
Bottles: Type-P nipple (wider and longer) versus standard nipple	Type-P
Syringe versus cup and spoon	Syringe
Syringe versus bottle and breastfeeding	Bottle and breastfeeding
Post op feeds with bottle or NG	Nasogastric tube feeds
Bottles: Regular NUK versus Cleft NUK	Regular NUK bottle
Bottle feeding (cross-cut nipple): caregiver training versus no training (e.g. feeding strategies).	Caregiver training
Cup (Paladai) versus bottle versus spoon	Cup

The interventions studied had many different outcomes. Overall, more positive outcomes than negative outcomes were reported. The studies comparing interventions confirmed which interventions had better outcomes than others.

4.3 Results of consultation

Semi-structured interviews were held with five speech and language therapists who had experience with intervention of feeding difficulties in the CLP population. Participants who met the inclusion criteria were included in the study after consent to participate was gained. Three interviews were carried out telephonically and two were in person. The interviews lasted no longer than 75 minutes. Varied years of experiences in the field of speech therapy were represented in the participants. Two of the participants had volunteered for Operation Smile on missions in Africa. This gave them an African perspective on CLP feeding intervention and not just a South African perspective. Table 7 details the biographical information of the included participants.

	Place of work	Province	Years of experience
Participant 1	Tertiary Hospital	Western Cape	8 years
Participant 2	Tertiary Hospital	Western Cape	30 years
Participant 3	Tertiary Hospital and volunteer on Operation Smile missions	Gauteng	15 years
Participant 4	Tertiary Hospital	Western Cape	20 years
Participant 5	Provincial Hospital, clinics and volunteer on Operation Smile missions	Western Cape	3 years

Themes

Different themes relating to feeding interventions and outcomes of patients with CLP, explored in the scoping review findings, were discussed during the interviews. The findings from the consultation stage of the scoping review are represented in four themes: 1) available research, 2) feeding management, 3) feeding utensils and 4) personal and environmental influences. A summary of the themes and subthemes are represented in Table 8 below.

1) <u>Available research</u> - Practice-based evidence - Limited research in South Africa
2) <u>Feeding management</u> - Caregiver/feeder training - Positioning
3) <u>Feeding utensils and prosthesis</u> - Bottles - Cup - Feeding obturator
4) <u>Personal and environmental influences</u> - MBFI - Low- and middle-income countries - Resources

Theme 1: Available research

The participants were asked about their opinions on the availability of research in CLP feeding intervention and what type of research influenced their practice. Whether they relied on

evidence-based research to inform their clinical decision making or more on their own experience was a point of discussion. Possible ideas for future research in South Africa were discussed as well. The common subthemes under available research were practice-based evidence and limited contextually relevant research in South Africa.

a) Practice-based evidence

Some participants were more inclined to use practice-based evidence as opposed to evidence-based practice when it came to CLP feeding intervention. They valued and relied on their clinical expertise to guide them in deciding which feeding intervention to use.

“You know there’s that whole thing of evidence-based practice and practice-based evidence and how they influence each other. So out of my practice I can see the evidence that’s there is working yes. Because I can’t think of new ideas and evidence to deal with a cleft relation.” (P1).

“And so, a lot of it is more practice-based evidence. Not evidence-based practice from reading. It’s more practice-based evidence. Does it work? You know if something happens and I can’t make with what I have available for me work, then I’ll see if I can find something in the literature to say what else can I do.” (P3).

b) Limited research in South Africa

The participants reported that there was an adequate amount of research available on CLP feeding practices. However, limited studies had been conducted in the South African context where they work. Participant 3, 4 and 5 conveyed that the location of the studies published can influence the practice. Having research in their clinical setting could potentially aid in using more applicable feeding interventions for their patients.

“Developing countries there’s not much research done. Partly because there’s not so many therapists there.” (P3).

“For South Africa, I think. So, I think a lot of the research is done in first world countries, as with all speech therapy research, and it’s not always relevant to the child that lives down the road. It’s a different approach when you can see someone every day and they can come into your sessions. And they have access to care. Or you can go into their home and you can sit

with them for a couple of hours. So, I think in South Africa the evidence-based research is very limited.” (P4).

“And there isn’t a lot of research done on the CLP patients in say the district that I’m working in. In my area or in the Western Cape even. Most of the research is coming from other countries. I think it’s quite important to get research from your specific area because patients differ everywhere. And we can’t just generalize. We’re just using the research that already exists as a guideline for the patients that we are seeing here.” (P5).

Theme 2: Feeding management

The success of the feeding management of an infant with CLP relies on how well the caregiver or the person feeding the child is applying the techniques taught by the therapist. Different feeding strategies and recommendations were discussed. The common subthemes that were discussed were caregiver training and positioning.

a) Caregiver training

The parent, caregiver or whoever feeds the baby, must be shown how to feed the infant or child with CLP by the therapist. The therapists agreed on the importance of demonstrating how to feed and then helping the feeder to do it themselves. This ensures that the infant with CLP can be fed at home.

“So, I will demonstrate show her and I put water in the bottle, and she’s got to squeeze a bit. We talk about positioning and not to hold the baby up like they would normally. Semi recline in front so that they can see us. When you are pushing you could see the little bubbles coming out. And then the same I let her do it. And I might assist her a little bit.” (P2).

“Ja so again I’ll see what happens when mom feeds or whoever feeds the baby. What does she do? Is it working or not? If it’s working, fantastic.” (P1).

“And it’s important to show and demonstrate and make sure that the parents do it themselves in front of you because you think it’s easy to squeeze but actually, they’re confused.” (P1).

b) Positioning

Part of the feeding management involves showing the caregiver the position in which to hold the infant with CLP while feeding. It is important for all cleft classifications and a standard recommendation that all therapists mentioned. A semi-upright position was consistent in the discussions.

“It’s something that’s routine that there’s not other positions. You tend to hold a baby in semi recline. Just so that there’s a little bit of gravity. I tend to not hold them up close because you want to see if you squeeze too much you want to see drooling. You want to see flow. So, I just say to moms I get them to sit like this that there’s some support for the head.” (P2).

“So, my hand is tucked under their bottom and then they rest up against my arm with their heads in the crook of my elbow, so they are as upright as possible, and cup feed them. And usually by the end of the first feed the babies have got the hang more or less. Sometimes they sit and feed.” (P3).

“Okay so when they’re small, well obviously usually when they’re small, it’s semi upright position (about 45 degrees). So, they mustn’t be lying flat. We hold them semi upright and we support the chin where necessary. Pretty much that.” (P4).

Theme 3: Feeding utensils and prosthesis

Different types of feeding utensils are being used with the feeding of infants with CLP. The most common utensils that were discussed in the interviews were bottles and cups, as well as palatal obturators as a prosthesis. The participants discussed what utensils or prosthesis they prefer and which utensils they do not use.

a) Bottles

A common theme that was discussed was the use of squeezable bottles. Participant 1 and 4 both advocated for the use of different kinds of bottles as the main feeding recommendation at their hospitals. Participant 2 reported that the type of bottle will not make a big difference and that it was more important to consider how well the person is following the therapist’s guidance on how to feed the CLP baby:

“And then the Medela, the Haberman, The Cleft Palate, there are a lot of ones. So, they say there’s no difference between them. It’s about the fact that you’re assisting putting the milk in. And if they get their technique, whatever it is.” (P2).

“Ideally basically any bottle that can squeeze. So, if it’s a R20 bottle from Dischem and it can squeeze the milk out it’s perfect.” (P1).

b) Cup

When breastfeeding is not possible, cup feeding with expressed breastmilk is recommended. Participant 3 advocated for cup feeding as one of the best methods to feed a CLP baby. The rest of the participants also used it as an option to feed their patients with CLP.

“You know I’m very pro cup feeding and seeing how well it works. How easy it is. It’s really just the mums following the baby’s cues. All she has to do is simple cueing. All she has to do is keep the milk at where the tongue can reach it.” (P3).

c) Feeding obturator

During the interview, participants were asked about their opinions on the use of palatal obturators to compensate for a cleft palate in order to improve feeding. Most participants reported that they did not recommend it at their facility as it requires frequent follow-up and they had not seen improvement in feeding efficiency.

“It’s not used mainly because of the high follow-up. Like it’s a big so when do you use it? When baby is usually or often in babies like a feeding obturator or something. But babies grow so fast. So, you need frequent follow-ups.” (P1).

“Those plates you would have to have an orthodontist on tap. There’s a burden of care because they’ve got to change as the baby changes. And so, if it’s a plate for feeding, then it’s of no value.” (P2).

A common theme from the interviews was that the participants felt that a palatal obturator does not improve feeding of an infant with CLP. In fact, it could result in a negative outcome.

“I don’t but there’s evidence for it. Because as I’ve said it doesn’t help to normalize feeding. All it does it might give a bit of roof to the hard palate, but the soft palate is still open. They still can’t breastfeed.” (P2).

“It’s not something that I would recommend. No, I actually recommend against it because of the readings. You know because of what I’ve read about them not being effective in terms of feeding and never having a problem with getting a baby to feed without one. For me they’re a waste.” (P3).

Theme 4: Personal and environmental influences

The feeding management, including parent or caregiver training, positioning and the use of feeding utensils, are influenced by personal and environmental factors that impact the clinical practice in the settings where the therapists work. According to the ICF (WHO, 2007), personal and environmental factors form part of contextual factors that should be taken into consideration when planning treatment. The common subthemes that were discussed regarding the South African context were: MBFI policy, low- and middle-income countries and resources.

a) MBFI policy

Where Participant 1 and 4 both advocated for the use of different kinds of bottles as the main feeding tool in their hospitals, the other participants were more in favour of breastfeeding and cup feeding practices. Participant 2, 3 and 5 all worked at facilities that are MBFI certified. Thus, hospital policy prevented them from using bottles.

“You can spoon feed them. You can syringe feed. You can cup. Now most of the hospitals are baby friendly. So, cup feeding is perfect. And they do just as well as others and they say don’t worry about this. It’s not harmful.” (P2).

“Yeah no we’re not because we’re a baby friendly hospital. You know cup feeding. If the mums can’t breastfeed, they have to cup feed. And so, the hospital provides them with these feeding cups.” (P3).

b) Low- and middle-income countries

Taking into consideration patients' geographical location has an influence on the subsequent feeding management decision making. Bottles need to be cleaned and sterilized. In the South African, as well as African, context this is a health risk as some of the patients do not have access to clean water nor electricity to boil water. Bottles frequently need to be replaced as well which results in increased expenses for the parents, who might not be able to afford it. If hospitals and clinics had enough bottles for each baby, it is still not cost-effective to give out bottles to each patient as they would still need to be replaced.

“And we are wanting the moms to avoid all the hygiene issues of bottles of cleaning them. So many of the mums are low socioeconomic status. They live in squatter camps and don't have access to electricity or boiling water. And more for electricity access issues are big ones for them.” (P3).

“Well I work in a Baby Friendly hospital. They prefer for us to use cups instead of bottles just because it is more hygienic.” (P5).

c) Resources

The types of resources available to therapists will influence what feeding utensils they recommend. Adapted feeding bottles can be costly for the patient and the healthcare institution providing them. Some participants advocated for the use of bottles, but it could be a cheaper squeezable bottle from the supermarket. One of the reasons why Participant 3 did not give out or recommend bottles for feeding with her patients with CLP, is because of the high cost.

“You know the bottle feeding in terms of just not having bottles available in the hospital. Not having had access to them being in a public sector hospital and not having access to bottles you just sort of say well I can't get the bottles. So, I'll try with what I can with what is available.” (P3).

“So, if you could find a Shoprite bottle that's very soft and a nice soft silicone teat. And you could tell the mom to make the cut in the teat a bit bigger. And she can manage with that. It's not very expensive. It's maybe something she would've purchased anyway. So not too high tech.” (P4).

4.5 Summary

Feeding interventions reported in the studies and feeding interventions used by speech therapists both corresponded and differed. Caregiver training was widely reported in both, while feeding utensils differed. Cup feeding was preferred by most of the speech therapist, but little research has been published on the use of cup feeding in CLP populations. Important aspects from both the research and the consultation are highlighted in Table 9.

Feeding interventions	Research	Consultation
Caregiver training	Most references (43%)	Most references
- Feeding strategies	46% in caregiver training	Very important part of intervention
- Positioning	23% in caregiver training	Part of all interventions when demonstrating how to feed.
Feeding utensils	Second most reported (40%)	Relies on resources available
- Bottles	33% modified bottles 28% regular bottles	If they use bottles, preference to squeezable bottles
- Cup	14% in feeding utensils	Preferred by most participants. Good outcomes
Prosthesis: feeding obturator	Evidence for and against using a feeding obturator	Not preferred in South Africa

The results from this scoping review displayed that the intervention and associated outcome themes from the studies and the themes that were discussed in the consultation with speech therapists have similarities and differences. Caregiver training had the most references in both research and consultation. Intervention types that were more favourable in the research were not necessarily more favourable in the interviews. The research studies favour feeding intervention with certain feeding utensils, such as modified bottles and regular bottles. In contrast, the interviews showed more support for cup feeding practices with infants with CLP. Both positive and negative outcomes were related to different intervention themes. Using a feeding obturator to improve feeding difficulties has research showing positive as well as negative outcomes, whereas the interviews conveyed that it is not commonly recommended in South Africa. The context in which the research was conducted, when considering the majority

of studies published in high-income countries, as well as the context where the speech therapists work had an influence on the intervention types studied and practiced.

CHAPTER 5: Discussion and Clinical Implications

The goal of this study was to determine the available evidence-based research on the management of feeding difficulties in the CLP population and the associated outcomes thereof. A scoping review was used to summarize available literature on CLP feeding management in terms of intervention strategies and the associated outcomes, as well as to identify research gaps in the evidence base of feeding management in the CLP population. The studies sourced during the scoping review process were summarized according to numerical data as well as themes. During the last stage of the scoping review, semi-structured interviews were held with experienced speech therapists on how they treat their CLP feeding patients.

The initial literature search yielded 3258 articles and, after various levels of screening, only 31 articles were included in this scoping review about feeding intervention in the CLP population. This is a small number considering that the articles sourced are dated between 1990 and 2018 and 5 electronic databases were used to obtain the studies. The research is outdated as only three articles have been published since 2015. One might argue that some interventions are standard and that there is nothing new to be studied for that specific intervention. Another reason could be that the type of research published recently was not appropriate for this review because of how the information was presented. Other types of reviews and articles from academic journals with no original research were not included, such as letters to the editor. Looking at the studies included in this scoping review, little research is available on this subject and on different types of evidence-based research in the field.

The predominantly used methodology in the included articles was randomized control trials. However, this methodology was utilized in only twelve articles of the 31 articles. Randomized control trials have been perceived as one of the high ranking methodologies to evaluate medical research (Ratner, 2006). Thus, when looking at evidence-based practice, randomized control trials can provide valuable information to inform clinical practice. Single case studies were the second most used methodology in the included articles. Case studies are singular and cannot be generalized to a population like infants with CLP. This suggests a gap in the evidence base for CLP feeding intervention. Having studies with more subjects, who show positive as well as negative outcomes, is important for speech therapists in order to make clinical decisions regarding which evidence-based practice to use, or not use, with their patients.

More than half of the studies were published in high-income countries. This agrees with the therapists' views that research is focussed on high-income countries where there are more resources, therapists and funding available, which will significantly impact intervention. This is significant as the research published might not be applicable to the healthcare settings in upper-middle-income countries such as South Africa. Speech therapists are then compelled to base their feeding intervention on Westernized practices in an African context. An aspect to consider could be the availability of healthcare across South Africa.

A possible barrier to CLP care in South Africa, and other low- and middle-income countries, could be the lack of healthcare professionals in relation to the number of patients. The therapists reported that there is a lack of research in their clinical contexts in Africa and South Africa. This study reviewed limited research published in Africa. Only one article was published in South Africa and one article in Nigeria. The challenges in healthcare services across low- and middle-income countries are similar but can be different in certain aspects. Each country has their own cultures and unique contexts which could influence healthcare service delivery in general. Therefore, having research available from South Africa will ease the translation to clinical practice in South Africa.

A reason for the lack of research in Africa could be an indicator of a lack of therapists who practice in those countries and, therefore, influencing the availability of healthcare for the patients. The environmental factors in the ICF framework refer to factors in the patient's environment that could affect the intervention (WHO, 2007). The availability of speech therapists in different areas of South Africa can be an environmental factor to consider. If there are not enough practicing speech therapists for the number of patients, then their interventions might look different to those of a therapist in a high-income country.

During the interviews, some of the therapists mentioned that they often see their patient with CLP for feeding management only once, as some patients live far away and cleft clinics are not run daily at their hospital. Follow-up by speech therapy and audiology services have been known to be poor in low- and middle-income countries (Furr et al., 2011). A possible solution to this barrier could be to support the patient and their family in their ability to feed their child at home, so that they are not dependent on frequent follow-up visits to the clinic. The duration of the appointment could then be longer in order to include assessment of the feeding difficulty, recommendations of feeding utensils and strategies, as well as to allocate time to assess how

the parent is feeding the infant after recommendations and explicit instructions have been given. During the interviews, the therapists placed emphasis on demonstrating and letting the parents do the feeding in front of them so that they could help them to adjust, if necessary. A functional feeding method needs to be established with the parent to ensure that they can feed their infant on their own. The first contact with the patient is thus important to implement a feeding management plan which is sustainable for the patient and their family.

Availability of speech therapists and distance to speech therapy services still pose a barrier to care in South Africa if the patients need follow-up feeding intervention. Speech therapy services should be available at primary healthcare level in South Africa to ensure better access to feeding intervention. If these services are scarce or not available, nurses in the primary healthcare clinics could be trained on what the warning signs are for feeding difficulties, what basic strategies they could give the patients and families to help, and when they need to refer to a speech therapist. This could reduce the number of patients with minor feeding issues that the speech therapist needs to see, and provide faster medical intervention for the patient with limited accessibility to such specialized services.

Another environmental factor in South African healthcare that could influence intervention, is language. Having 11 official languages in South Africa, it is impossible for every speech therapist to be able to provide services in all languages. An interpreter is one option to overcome a language barrier. The patient's family could then understand what the intervention entails in their own language. Their questions, comments and answers could also then be translated for the therapist to understand and respond to. However, interpreters might not be available in all clinical settings. Another disadvantage in the case of feeding intervention is the personal nature of feeding your child in front of a stranger. Feeding an infant, especially when breastfeeding, is a very personal experience between the mother and her baby. Having an interpreter in the room, who they do not know and who is not a healthcare professional, could make them feel uncomfortable.

Another alternative to overcoming a language barrier in the healthcare setting, could be to design and give out pamphlets on feeding infants with CLP. With the help of translation services, the pamphlet could be made available in many languages. In South Africa, however, only 93,9% of youth and 78% of adults are literate (Statistics South Africa, n.d.). The pamphlet should thus be accessible to illiterate people as well. This can be done by providing pictures of

the different feeding strategies and instructions. For example, a picture of the correct positioning when feeding could be provided alongside the text. Having a pamphlet to take home will allow the family to share the information with others and to go back to the information if they forget or needs clarification. In this manner the healthcare information becomes accessible to more people.

The context of evidence-based practice in South Africa should be considered when looking at feeding intervention for infants with CLP. It is important to recognise that evidence-based healthcare consists of three different components: the best external evidence for the chosen therapy, the patient's values and expectations, and the clinical expertise of the clinician providing the therapy (Mccurtin & Roddam, 2012). During the interviews, the therapists expressed that they predominantly used practice-based evidence as opposed to evidence-based practice. Being experienced therapists, they felt that their experience was more valuable than the available research, when deciding on CLP feeding intervention. Having found a limited number of appropriate research in this scoping review on the topic of feeding intervention in the CLP population, one can understand why practice-based evidence is happening in South Africa. This is not necessarily a solution to the limited amount of research, but it can benefit the service being provided as it could be based on the specific population in that specific context receiving the feeding intervention. Consequently, the barriers to CLP care in South Africa can be taken into consideration when deciding on a treatment plan.

In several low- and middle-income countries where CLP surgery cannot be provided, or sufficiently provided, healthcare professionals from high-income countries visit as part of a multidisciplinary team funded by organisations dedicated to CLP healthcare, such as Operation Smile and Smile Train. Therapists could be giving intervention as part of a CLP outreach visit, providing corrective surgery and multidisciplinary care. However, they may not have the time to do research in those countries when they are not living and working there permanently. More research is needed in the context of low- and middle-income countries, such as South Africa, to take into consideration the specific context and needs of the population that is being served. The patients coming to public healthcare facilities in South Africa cannot afford expensive treatments nor expensive feeding utensils.

Summarizing the available literature on CLP feeding intervention was an objective for this scoping review. With feeding intervention in the South African context, training of the parent

or family members becomes the basis of the feeding intervention given and the therapists agreed with this statement. It could be that this intervention was reported the most because it is a broad theme with different types of feeding strategies and education that could form part of the intervention. Usually the infants with cleft lip, and other minor facial clefts, can have successful feeding with breastfeeding if the mother is taught how to feed the infant and how to position the infant during feeding. Thus, no other interventions are then required. Infants with CLP might need more than just the training of the caregiver to improve feeding.

Most of the studies that included a form of caregiver training showed positive outcomes, such as improved sucking and decreased feeding duration. The therapists agreed with this finding that the training of the caregiver in feeding the infant with CLP has more favourable outcomes. This follows a logical argument that the caregiver will be the one continuing the feeding at home, when the infant with CLP is discharged from hospital. If the caregiver feels confident in applying feeding strategies taught by the therapist, then it should lead to positive outcomes. In the context of South Africa, where patients do not come for regular follow-up visits and sometimes come only once for feeding intervention before corrective surgery, the training of the caregiver becomes an integral part of the treatment plan. Having positive outcomes, according to the research, for caregiver training, demonstrates that it is successful and should be applied in clinical practice. One of the feeding strategies often taught by therapists, is the positioning of the infant with CLP while feeding.

It was evident, during the interviews, that positioning is an important aspect in feeding management, but this was not reflected in the review as very few of the studies refer to it as a management strategy. The positioning of the infant with CLP while feeding was never the main focus of a study but rather part of a treatment plan in the included studies. It was expected that this type of intervention would be more widely published, as it is an important part of CLP feeding management. However, the positioning of the infant with CLP is not a new phenomenon in feeding intervention and will most likely not change soon. Regardless of the feeding utensil used or if the infant is being breastfed, the positioning of the infant will stay the same. To prevent nasal regurgitation, the infant with CLP must always be positioned semi-upright (Burca et al., 2016). During the interview, the therapists noted that there are no other positions and that it is a routine recommendation to have the infant with CLP in a semi-upright position whilst feeding. It could be that the authors who published the articles believe that the

correct positioning of the infant with CLP during feeding is a given and that other aspects of CLP feeding need to be reported in their research, such as different types of feeding utensils.

The prescription of different feeding utensils for infants with CLP, to compensate for feeding difficulties, is a recurring theme in the research. It could be that because of the country where the research occurred that more research has been published on feeding utensils used in those countries. The bottles used in the studies were mostly adapted feeding bottles, such as a Haberman feeder or a Medela bottle. These types of bottles could be more accessible in high-income countries where there is funding to procure them for patients. However, the therapists' interviews indicated that a squeezable bottle to squeeze the milk into the infant's mouth is sufficient. One of the studies compared squeezable bottles versus rigid bottles and the mothers preferred the squeezable bottle because it was easier to use (Shaw, Bannister, & Roberts, 1999).

A squeezable bottle can be bought in a supermarket and costs less than a modified bottle. However, bottles also needed to be replaced after a period of use, making it less sustainable. Hospitals would need sufficient stock of bottles to issue patients more than one bottle. Even if the hospitals had enough bottles to issue, it is not sustainable as the patient would need to come for more follow-up appointments. In Africa, patient follow-up visits have been seen as a significant barrier to cleft healthcare (Massenburg et al., 2016). This could be due to travel costs and distances to the hospital. The use of bottles in this context brings other challenges as well, such as hygiene. Fortunately, other feeding utensils are available to be used as an alternative to bottles, such as a cup.

Cup feeding with infants with CLP is not well-represented in the research. New interventions are still being sought, especially in low- and middle-income countries, such as a paladai cup, which is an exclusive feeding cup made of metal with an extended spout that is used in India. (McKinney et al., 2016). Infants with other medical conditions, such as low birth weight and prematurity, who have feeding difficulties are fed with a cup as per the South African Infant and Young Feeding Policy (Department of Health, 2013). As seen with other feeding interventions, not enough research has been done to be able to generalize the findings. During the interviews, most of the therapists were more in favour of cup feeding than bottle feeding for their patients with CLP. Although there is little research on cup feeding within this population, using this method takes both the patient and their environment into account when providing feeding intervention. Consequently, this is still contributing towards evidence-based

practice by incorporating clinical expertise and the patient's expectations. In the South African clinical context, hospital policies such as MBFI is a factor that influences the distribution of feeding cups.

In South Africa, certain hospitals and clinics fall under the MBFI regulations which explicitly state that no bottles can be given out at the facility (WHO & UNICEF, 2009). This includes infants with CLP and other craniofacial syndromes. The MBFI promotes breastfeeding as the best method of feeding a baby. The clinical implication of such policies is that the patients who are treated at MBFI facilities, will not be allowed to use bottles to feed their infants and will most likely be encouraged to breastfeed. Most infants with a cleft lip can breastfeed with the correct positioning. The therapists stated that they rarely see cleft patients to help with breastfeeding as the ones that they see have either already tried breastfeeding or have a more severe cleft classification than just a cleft lip. In the event that the infant cannot breastfeed, the alternative options of feeding utensils available, to give to the patients with CLP, can be based on the MBFI policies implemented by the hospital or clinic.

The MBFI policies are very strict and can potentially make it difficult for infants with CLP to feed alternatively. The therapists who work in MBFI facilities, expressed that the MBFI policy has not negatively influenced their practice. They give out what is available, which are often medicine cups, to be used for feeding. An acceptable alternative to breastfeeding when, for some reason the mother cannot breastfeed, is cup feeding with expressed breastmilk. One of the therapists felt very strongly about cup feeding being the better feeding alternative opposed to bottle feeding, especially in the African context. Clearly the policy of the institution as well as the environment of the patient influenced the practice more than the research as there are not many studies on cup feeding in the available literature and no studies on cup feeding in South Africa with infants with CLP. The clinical implication is that practice-based evidence then becomes the motivation for the feeding intervention rather than evidence-based practice.

Feeding with a spoon or a syringe was not a main theme under the studies nor with the interviews. Of all the feeding utensils recorded in the studies, spoon and syringe had the least references. In the studies it was used in conjunction with other utensils or compared to different feeding utensils. Once again, the availability these utensils to be issued for use at home might have an influence on if they are utilised in practice. It could be that feeding with a spoon or a syringe will take longer than feeding with a cup or bottle, as the baby can take larger sips at a

time and cups and bottles can take larger volumes of milk. Different utensils can still be used with different patients, depending on the severity of the cleft, while waiting for corrective surgery.

The use of a feeding obturator to close the cleft palate for feeding was another method of feeding intervention reported in the review. It is interesting to note that the outcomes reported in the studies were conflicting: some studies showed positive outcomes such as weight gain while others reported no improvement in feeding. During the interviews, all the therapists' stated that feeding obturators were not recommended at their hospitals or clinics because of the frequent follow-ups needed, as well as due to seeing no improvement in feeding efficiency. The craniofacial team would then require having an orthodontist to fit the feeding obturator and be available for frequent follow-up visits as the baby's palate grows. As previously mentioned, patients with CLP in South Africa do not necessarily have regular access to the healthcare facilities to attend regular follow-up visits. When there are other alternatives that do not require such a heavy follow-up burden and when the intervention has problems in achieving the desired feeding outcome, then it should perhaps not be considered as a first choice of treatment in South Africa.

An objective for this study was to summarize the available literature on CLP feeding intervention in terms of the outcomes associated with the intervention. Part of the inclusion criteria was that the study had to reference an associated outcome following the feeding intervention studied. Most studies did not have measurable outcomes but rather comments indicating a positive or negative outcome or comparison of different methods. A reason for the lack of measurable outcomes could be as a result of the different methodologies included in the review. Many of the studies in the review were case studies. Having only one study participant means there are no other participants to compare the intervention with and could only comment on one case. More studies are needed with measurable outcomes in order to contribute towards evidence-based practice.

The type of outcomes that were recorded the most, were positive outcomes. Feeding efficiency, comparing of interventions, improved intake, and weight gain were some of the prevalent positive outcomes in the studies. The clinical implication for these positive outcomes is that the therapist can possibly rely on the feeding interventions reported in these studies as they have shown positive outcomes. However, it was interesting that some interventions that were

recorded in multiple studies had conflicting outcomes, such as the use of modified bottles. Some studies showed that the type of feeding utensil did not make a difference in the outcome of the feeding intervention. Other studies had bottle feeding with a feeding obturator show positive as well as negative outcomes. The clinical implication could be that, potentially, there is no need for an expensive adapted bottle if the research shows that there is no difference in the outcomes. This agrees with the finding of the therapists' interviews. They found no need for expensive modified bottles in their clinical settings, as a regular, squeezable bottle or feeding cup is often sufficient. One of the participants even discussed that the type of modified bottle does not make a difference towards the feeding intervention but rather how well the person feeding the baby is assisting the feeding process, which highlights the importance of caregiver training. The implication of conflicting research is that the therapists must then rely on their own clinical experience to decide which feeding utensil is suitable for each patient.

Another objective for this scoping review was to identify gaps in the evidence base of feeding intervention in the CLP population. This review has shown that there are areas of research that are limited with regards to CLP feeding intervention and associated outcomes. One of the major themes that emerged was the lack of research in low- and middle-income countries, including South Africa. Performing studies in the context of an upper-middle-income country, such as South Africa, can benefit the practice of feeding intervention in South Africa. It can be valuable to measure, for instance, the success of cup feeding with infants with CLP as MBFI hospitals and clinics in South Africa only hand out cups as supplemental or alternative feeding methods to exclusive breastfeeding.

The resources available at healthcare facilities to provide patients with can influence the feeding utensils that are chosen and issued to patients with CLP. Bottle feeding has been one of the biggest themes in the research. However, it is not necessarily the best recommendation in the South African context. Most of the therapists advocated for low-cost squeezable bottles from the supermarket, as opposed to expensive, imported modified bottles. The therapists who work at MBFI facilities do not have access to modified bottles nor regular squeezable bottles for feeding. Thus, they must rely on alternatives such as cup feeding, spoon feeding and syringe feeds.

Limitations

The first limitation of this study is the limited access to academic articles. Five articles could not be obtained through the university's library access and could have influenced the results of the study.

The search terms used to search for articles on electronic databases could have been a limitation. The researcher tried different search strings, with different synonyms for each concept, to obtain articles. However, the search strings were very specific. In this manner, some articles could have been missed when they did not have the same word in the title or abstract. Only five databases were chosen due to time constraints as only one researcher collected the data. More databases could have provided other articles which could have influenced the results of the study.

The specific inclusion and exclusion criteria for the study selection could have influenced the number of studies included in the scoping review. Many articles were only available in languages other than Afrikaans or English, such as Spanish and German. These articles could not be reviewed as the researcher could not understand the language of publication.

Another potential limitation is the quality of the articles included in the study. A scoping review methodological design does not control for quality of research. The electronic databases used in this study allowed selecting only peer reviewed articles when searching their database. The amount of research on a certain topic was more important than how the study was conducted.

In the qualitative section of the study, there were some limitations. Due to time constraints and the interviews forming only a small section of the scoping review process, only five participants were interviewed. The transcriptions of the recordings and the thematic analysis of the transcriptions was conducted only by the researcher. This could have influenced the results of this section as only one person transcribed and analysed.

Suggestions for future studies

This scoping review highlights the type of research available in the field of CLP feeding intervention. The type of studies that were not in this review could be recommendations for future research to provide more evidence-based healthcare. Any feeding intervention studies

with infants with CLP in South Africa will be beneficial as only one study was found to be published in South Africa. This could lead to better professional services, in feeding intervention, in South Africa.

The effect of MBFI policies in South Africa on the treatment of feeding difficulties in infants with CLP should be investigated. Cup feeding an infant with CLP in South Africa is a possible theme for future research as this study has shown a lack of research in this area. It could be explored further, even in other countries that do not have the resources to provide bottles for feeding.

The interview part of this study looked mostly at the perceptions of the therapists. The personal factors of the patients and their families, according to the ICF (WHO, 2007), could provide other perceptions of CLP healthcare in South Africa. This information can be valuable to therapists in guiding how they could adapt their intervention to suit the needs of their patients with CLP.

Conclusion

Feeding intervention for the infant with CLP is an important healthcare service provided by the speech therapist before and after corrective cleft surgery occurs. This scoping review has shown that the main categories of interventions researched and practiced mostly overlap. However, the specific intervention under each category is different when looking at the research versus the perceptions of the speech therapists. The training of caregivers in the use of feeding strategies forms the base of the intervention, to ensure the success of the feeding once discharged. The use of modified bottles was a major theme in the research. However, in South Africa, other utensils, such as feeding cups, might be used due to the environmental factors. Although the use of a cup to feed an infant with CLP is not seen in the available research in the South African context, it is being promoted in the MBFI hospitals and the outcomes have been positive. These policies need to be considered as an environmental factor of the ICF as it influences the feeding intervention (WHO, 2007).

The feeding intervention researched had a variety of associated outcomes. The types of outcomes for the feeding interventions for CLP were mostly comparing two or more interventions or referencing a positive outcome. The studies provided both corresponding and conflicting evidence for outcomes of the feeding interventions. Some studies showed preference towards a specific modified bottle whereas others indicated no difference in outcome regardless of the bottle used. Conflicting evidence could make it difficult for the clinician to decide which feeding intervention to choose for their patients. Besides, other aspects should also be considered when deciding on feeding intervention, such as the resources available in the therapist's clinical setting.

This study has highlighted that, in low- and middle-income countries, such as South Africa, healthcare services are influenced by the environment and the population that is served. Environmental and personal factors mentioned in the ICF apply when delivering feeding intervention to infants with CLP. As highlighted by this scoping review, there is a lack of research in Africa, and more specifically in South Africa, to be able to take into consideration the unique environmental and personal factors of the South African clinical context. The patient and caregiver's values and expectations form part of evidence-based practice (McCurrtin & Roddam, 2012) and should be considered when evaluating the value of the research for clinical use by looking at the environment in which the research took place. Having limited or no

research on feeding interventions in the patient's clinical context compels the healthcare professional to rely on practice-based evidence rather than evidence-based practice. The clinical implication for this is that the speech therapist must rely on clinical experience and rather than relying solely on the research that is available, as it has been found to be limited in the South African context.

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Appendix C: Data Charting table

Title	Author/s	Year	Location	Design	Demographics of participants	Timing of intervention	Dysphagia intervention	Associated outcomes
Feeding children in the immediate perioperative period after palatoplasty: a comparison between techniques using a cup and a spoon	A. Trettene C. Mondini I. Marques	2013	Brazil	cross-sectional study	Children in the immediate postoperative period after palatoplasty	Postoperative	Cup feeding versus spoon feeding post palatoplasty Feeding instruction	Feeding more efficient with spoon than cup: less coughing, more food acceptance, less spillage
A feeding adaptation by an infant with a cleft palate	L. Sykes R. Essop	1999	South Africa	case study	14 month old infant	Preoperative	Bottle feeding	Effective when used with thumb to close palatal cleft
A feeding aid prosthesis for a preterm baby with cleft lip and palate.	A. Sultana, M. M. Rahman, M. M. Rahman, J. Nessa, M. M. Rahman, M. S. Alam	2011	Bangladesh	randomized control trial	10 infants with palatal defects (3 male and 7 female)	Preoperative and postoperative	Feeding plate	Decreased feeding time and increased volume intake
A feeding appliance for a newborn baby with cleft lip and palate.	A. Agarwal, V. Rana, S. Shafi	2010	India	case study	3-day old neonate with CLP	Preoperative	Feeding plate	Easily fed with feeding plate
A modified feeding plate for a newborn with cleft palate.	M. Erkan, S. Karaçay, A. Atay, Y. Günay,	2013	Turkey	case study	3-day old neonate with CLP	Preoperative	Feeding plate	Adequate feeding and normalized weight gain

A novel approach for prosthodontic management of patient with cleft of palate	S. Goyal, S. Rani, S. Pawah, P. Sharma	2017	India	case study	6-month old infant with Cleft Palate	Preoperative	Feeding plate	Easily fed with feeding plate and increased weight gain
A Preoperative appliance for a newborn with cleft palate	B. Karayazgan, Y. Gunay, B. Gurbuzer, M. Erkan, A. Atay,	2009	Turkey	case study	3-day old neonate with soft palate defect	Preoperative	Feeding plate	Supported high volume intake with less infant fatigue
A randomized control trial investigating the effect of presurgical orthopedics on feeding in infants with cleft lip and/or palate.	A. G. Masarei, A. Wade, M. Mars, B. C. Sommerlad, D. Sell	2007	UK	randomized control trial	34 CLP and 16 CP infants	Preoperative and postoperative	Feeding plate	Did not improve feeding efficiency
An evaluation of factors influencing feeding in babies with a cleft palate with and without a cleft lip	V. Martin, S. Greatrex-White	2014	UK	mixed methods	50 infants including CLP and CP (complete and incomplete)	Preoperative	Different feeding bottles and teats	Feeding method did not influence weight gain
Analysis of tongue movements during sucking by infants with cleft lip and palate using a diagnostic ultrasound device: Changes during the six months after birth	R. Sasaki, K. Arakaki, F. Tamura, T. Kikutani, H. Sunakawa	2014	Japan	randomized control trial	11 CLP infants and 16 healthy infants	Preoperative	Hotz plate with bottle feeding	Improved sucking pattern

Assisted feeding is more reliable for infants with clefts—a randomized trial	W. C. Shaw, R. P. Bannister, C. T. Roberts,	1999	England	randomized control trial	101 infants with either CL, CP or CLP	Preoperative	Squeezable bottle versus rigid bottle	Similar outcomes; mothers prefer squeezable bottle for easy use
Breast feeding for cleft lip and palate patients, using the Hotz-type plate.	Kogo, M Okada, G Ishii, S Shikata, M Iida, S Matsuya, T	1997	Japan	randomized control trial	10 CLP infants	Preoperative	Breastfeeding with Hotz plate	Not enough milk intake. Needs supplemental bottle feeds
Breast feeding or spoon feeding after cleft lip repair: a prospective, randomised study.	M. A. Darzi, N. A. Chowdri, A. N. Bhat	1996	India	prospective randomized study	40 infants with cleft lip	Postoperative	Breastfeeding versus spoon feeding	Breastfeeding is safe and efficient; more economical than spoon feeding
Breastfeeding a Baby with a Cleft Palate: A Case Report	K. Crossman	1998	Australia	Case report	Baby with unilateral cleft palate	Preoperative and postoperative	Breastfeeding	Needed supplemental bottle feeds for enough nutrition before surgery; spoon and cup feeding supplemented breastfeeding after surgical repair

Breastfeeding After Early Repair of Cleft Lip in Newborns With Cleft Lip or Cleft Lip and Palate in a Baby-Friendly Designated Hospital	I. Burianova, K. Kulihoa, V. Vitkova, J. Janota	2017	Czech Republic	Retrospective cohort study	104 infants: 56 with CL and 48 with CLP	Postoperative lip repair	Breastfeeding	CL: higher feeding rate CLP: low feeding rate
Effect of unrestricted bottle-feeding on early postoperative course after cleft palate repair.	Kim, Eun Key Lee, Taik Jong Chae, Soo Wook	2009	South Korea	Prospective randomized study	82 infants with CP or CLP before repair	Postoperative palate repair	Bottle feeding post palate repair	No adverse effects on intake and weight gain
Effectiveness of two feeding methods in improving energy intake and growth of infants with cleft palate: a randomized study.	E. A. Brine, K. A. Richard, M. S. Brady, E. A. Liechty, A. Manatunga, M. Sadove,	1994	USA	randomized study	31 infants: 22 with CLP and 9 with CP	Preoperative and postoperative	Cleft lip/palate feeding bottle versus normal feeding bottle with cross cut nipple	Both equally effective
Feeding behaviour of infants with cleft lip and palate.	K. Mizuno, A. Ueda, K. Kani, H. Kawamura,	2002	Japan	randomized control trial	15 infants with CLP	Preoperative	Bottle feeds: type-p teat versus standard teat (in semi upright position)	Type-p teat better outcomes
Feeding intervention in cleft lip and palate babies: A practical approach to feeding efficiency and weight gain	I. N. Ize-Iyamu, B. D. Saheeb,	2011	Nigeria	randomized control trial	57 CLP infants	Preoperative	Syringe versus cup and spoon	Syringe better outcomes

Feeding obturator appliance for an infant with cleft lip and palate.	P. Chandna, V. K. Adlakha, N. Singh	2011	India	case report	11-day old neonate with CLP	Preoperative	feeding obturator	Successful feeding with obturator
Immediate Unrestricted Feeding of Infants Following Cleft Lip and Palate Repair	M. Cohen, M. A. Marschall, M. E. Schafer	1992	USA	retrospective study	80 infants with CLP	Postoperative	syringe versus bottle and breastfeeding	Bottle and breastfeeding safe after surgery
Infant orthopedics in UCLP: effect on feeding, weight, and length: a randomized clinical trial (Dutchcleft).	C. Prah, A. M. Kuijpers-Jagtman, A. M. Van 't Hof, B. Prah-Andersen	2005	Netherlands	randomized control trial	54 infants	Preoperative	Feeding plates with breastfeeding and bottlefeeding (feeding instruction given)	Not beneficial to feeding
Infant Palatal Obturator	S. Nagda, D. S. Deshpande, S. W. Mhatre	1996	India	case report	one-year old infant with Cleft palate	Preoperative	Feeding obturator	Improved feeding efficiency
Nasogastric feeding for infants who have undergone palatoplasty for a cleft palate.	R. Kent, V. Martin	2009	UK	retrospective study	34 infants with CLP	Postoperative palatoplasty	Bottle versus nasogastric feeding	Nasogastric better outcome
Post-operative feeding strategies for infants with cleft lip.	J. Skinner, J. C. Arvedson, G. Jones, C. Spinner, J. Rockwood	1997	USA	retrospective study	60 infants with CL or CLP	Postoperative	Cup feeding Education and positioning	Surgical site intact

Simplified feeding appliance for an infant with cleft palate	R. A. Chacko, A. B. Thomas, N. Singh, R. Thomas, D. Abraham, S. Masih	2014	India	case report	1-month old with cleft palate	Preoperative	Feeding appliance with bottlefeeding	Positive outcome
Sucking efficiency of early orthopaedic plate and teats in infants with cleft lip and palate	B. H. Choi, J. Kleinheinz, U. Joos, G. Komposch,	1991	Germany	randomized control trial	28 infants: 7 noncleft and 16 with cleft lip or cleft palate	Preoperative and postoperative	Regular NUK and Cleft NUK bottles	Cleft NUK: no negative pressure Reg NUK: CL increased negative pressure
The effects of lactation education and a prosthetic obturator appliance on feeding efficiency in infants with cleft lip and palate.	L. Turner, C. Jacobsen, M. Humenczuk, V. K. Singhal, D. Moore, H. Bell	2001	USA	randomized control trial	8 infants with cleft lip and/or palate	Preoperative	Lactation education and Habermann feeder	Decreased feeding time and increased volume intake
The promotion of exclusive breastfeeding in infants with complete cleft lip and palate during the first 6 months after childbirth at Srinagarind Hospital, Khon Kaen Province, Thailand	P. Pathumwiwatana, S. Tongasukho, T. Naratippakorn, S. Pradubwong, K. Chusilp	2010	Thailand	randomized control trial	20 infants with cleft lip and/or cleft palate	Preoperative	Breastfeeding	Positive outcome with correct positioning of infant and breast

Weight comparisons of infants with complete cleft lip and palate.	M. E. Richard	1994	USA	randomized control trial	69 infants with CLP	Preoperative	ESSR method with standard bottles versus specialized bottles with enlarged nipples	ESSR showed better weight gain
Weight Gain Pattern of Infants with Orofacial Cleft on Three Types of Feeding Techniques.	B. K. Ravi, L. N. Padmasani, A. J. Hemamalini, J. Murthy	2015	India	cohort prospective study	150 infants at 2 months of age with cleft lip and palate	Preoperative	Paladai, Bottle feeding and Spoon feeding	Paladai feeding better weight gain

Appendix D: Interview schedule

Semi-structured interview schedule

Introduction:

“The researcher performed a scoping review on the feeding and swallowing management of the cleft lip and palate patient and the associated outcomes thereof. As part of the scoping review process, the researcher needs to consult with experts in this field of study regarding their real-life experience treating cleft lip and palate patients for feeding and swallowing difficulties. You will be asked a series of questions regarding your experience as a speech therapist treating cleft lip and palate patients at your hospital/clinic/practice. This interview is not a test on your knowledge but rather an interview on your opinion given your experience with this population.

This interview will be recorded for the researcher to be able to keep an accurate record of what has been discussed today. All participants will be kept anonymous throughout the study. Recordings will be deleted after transcriptions have been made. Do you have any questions before we start the interview?”

	Questions
1	Please tell me about your experience with treating patients with CLP for feeding and swallowing difficulties.
	Is it a challenging population to work with? How often do you come across a patient with a cleft related feeding difficulty?
2	Which types of feeding and swallowing intervention have you as a speech therapist used with your patients with CLP?
Probes	Have you used bottles? Have you used cup feeding? Any postural intervention?
3	What is your opinion on CLP feeding obturator/plate for feeding and swallowing intervention with patients with CLP?
Probes	Will you recommend the use of feeding obturators/plates for feeding and swallowing management?
4	What is your opinion on breastfeeding with an infant with CLP?
Probes	Is breastfeeding recommended in your place of work for infants with CLP? For infants with cleft lip only or cleft palate as well?
5	What are the barriers to feeding and swallowing intervention for the CLP patient in your place of work?
Probes	Availability of therapy equipment? Patient follow-up? Delayed surgery?

6	What is your opinion on the outcomes of the feeding and swallowing intervention given to patients with CLP?
Probes	Which intervention has shown positive outcomes? Which intervention has shown negative outcomes?
7	How do you decide which therapy methods to use with your patients with CLP?
Probes	Have you read research articles about the intervention methods that you practice? Are there other colleagues that you ask for advice?
8	What is your opinion on the available research in this area of feeding and swallowing intervention for patients with CLP?
Probes	Is there enough research for you to practice evidence-based therapy?
9	In your opinion, what types of studies will be beneficial for the patient with CLP with regards to feeding and swallowing management?
Probes	In which geographical location/s should the studies take place? Before surgical intervention or after?
10	What types of feeding and swallowing intervention for patients with CLP would you like to have available research on?
Probes	Studies on postural intervention? Studies on cup feeding? Studies on indirect treatment e.g. counselling?

Appendix E: Letter of ethical clearance



UNIVERSITEIT
STELLENBOSCH
UNIVERSITY

Approval Notice

New Application

19/05/2019

Project ID :8106

HREC Reference #: S18/08/169

Title: Cleft lip and palate: a scoping review

Dear Miss Bea-Mari Brand,

The **Response to Deferral** received on 05/03/2019 09:21 was reviewed by members of **Health Research Ethics Committee 2 (HREC2)** via **expedited** review procedures on 19/05/2019 and was approved.

Please note the following information about your approved research protocol:

Protocol Approval Period: This project has approval for 12 months from the date of this letter.

Please remember to use your **project ID [8106]** on any documents or correspondence with the HREC concerning your research protocol.

Please note that the HREC has the prerogative and authority to ask further questions, seek additional information, require further modifications, c monitor the conduct of your research and the consent process.

After Ethical Review

Please note you can submit your progress report through the online ethics application process, available at: Links Application Form Direct Link and the application should be submitted to the HREC before the year has expired. Please see [Forms and Instructions](#) on our HREC website (www.sun.ac.za/healthresearchethics) for guidance on how to submit a progress report.

The HREC will then consider the continuation of the project for a further year (if necessary). Annually a number of projects may be selected randomly for an external audit.

Provincial and City of Cape Town Approval

Please note that for research at a primary or secondary healthcare facility, permission must still be obtained from the relevant authorities (Western Cape Department of Health and/or City Health) to conduct the research as stated in the protocol. Please consult the Western Cape Government website for access to the online Health Research Approval Process, see: <https://www.westerncape.gov.za/general-publication/health-research-approval-process>. Research that will be conducted at any tertiary academic institution requires approval from the relevant hospital manager. Ethical approval is required BEFORE approval can be obtained from these health authorities.

We wish you the best as you conduct your research.

For standard HREC forms and instructions, please visit: [Forms and Instructions](#) on our HREC website <https://applyethics.sun.ac.za/ProjectView/Index/8106>

If you have any questions or need further assistance, please contact the HREC office at 021 938 9677.

Yours sincerely,

Mr. Francis Masiye,

HREC Coordinator,

Health Research Ethics Committee 2 (HREC2).

National Health Research Ethics Council (NHREC) Registration Number:

REC-130408-012 (HREC1)•REC-230208-010 (HREC2)

Federal Wide Assurance Number: 00001372
Office of Human Research Protections (OHRP) Institutional Review Board (IRB) Number:
IRB0005240 (HREC1)•IRB0005239 (HREC2)

The Health Research Ethics Committee (HREC) complies with the SA National Health Act No. 61 of 2003 as it pertains to health research. The HREC abides by the ethical norms and principles for research, established by the World Medical Association (2013) Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects; the South African Department of Health (2006) Guidelines for Good Practice in the Conduct of Clinical Trials with Human Participants in South Africa (2nd edition); as well as the Department of Health (2015). Ethics in Health Research: Principles, Processes and Structures (2nd edition).

The Health Research Ethics Committee reviews research involving human subjects conducted or supported by the Department of Health and Human Services, or other federal departments or agencies that apply the Federal Policy for the Protection of Human Subjects to such research (United States Code of Federal Regulations Title 45 Part 46); and/or clinical investigations regulated by the Food and Drug Administration (FDA) of the Department of Health and Human Services.

Appendix F: Information and consent forms

PARTICIPANT INFORMATION LEAFLET AND CONSENT FORM

TITLE OF THE RESEARCH PROJECT:

Cleft lip and palate feeding intervention: a scoping review

REFERENCE NUMBER: 8106

PRINCIPAL INVESTIGATOR: Bea-Mari Brand & Alida de Beer (supervisor)

ADDRESS: Discipline of Speech-Language and Hearing Therapy

P.O. Box

Tygerberg

7505

South Africa

CONTACT NUMBER: 021 938 9494

You are being invited to take part in a research project. Please take some time to read the information presented here, which will explain the details of this project. Please ask the study staff any questions about any part of this project that you do not fully understand. It is very important that you are fully satisfied that you clearly understand what this research entails and how you could be involved. Also, your participation is **entirely voluntary**, and you are free to decline to participate. If you say no, this will not affect you negatively in any way whatsoever. You are also free to withdraw from the study at any point, even if you do agree to take part.

This study has been approved by the **Health Research Ethics Committee at Stellenbosch University** and will be conducted according to the ethical guidelines and principles of the international Declaration of Helsinki, South African Guidelines for Good Clinical Practice and the Medical Research Council (MRC) Ethical Guidelines for Research.

What is this research study all about?

- *A scoping review was performed on the treatment and associated outcomes of feeding and swallowing difficulties in the cleft lip and/or palate (CLP) patient.*
- *The findings from the scoping review needs to be compared to the treatment that is being practiced in the field. Interviews with speech therapists will be conducted.*
- *The aim of the interview is to compare the findings from the study with the clinical opinions from speech therapists who treat patients with CLP.*

Why have you been invited to participate?

- *You have been invited to participate in this interview because you have clinical experience with the treatment of patients with CLP.*

What will your responsibilities be?

- *It will be required from you to sign a consent form to participate in this study.*
- *You will be required to attend an interview with the researcher.*

Will you benefit from taking part in this research?

- *There are no personal benefits for the participants taking part in this study. However, your participation might benefit future practice of healthcare professionals (such as speech therapists) with regards to treatment of feeding and swallowing difficulties in the CLP patient.*

Are there any risks involved in your taking part in this research?

- *There are no physical risks of taking part in this study.*

Will you be paid to take part in this study and are there any costs involved?

- *The participants will not be paid to take part in this study.*
- *There will be no costs involved for the participants if they do take part*

Is there anything else that you should know or do?

- *You can contact the Health Research Ethics Committee at 021-938 9207 if you have any concerns or complaints that have not been adequately addressed by your study doctor.*
- *You will receive a copy of this information and consent form for your own records.*

Declaration by participant

By signing below, I agree to take part in a research study entitled (*cleft lip and palate feeding intervention: a scoping review*).

I declare that:

- I have read or had read to me this information and consent form and it is written in a language with which I am fluent and comfortable.
- I have had a chance to ask questions and all my questions have been adequately answered.
- I understand that taking part in this study is **voluntary** and I have not been pressurised to take part.
- I may choose to leave the study at any time and will not be penalised or prejudiced in any way.
- I may be asked to leave the study before it has finished, if the study doctor or researcher feels it is in my best interests, or if I do not follow the study plan, as agreed to.

Signed at (*place*) on (*date*)
2019.

.....
Signature of participant

.....
Signature of witness

Declaration by participant for Audio recording

I declare that:

- I have read and understand the reason for recording the audio of the interview for this study.
- I give permission for the researcher to record my responses on audio tapes.

Signed at (*place*) on (*date*)
2019.

.....
Signature of participant

.....
Signature of witness

Declaration by investigator

I (*name*) declare that:

- I explained the information in this document to
- I encouraged him/her to ask questions and took adequate time to answer them.
- I am satisfied that he/she adequately understands all aspects of the research, as discussed above
- I did/did not use a interpreter. (*If an interpreter is used then the interpreter must sign the declaration below.*)

Signed at (*place*) on (*date*)
2019.

.....
Signature of investigator

.....
Signature of witness