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Self-regulation of preterm infants in the Neonatal Intensive Care Unit while engaged with Sensory Integration-informed intervention and Octo-Sense technology

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Submitted in fulfilment of the requirements in respect of the Master's degree in the Department of Occupational Therapy in the Faculty of Health Sciences at the University of the Free State

29 November 2024

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DECLARATION

I, René Anna de Bruin, declare that the dissertation that I herewith submit for the Master's Degree in Occupational Therapy at the University of the Free State is my independent work and that I have not previously submitted it for a qualification at another institution of higher education.

Signature: RA de Bruin Date: 29 November 2024

DEDICATION

TO GOD BE THE GLORY

All preterm infants and their families

My loving family for their endless support and love

ABSTRACT

Premature birth, a global health concern, often results in developmental challenges for infants due to their exposure to the Neonatal Intensive Care Unit (NICU) environment. This thesis investigates the self-regulatory capacities of preterm infants during sensory integration-informed interventions, emphasizing the role of assistive technology, specifically the innovative Octo-Sense device. The study bridges the gap in occupational therapy research by exploring non-nutritive sucking (NNS) as a vital mechanism for self-regulation and its potential enhancement through Octo-Sense.

The research employs a quantitative, experimental design to compare self-regulation responses in preterm infants receiving sensory integration-informed interventions with and without Octo-Sense technology. The randomised study sample included preterm infants with specific inclusion criteria, such as corrected age and medical conditions. Self-regulation was measured through autonomic and behavioural responses captured in structured observation sessions.

Key findings underscore the challenges of sensory overstimulation in the NICU, which can disrupt neural and sensory development, and highlight the critical role of sensory integration-informed therapy in mitigating these effects. Although statistical significance in some outcomes was limited, the use of Octo-Sense demonstrated promising trends in supporting self-regulation through enhanced NNS, contributing to faster weight gain and potentially shorter NICU stays. The findings advocate for occupational therapy interventions tailored to the unique sensory needs of preterm infants and emphasize the necessity of assistive technologies compliant with stringent NICU hygiene protocols.

This research contributes to a growing body of knowledge on developmental care in the NICU. It provides a framework for integrating sensory integration-informed approaches and innovative technologies into clinical practice. Recommendations include further investigating cost-effective assistive devices for preterm infants and expanding parental education to support post-discharge care. This thesis establishes a foundation for future studies exploring the interplay between sensory integration, assistive technology, and early neurodevelopmental outcomes in preterm populations.

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GLOSSARY

Autonomic responses	The autonomic nervous system is a component of the peripheral nervous system that regulates involuntary physiologic processes, including heart rate, blood pressure, respiration, and digestion. It contains three anatomically distinct divisions: sympathetic, parasympathetic, and enteric (Waxenbaum et al., 2023). Activation of the SNS leads to a state of overall elevated activity and attention: the "fight or flight" response. Furthermore, as discussed by Waxenbaum et al. 2023, this process includes increased blood pressure and heart rate, glycogenolysis ensuing, and gastrointestinal peristalsis ceasing. The SNS innervates nearly every living tissue in the body.
Affordances	Don Norman, a user experience researcher, defines affordances as the properties of an object that demonstrate to the user which actions to take and the agent's relationship and capabilities that determine how a person should use the object (Norman, 2013). In this study, affordances will specifically refer to the properties described by *Octo-Sense.*
Behavioural state	According to Lubbe et al. (2018), there are six different behavioural states: 1. Quiet sleep (no eye movements, vital signs regular) 2. Active sleep (REM sleep, irregular respiration) 3. Drowsiness (dazed look, not able to interact) 4. Quiet awake (can focus attention on stimulation) 5. Active awake (irritable, irregular breathing) 6. Crying (respiration irregular, excessive movement) The infants in the NICU would be in one of these states or transitioning between named states. Therefore, the fieldworker must continuously observe and record the behavioural states.

Crochet/knitted octopus	This toylike object, crocheted from wool/cotton, resembles an octopus and is used in the NICUs of some First World countries like Denmark to calm premature infants (Bastons-Compta et al., 2019). Since its inception, crocheted octopi have found their way into the NICUs of South Africa.
Cluster care	Multiple routine care activities/procedures provided by medical nursing personnel and therapists are grouped in a one-time slot to allow for more extended periods of uninterrupted deep sleep (Valizadeh et al., 2014).
Infant	The WHO defines a newborn infant, or neonate, as a child less than 28 days old (Halfon et al., 2017).
Gastric tube feeding (GT)	This kind of feeding is a means to supply nutritional substances through a thin plastic tube, via the nose (nasogastric tube - NGT) or mouth (orogastric tube - OGT), directly into the stomach of a preterm infant while in the NICU. This type of feeding results from a preterm infant's feeding difficulties that "encompass a heterogeneous group of neurological, pulmonary, and aerodigestive disorders" (Sarapuk et al., 2017). Infants included in this study present these difficulties i.e., an inability to synchronise sucking, swallowing, and breathing while feeding (Bundy & Lane, 2020).
Nest/nesting	According to Lubbe (2019), nesting mimics the boundaries characteristic of the womb. There should be a balance between movement and maintaining appropriate positioning and flexion. When contained in midline and flexion, the infant can increase self-regulation, which promotes calmness.
Non-nutritive sucking (NNS)	Non-nutritive sucking occurs when an infant sucks on an object that does not provide food (non-nutritive tool), e.g., a pacifier, empty breast, fingers, fist, or thumb, but promotes calmness and assists with falling asleep. The sucking reflex thus performs a pivotal role in the development of emotional control and self-regulation (VandenBos, 2015). NNS is a forerunner of breastfeeding and is advantageous to preterm and sick infants since they not only associate sucking with emotional control but also address a basic need, namely feeding (Thames Valley and Wessex Neonatal ODN Quality Care, 2019).

Octo-Sense	It is an aiding technology manufactured from non-toxic silicone that resembles an octopus. Crocheted octopi are currently found worldwide in NICUs. The Octo-Sense is used in the study to assist NICU infants in self-regulation.
Oral sucrose (OS), namely "Syrup Simplex"	Multidisciplinary team members may use this simple sugar solution to comfort infants during painful procedures. The solution's ingestion could stimulate endorphin release (Liu et al., 2017).
Preterm infant	According to the WHO (2018), preterm babies are classified as infants born alive before 37 weeks of pregnancy. Preterm infants are classified according to their gestational age; namely, less than 28 weeks are extremely preterm, 28 to 32 weeks are classified as very preterm, and 32 to 37 weeks are moderate to late preterm. This study includes the following infants: moderate to late preterm infants, born at 32 weeks and 0 days, to those born at 36 weeks and six days (32/0 – 36/6). Thus, indicating preterm infants within this study refers to the infants discussed in the study.
Self-regulation	According to Bundy and Lane (2020, p. 591), it is the ability to attain, maintain, and change one's arousal appropriately or a task or situation.
Self-regulatory strategies that leads to different responses	According to Dunn (2007:85), the four patterns that result in different responses: a) Sensory seeking, which represents high thresholds and an active self-regulation strategy; b) sensation avoiding, which includes low thresholds and an active self-regulation strategy; c) sensory sensitivity, which includes low thresholds and a passive self-regulation strategy, d) low registration, which represents a high threshold and a passive self-regulation strategy.
Sensory integration (SI)	Sensory integration, as founded by Ayres Sensory Integration ® (ASI), is an intervention activity based on a specific fundamental way of using sensory integration, which separates it from other sensory-based approaches (Bundy and Lane, 2020).

Sensory perception	Sensory perception is how an individual interprets the sensory stimuli in his environment and how that specific individual reacts to these stimuli (Bundy & Lane, 2020).
Neonatal Intensive Care Unit (NICU)	The Neonatal Intensive Care Unit (NICU) is the ward where paediatricians would admit preterm infants.
Paediatric Intensive Care Unit (PICU)	The NICU can accommodate up to ten infants at any given time. In unforeseen circumstances, when an additional infant needs admission, the most medically stable infant would be transferred to the Paediatric Intensive Care Unit (PICU), the private hospital in Bloemfontein. A moderate to late preterm infant transferred from another hospital to the PICU, the private hospital in Bloemfontein, would also be considered for the study if it fits the inclusion criteria. Infants in the PICU receive the same standard of care as in the NICU.

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LIST OF ACRONYMS

ASI	Ayres Sensory Integration®
COVID-19	Co stands for Corona, VI for virus and D for the disease that originated in 2019
HIV	Human Immunodeficiency Virus
HPCSA	Health Professions Council of South Africa
NICU	Neonatal Intensive Care Unit
NIDCAP	New-born Individualised Developmental Care and Assessment Program
OTASA	Occupational Therapy Association of South Africa
PICU	Paediatric Intensive Care Unit
VON	Vermont Oxford Network
WHO	World Health Organization

LIST OF ABBREVIATIONS

ASI®	Ayres Sensory Integration
ANS	Autonomic Nervous System
CNS	Central Nervous System
CPG	Central Pattern Generators
dB	Decibels
ELS	Early Life Stress
EBM	Expressed Breast Milk
FC	Footcandles is the Imperial measurement, and Lux is the Metric measurement
ELBW	Extremely low birth weight
GA	Gestational age

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HR	Heart Rate
LBW	Low Birth Weight
Lux	This is the unit of illuminance in metric measures
MRI	Magnetic Resonance Imaging
MORE	Integrating the Mouth with Sensory and Postural Function
NEC	Necrotising Enterocolitis
NMDARs	N-Methyl-D- aspartate-Receptors
NS	Nutritive Sucking
NGT	Naso Gastric Tube
NPO	Nil Per Os
NS	Non-Nutritive Sucking
OGT	Oro-Gastric Tube
PDA	Patent Ductus Arteriosus
POPI Act	Protection of Personal Information Act
REM	Rapid Eye Movement
RDS	Respiratory Distress Syndrome
RN	Registered Nurse
ROP	Retinopathy of Prematurity
RR	Respiratory Rate
sCPG	Suck Central Pattern Generator
SI	Sensory Integration
SIPAP	Synchronised Inspiratory Positive Airway Pressure
SSB	Suck Swallow Breath
SpO2	Oxygen Saturation

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CHAPTER 1: INTRODUCTION AND ORIENTATION

1.1 INTRODUCTION

Premature birth means that an infant is unexpectedly removed from the protective environment of the womb, leaving their immature organs, particularly the brain and lungs, in need of further development (Lubbe, 2021). Premature infants may remain in the NICU for days to months, depending on their specific needs. During this time, Lewkowicz (2012) noted that during admission to the Neonatal Intensive Care Unit (NICU), there unusually are bright lights, highly patterned visual stimuli, and mid-to high-frequency sounds. This developmental period would have occurred while still in the womb when they are typically exposed to diffuse, low-intensity visual stimuli and low-frequency sounds if still in the womb (Lewkowicz 2012). Although the multi-disciplinary team considers neurodevelopmental care to minimise sensory overstimulation in the NICU's lighting, the bustling environment and the constant beeping of monitors, it still can agitate sensitive premature infants and influence this critical development period.

The tactile sensory abilities of preterm infants still need to be explored in research. Gottlieb (1971) established that tactile perception is the first sensory modality to develop in utero, with early receptors and neural pathways forming. Extensive research by Killackey et al., 1995, highlights peripheral sensory receptors' role in shaping somatosensory maps' development. These refinement processes continue during the perinatal period and early postnatal life through activity-dependent plasticity mechanisms. Additionally, substantial evidence indicates that abnormal somatosensory experiences, such as painful stimuli, can disrupt thalamocortical connectivity. Factors considered by Duerden, 2018, are that premature infants are particularly vulnerable, as the NICU environment dramatically differs from the conditions they would experience in the womb.

Recent observations by André et al. (2020) indicate that some parents and healthcare providers have noticed unusual sensitivity to light tactile stimuli in preterm infants. The heightened sensitivity to passive touch, or stimulation applied directly to the skin, is particularly relevant for infants born before 37 weeks, who often require intensive care in the

NICUs. These units expose preterm infants to various sensory inputs, some potentially distressing, such as repeated blood sampling, during a critical phase of brain development (André et al., 2020). In the auditory system, the synchronised firing of neighbouring inner hair cells is necessary to form clusters of primary auditory cortical neurons and establish tonotopic sensory maps, as was emphasised by Trtsch et al., 2007. Similarly, Chang and Merzenich (2003) describe that exposure to environmental noise can hinder the development of tonotopic maps in the auditory cortex.

In the same way, Huberman et al., 2008, mention that the formation of precise sensory neural networks occurs during critical periods that span the final months of gestation and the first month after birth. During this time, specific patterns of neuronal activity drive the refinement processes essential for establishing accurate sensory networks. For example, even before birth, neighbouring retinal cells fire in synchrony to shape the functional architecture of the visual thalamus and cortex. As a result, inadequate or inappropriate exposure to visual, auditory, or somatosensory stimuli during these early developmental stages can lead to lasting changes in the connectivity and function of sensory cortices. Huberman et al., 2008, also explain that disruptions in visual input can cause conditions like amblyopia, strabismus, and alterations in the orientation selectivity columns of the visual cortex. The study by Pétursdöttir and Holmstörm (2022) aimed to evaluate strabismus, stereo acuity, accommodation and convergence in prematurely born young adults screened for retinopathy of prematurity in the neonatal period and compared with term-born individuals of the same age. Their study showed that prematurely born young adults had a higher prevalence of strabismus, reduced stereo acuity and worse amplitude of accommodation than term-born adults of the control group.

As previously discussed, the abundance of sensory stimuli, such as excessive noise, bright lights, and painful medical procedures, can result in sensory overload during a critical period of brain development. As explained by Mitchell et al., 2015, this overload may impair the infant's physiological responses and potentially negatively affect motor, neurological, and sensory development. Specifically, disruptions in sensory input from the vestibular, proprioceptive, and tactile systems can hinder the development of adaptive behaviour,

postural control, movement coordination, and overall motor development (Mitchell et al., 2015).

The study by Kaya Kara et al. (2020) was the first to examine the relationship between gross and fine motor development and sensory development in very preterm or high-risk infants during their first four months of life. Kaya Kara et al. (2020) observed a strong connection between gross and fine motor skills and sensory functions like tactile and proprioception at one month. Additionally, the researchers found correlations between fine motor development and vestibular processing, as well as fine motor development and tactile and visual processing, by four months of age.

In the previous discussion, all the sensory systems, namely vestibular, proprioceptive, tactile, visual and auditory, were mentioned as being affected by preterm birth and the noxious environment of the NICU. Due to immature self-regulatory capacities, preterm infants require external regulation to modulate negatively affected sensory systems and physiological needs (Mohr et al., 2019). Difficulty with early regulatory behaviours signals the infant's need for increased assistance with self-regulation. Pindea et al. (2019) research shows that Non-nutritive sucking (NNS) emerges early in gestation, with observations of as early as 15 weeks post-conception. By 20 weeks, foetuses exhibit rhythmic NNS patterns, marked by repetitive mouth movements in organised bursts followed by pauses. Therefore, according to the literature, when a preterm sucks a pacifier, NNS provides calmness and psychological stability (Foster et al., 2016). NNS is a critical developmental milestone in infancy, crucial in oral feeding and self-regulation.

Since January 2006, the researcher has worked with infants, including preterm infants, as part of her role as an occupational therapist in the NICU. The researcher started using sensory integration-informed interventions. The researcher noted how difficult it was for preterm infants to self-regulate without assistance. Deep pressure and containment hold, as well as NNS using a pacifier, assisted preterm infants to start to self-regulate. As the researcher started neurodevelopmental care, explicitly using an SI-informed approach, she saw a change in the preterm infants' behaviour through early intervention. The researcher involved nursing personnel and parents/caregivers during these sessions.

The researcher was also profoundly concerned about the shortage of appropriate pacifiers for preterm infants in the NICU, as the literature highlighted the critical role of NNS. Not only was NNS necessary for oral feeding, which would develop later during their NICU stay, but it was also essential for self-regulation, which the absence of NNS could hinder. The positive outcomes, as shown in the literature of preterm infants who can actively suck on a pacifier to achieve self-regulation while in the NICU, sparked a particular interest in researching the specifications needed for a cost-effective, preterm infant pacifier they could take home after discharge.

During this time, compassionate individuals began donating crocheted octopi to the NICU at a private hospital in Bloemfontein, inspired by social media posts showcasing their use as toys in NICUs abroad. However, these well-meaning donors were unaware that soft toys could harbour bacteria in the NICU if not adequately cleaned. Discussions with the registered nurses (RNs) in the NICU confirmed the researcher's concerns. In response, the inventor developed the Octo-Sense as an assistive technology for NICU use.

1.2 PROBLEM STATEMENT

An estimated 13.4 million babies were born preterm in 2020, with nearly 1 million dying from preterm complications, according to a report released by the World Health Organisation (WHO) and UNICEF. Worldwide, this is equivalent to around 1 in 10 babies born too soon, before 37 weeks of pregnancy. Preterm infants in the NICU face many developmental challenges, one of them being their inability to self-regulate. Individual pathways, shaped by self-regulation skills through life course alterations, have the potential to produce protection against dysfunctional behaviour (Halfon et al., 2017). In their study, Miller et al., 2007, recorded that when preterm infants in the NICU are in an environment where sensory over- and/or under-stimulation occurs, infants are at high risk of having altered structural brain organisation, which might lead to sensory processing dysfunctions. Working as part of the multi-disciplinary team in the NICU, occupational therapists specifically focus on providing developmentally supportive care and preventing prematurity-related complications, e.g., plagiocephaly, torticollis and extreme malalignment, and other musculoskeletal and neurodevelopmental complications. Unfortunately, over- and under-stimulation occurs in the

private hospital in Bloemfontein despite implementing this private hospital's Developmental Supportive Care Policy (Addendum A). Also, the NICU accepted the crochet octopi/soft toys donated by good Samaritans despite the Disinfection Guidelines Policy of the private hospital (Addendum B), which states that no soft toys should be available to infants in the NICU. Adding to the challenge is that the parents need to be educated by the multi-disciplinary team on how to support the infant's development after discharge. Now, there is no single solution to the following: how to assist the infant to self-regulate while attempting NNS; what to give infants in the NICU to hold on to when disorganised and stressed; what to give parents to take home to continue assisting their infant in the same way as when in the NICU. This solution should comply with the private hospital's policy on developmentally supportive care, namely Disinfection Guidelines, Policy C.IPC.1.5 (Addendum B), which states that no soft toys are allowed into the NICU, as all objects must be fully washable. These difficulties are of great concern to the researcher. If developmental delays occur, it might lead to participation challenges for the infant in all occupational spheres or activities of daily living (ADL), which include sleep, play, social participation and education.

Working in a NICU environment, the researcher uses an intervention plan consisting of principles derived from the sensory integration frame of reference to assist the infant with self-regulation. The researcher is the first to attempt a study using the Octo-Sense in the NICU. Limited occupational therapy research has focused on self-regulation while active NNS occurs while the preterm infant is in the NICU (Brownell & Kopp, 2007). Therefore, the focus of this study is to address this gap in research by focusing on the Octo-Sense as an assistive technology used in conjunction with sensory integration-informed occupational therapy intervention and the potential of this technology in assisting preterm infants in their diligent efforts to self-regulate by NNS. Using the Octo-Sense to self-regulate could support infants' shorter stay in the NICU, indicating more than adequate weight gain in a shorter period.

Global and national sources indicate an upward trend in premature births. Preterm infants in the NICU encounter numerous developmental challenges, particularly in their ability to self-regulate. Life course changes influence the preterm infant's self-regulation pathways, which can offer protection against dysfunctional behaviours (Halfon et al., 2017). According to a

study by Miller et al. (2007), preterm infants exposed to either sensory over- or under-stimulation in the NICU are at a heightened risk for altered brain structure, potentially leading to sensory processing problems.

Another issue is that parents need to retain and utilise the knowledge provided by the multi-disciplinary team after the infant's discharge. There isn't a comprehensive solution to several critical questions: How can we aid infants in self-regulating during NNS? What can infants in the NICU hold onto when feeling disorganised or stressed? What resources can parents take home to help their infant continue the same level of support provided in the NICU? Any proposed solutions must align with every hospital's policy (Addendum A and B). These challenges are of significant concern to the researcher, as developmental delays could hinder an infant's participation in vital activities of daily living (ADLs), such as sleep, play, social interaction, and education. In the NICU environment, the researcher employs an intervention plan rooted in the sensory integration frame of reference to support infants in self-regulation. The study is inaugural and aims to use Octo-Sense in the NICU. Research on occupational therapy concerning self-regulation during active NNS in preterm infants remains limited (Bronwell & Kopp, 2007). Therefore, this study aims to fill this research gap by examining the Octo-Sense as an assistive technology used alongside sensory-integration-informed therapy to aid preterm infants self-regulating during NNS.

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1.3 Literature overview

The concept of self-regulation in humans has been studied from diverse perspectives (Geldhof et al., 2010). According to Williams and Shellenberger (2020:432), self-regulation is "the ability to attain, maintain, and change one's arousal appropriately for a task or situation". Still, consensus exists amongst researchers that self-regulation has significant implications for individual trajectories of development, health, and well-being across the course of life (Halfon et al., 2017). Various factors contribute to successful self-regulation, e.g. a genetic predisposition, internal- and external motivation, caregiver support, and social- and environmental interaction (Wesarg-Menzel et al., 2023). From a developmental perspective, no single theory sufficiently explains all aspects (Lynn et al., 2011). Subsequently, Heidelise Als, a psychologist, developed the Synactive theory (Als, 1982). She also created the Newborn Individualised Developmental Care and Assessment Program (NIDCAP), which explicitly cares for infants in the NICU. The NIDCAP describes the self-regulatory capacities of the infant as a dynamic system that includes the autonomic-, motor-, state- and attentional or interactive subsystems.

In 1972, Ayres (1972:11), an occupational therapist and a neuropsychologist, defined sensory integration as "the neurological process that organises sensation from one's own body and the environment and makes it possible to use the body effectively within the environment". Although Ayres focused on the contribution of the tactile, vestibular, and proprioceptive systems to development and learning, she would include the visual and auditory systems (Van Jaarsveld, 2011). The Sensory Integration Theory, as described by Bundy and Lane (2020:4-5), is not only concerned with dysfunction and intervention as it comprises three broad postulates. Firstly, the ability to process and integrate sensation, use it to plan and integrate sensation and then plan and organise behaviour that would lead to learning. Secondly, a decreased ability to process and integrate sensation may result in difficulty producing appropriate actions, which may interfere with learning and behaviour. Thirdly, sensations are generated and incorporated in the context of a "just right challenge” The term "just right challenge" is widely used but specifically mentioned by Bundy and Lane (2020:5). This postulate has given rise to sensory integrative therapy (Bundy & Lane 2020:4-5).

Sensory integrative therapy, trademarked as Ayres Sensory Integration® (ASI), is based on the lifelong work of Jean Ayres (Lane et al., 2019). According to Lane et al. (2019:7), "ASI proposes that active engagement, in individually tailored sensorimotor activities, contextualised in play, at the just-right-challenge, promotes adaptive behaviours enhancing neuroplasticity in response to these experiences". Within occupational therapy, ASI® could improve function and behaviour and form a basis for participation in daily activities (Lane et al.,2019). Another program grounded in Ayers' Sensory Integration Theory is the Alert Program®, which provides a framework for addressing and processing self-regulation difficulties. As described by Williams and Shellenberger (2020:432), arousal is a state of the nervous system, explaining how alert one feels, and they also described that self-regulation is the ability to attain, maintain, and change one's arousal appropriately for a task or situation.

Self-regulation is the capacity to achieve, maintain, and adjust one's arousal levels appropriately according to the demands of a task or situation. Thus, this study explores self-regulation, the ability to process and integrate sensory information. Hence, the observation of self-regulation responses of infants in the NICU during the sensory integration-informed intervention assisted by different pacifiers.

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1.4 AIM AND OBJECTIVES

The researcher will outline the purpose of this research study through its aim and objectives.

1.4.1 Aim

To describe and compare the self-regulation responses of infants in the Neonatal Intensive Care Unit during a sensory integration-informed intervention, with or without the support of assistive technology.

1.4.2 Objectives

1.3.2.1 To describe the self-regulatory responses of infants in the Neonatal Intensive Care Unit regarding self-regulatory behaviour and autonomic responses while receiving sensory integration-informed sessions.

1.3.2.2 To describe the self-regulation responses of infants in the Neonatal Intensive Care Unit regarding self-regulatory behaviour and autonomic responses while receiving sensory-informed-intervention sessions supported by Octo-Sense technology.

1.3.2.3 To compare the self-regulation responses of the infants in the Neonatal Intensive Care Unit whilst receiving the sensory integration-informed intervention with those of the infants receiving the sensory integration-informed intervention, supported by the Octo-Sense assistive technology.

1.3.2.4 Describe the affordances of Octo-Sense assistive technology the infants engaged with during sensory-integration-informed intervention sessions.

1.5 METHODOLOGY

The researcher conducted a thorough literature review to assess the relevance of this study concerning previous research and relevant literature. After the review, the researcher determined the population for the analysis and decided to employ a quantitative research

approach with an experimental design. According to Marlow (2005:139), simple random sampling is one of the most straightforward methods, where every individual in the population has an equal chance of being selected. The researcher used the random assignment to reduce the likelihood that either group would be unrepresentative of the population (De Vos et al., 2020). The criteria for the randomised list were used based on corrected age, gender, delayed oral feeding due to prolonged nil per os (NPO), prolonged invasive ventilation, and patent ductus arteriosus (PDA) to determine inclusion in the study. Both groups received the same sensory integration-informed intervention sessions. The Experimental group was exposed to the Octo-Sense with an attached pacifier, while a standard NICU pacifier was available for the Control group. The researcher worked towards NNS to obtain self-regulation during both groups' sessions. In alignment with the fourth objective (1.3.2.4), the researcher used the Octo-Sense pacifier to facilitate self-regulation and manipulated it for observers to identify the potential affordances of the Octo-Sense in aiding self-regulation. All intervention sessions were recorded, with each video lasting 10 minutes. The researcher aimed for an ideal of five video sessions per infant.

The Department of Biostatistics at the University of the Free State compiled the randomised list. At the same time, the Department of Actuarial Studies did a statistical analysis of the results described in Chapter 4.

1.6 THE IMPORTANCE OF THE STUDY

Research on effective intervention strategies to promote developmental progress and prevent delays in premature infants remains limited. Although most of the results of the data analysis for this study were not statistically significant, they did show that preterm infants need sensory interventions to enhance their neurological development through sensory integration-informed interventions. This study is the first to explore the use of the Octo-Sense as an assistive technology, potentially laying the groundwork for future research in this area. Researchers should Investigate the impact of using appropriate pacifiers in the NICU to support preterm infants in performing NNS for self-regulation. Given the critical role of sensory integration in the typical development of preterm infants, it is crucial to advocate for the involvement of occupational therapists in the NICU, as their expertise includes the belief

in early intervention, using Sensory Integration to promote neurodevelopmental care. During the study, the parents from both groups became more involved. They showed more interest and a better understanding of their infants' developmental progress and sensory processing while using pacifiers for NNS. Having an appropriate pacifier for the infant to perform NNS might assist in gaining weight faster and shorten the preterm infant's stay in the NICU.

1.7 ETHICAL CONSIDERATIONS

The Health Science Research Ethics Committee of the University of the Free State approved the research proposal for this study with ethics number UFS-HSD2021/0148-0002 (Addendum C). In 2024, the researcher sought ethical clearance again due to amendments to the original proposal and the appointment of another biostatition (Addendum C). As a result, the researcher created an amended consent form that was compliant with the Protection of Personal Information Act of 2018 (POPIA Act), which all the parents or legal guardians signed. The head office of the private hospital approved the study conducted in the NICU of the private hospital in Bloemfontein and the amendments to the consent forms (Addendum D). The researcher again obtained written consent from all paediatricians and the Unit Manager involved (Addendum E and F). The researcher added a new Data Management Plan (Addendum G) that is compliant with the POPIA Act 2018. Consequently, the researcher transferred all hard copies of the Observational checklist during Sensory integration - informed intervention WITHOUT Octo-Sense Technology and the Observational checklist during Sensory integration - informed intervention WITH Octo-Sense Technology (Addendum S) and videos to Figshare. Figshare is a repository that allows users to make their research outputs citable, shareable, and discoverable, and the SASOL Library manages it at the University of the Free State. Parents and legal guardians may request access to the videos stored on this platform. Since the Octo-Sense, utilised with the experimental group, is the intellectual property of Mr. B. Halasz, the Directorate: Research Development (Addendum H) needed to verify that there was no conflict of interest. As a result, the Health Science Research Ethics Committee approved the study's proceeding.

1.8 OUTLINE OF CHAPTERS

This dissertation consists of six chapters, arranged as follows:

Chapter 1 - *Introduction, problem statement and purpose of the study:* This chapter provides an overview of the study, commencing with clearly articulating the problem statement. The purpose of the study is to outline its aim and objectives. Additionally, this chapter summarises the study's scope and significance, as well as its methodology and ethical considerations.

Chapter 2 – *Literature review.* The researcher discusses the epidemiological information regarding preterm infants, the characteristics of the premature infant, and the complications, challenges, and impairment associated with prematurity are conversed about, followed by the clinical significance of the limbic system, the sucking activity, and experiencing the NICU as a sensory harsh environment. Self-regulation and the difficulty preterm infants in the NICU have in performing self-regulation follows. The researcher then discusses different therapeutic approaches in the NICU and occupational therapy, specifically Sensory integration-informed intervention, as part of these approaches. Lastly, the researcher discusses using the Octo-Sense technology during the sensory-integration-informed occupational therapy intervention to promote self-regulation of preterm infants in the NICU.

Chapter 3 – *Research approach and methodology.* The researcher presents the approach and methodology. This study follows a quantitative, experimental research approach. The researcher thoroughly discusses the study design, a randomised controlled clinical trial, methods used during the implementation of the study in terms of sampling of preterm infants, data collection, data analysis, and ethical aspects.

Chapter 4 – *Results.* The research findings are showcased in tabular and graphical formats, accompanied by concise summaries, and include the preterm infants' anthropometric data.

Chapter 5 – *Discussion of results.* This chapter delves into an in-depth analysis of the research findings presented in Chapter 4, providing interpretations and comparisons with existing literature.

Chapter 6 - Conclusions *and recommendations.* This chapter discusses the overall findings in terms of the aim and objectives of the study. Then, this chapter follows with a reflection on this study's contribution to the field, especially regarding possible clinical application. The researcher considers the study's limitations and recommendations for future research. A closing summary concludes this last chapter of the dissertation.

1.9 SUMMARY

This introductory chapter sets the stage for the dissertation, outlining its scope and organisation. The subsequent chapter provides a comprehensive literature review, delving into the relevant aspects of premature infants and laying the groundwork for the following research. Preterm infants exhibit distinctive characteristics and face various complications, challenges, and impairments due to their prematurity. Structural changes in their brains, particularly affecting muscle tone and the somatosensory region of the cerebral cortex, play a crucial role in their development. An understanding of the anatomical relationships of the tongue with the body systems, as well as systemic relationships, is essential. The sucking mechanisms of preterm infants are significantly affected, showcasing key differences between nutritive and non-nutritive sucking. The members of the multi-disciplinary team working in the NICU environment view the NICU as a harsh environment. It presents substantial challenges for self-regulation, which impacts the infants' ability to achieve the critical suck/swallow/breathe synchrony. However, adopting a more positive perspective on the NICU experience is possible. Therapeutic approaches in the NICU, including occupational therapy interventions, are vital for enhancing self-regulation and supporting non-nutritive sucking development with the use of the standard pacifier or the Octo-Sense as an assistive technology. Employing sensory integration-informed interventions can foster improved outcomes for preterm infants.

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CHAPTER 2: LITERATURE REVIEW

2.1 IINTRODUCTION

In Chapter 1, the researcher mentions the problem statement, the study's aim, the methodology, and the ethical considerations. The researcher noted the general outline of the different Chapters. The following literature review will discuss the relevance of this study. The researcher will first discuss the epidemiological information regarding preterm infants, the characteristics of the premature infant, and the complications, challenges, and impairment associated with prematurity, followed by the clinical significance of the limbic system, the sucking activity, and experiencing the NICU as a sensory harsh environment. Self-regulation and the difficulty preterm infants in the NICU have in performing self-regulation follows. The researcher then discussed different therapeutic approaches in the NICU and occupational therapy, specifically sensory integration-informed therapy, as part of these approaches. Lastly, the researcher discusses using the Octo-Sense technology during the occupational intervention to promote self-regulation of preterm infants in the NICU.

2.2 EPIDEMIOLOGICAL INFORMATION REGARDING PRETERM INFANTS

2014, as recorded by Walani (2020), an estimated 11% of live births globally were classified as premature births, resulting in 15 million infants born before the gestational age of 37 weeks. Recorded preterm births vary according to the level of income of a country, as well as by geographic region. The preterm birth rate for above-average income countries has increased by 9,3%, the middle-income class countries by 9,4%, and the low-income countries show a 12% increase (Walani, 2020). A lack of accurate nationally representative preterm birth estimates limits our epidemiological understanding of preterm birth and the extent to which health services can respond appropriately. According to an article by Ohuma et al. (2023), the Bayesian-based modelling approach is the most extensive dataset developed, which is more reliable than previous models. Therefore, the 2010 to 2020 estimates of live births could be more reliable than earlier data sets. More importantly, according to Ohuma et al. (2023), the WHO and UNICEF guarded this process for updating the estimates of preterm live births, and the consultations with the countries included proved valuable. Globally, as

noted by Gruending and Jacobsson, 2023, there has not been a calculable difference in the rate of live preterm births from 2010 (9.8%) to 2020 (9.9%). Ohuma et al. (2023) observed that in sub-Saharan Africa, the total number of infants born preterm increased by 563 100 babies between 2010 and 2020. According to the researchers, this rise might be due to high fertility in those regions (Ohuma et al., 2023). Also mentioned in the same article by Ohuma et al. (2023) is that in 2020, Malawi had the highest preterm birth rate of 14.5%, followed by South Africa with 13.2%. In high-income countries such as Greece and the USA, preterm births are 10% of all live births. Ohuma et al. (2023) suggest that it is vital to identify the groups that are most affected. Action is needed; therefore, engaging with those groups and assisting in practical strategies to reduce preterm births in those populations is crucial.

In the report published by the WHO: Born Too Soon - Decade of Action on Preterm Birth (Lawn, 2023), turmoil worldwide, climate change, COVID-19, and the lack of capital have contributed to the rise of these figures. The report by Lawn (2023) adds to this the multiple burdens of diseases in South Africa. According to the National Institute for Communicable Disease, an estimated 30% of pregnant women in South Africa live with HIV. Several studies show an increased risk of preterm births for mothers with HIV, and the use of antiretroviral therapy is also associated with preterm deliveries(Lawn, 2023).

According to Lan et al. (2021), the COVID-19 pandemic impacted social behaviour, financial decisions, and economic and psychological dimensions, and apparently, the number of newborns is declining globally. As reported by the WHO, the newborn rate was 17,96% in 2020 and would keep declining to 14,42% in 2025 and 16,30% in 2030. Another essential point is that in Taiwan, the birth rate was 7,01% in 2020, which was markedly lower than the global birth rate. As disputed by May et al. (2023), there is limited evidence of the national burden of preterm births in South Africa. In current estimates, Ramokolo et al. (2019) say that hospitals provide the mortality data of deceased *preterm infants.* Subsequently, Edwards et al. (2019) noted that the Vermont Oxford Network (VON) is a data-driven platform that volunteers maintain and is used worldwide by individuals and organisations to improve newborn medicine. The VON system generated the information presented in Table 2.1 on

the preterm births at the private hospital in Bloemfontein, Free State, South Africa, from January 2019 to December 2023.

Table 2.1 Preterm births at the private hospital in Bloemfontein, January 2019 to December 2023

Infants gestational age	Infants born in 2019	Infants born in 2020	Infants born in 2021	Infants born in 2022	Infants born in 2023
32/0 - 32/6	14	9	9	18	9
33/0 – 33/6	16	21	9	10	8
34/0 – 34/6	26	46	16	25	15
35/0 – 35/6	45	27	21	21	31
36/0 – 36/6	27	14	30	20	32
TOTAL	128	117	85	94	95

The factors mentioned earlier could partially explain why the preterm births recorded in 2020 by the private hospital in Bloemfontein are lower than in previous years. Worldwide, countries' governments demanded that citizens remain inside their homes during the COVID-19 lockdown from 2020 to 2021. The researcher wanted to determine whether there was a correlation between being pregnant during the lockdown period and the lower number of preterm births during this period. Globally, pregnant females did not have to get up early, rush to work, do grocery shopping after work, and get caught up in traffic. Throughout the COVID-19 pandemic lockdown period, Delius et al., 2023, from the tertiary University Centre in Germany, reported that the rate of preterm-born infants is decreasing compared to the same period in 2018 and 2019. Fewer multiples were born preterm during COVID-19, and the researchers postulated that when pregnant females are less active, as during the COVID-19 period, while pregnant, it could prevent preterm labour. Due to the predominant reduction in preterm multiples, these researchers postulated that less physical activity might have led to the protective effect of lockdown measures (Delius et al., 2023). The researcher surmised that when pregnant females are less occupied, they tend not to have high blood pressure,

unexpected rupture of membranes, or re-occurring infections, which are medical conditions that may lead to premature labour.

Furthermore, according to Farmania et al. (2017), *preterm infants* are at risk of the need for long-term care. As reported by Ramdin et al. (2022), preterm birth occurs in 15% of all births, which relates to one in seven infants *being preterm infants*. Fortunately, advances in neonatal care over the last few years have improved the survival of premature infants. On the other hand, Ramdin et al. (2022) predicate their concerns about these *preterm infants'* morbidity and possible poor neurological development. To understand the risks involved in premature birth, one must investigate the characteristics of the premature infant.

2.3 THE PREMATURE INFANT

According to Chelli et al. (2015), referring to an infant 28 days or younger as a neonate or newborn is customary. Furthermore, there is a variance between infants born full-term, between 37 to 42 weeks, and infants born before the whole gestational period, thus being called prematurely born infants. According to the World Health Organisation (WHO) (Haas, 2018),infants born alive before the gestational age of 37 weeks *are* preterm infants. The sub-categories of preterm birth, based on gestational age, are as follows:

- Extremely preterm – less than 28 weeks
- Very preterm – 28 to 32 weeks
- Moderate to late preterm – 32 to 37 weeks

According to Farmania et al. (2017), birth weight and gestational age predict the growth and development of preterm infants and their functional and structural evolvement. As explained by Bergman and Bergman (2010) and confirmed by Lubbe (2021), it is widely accepted to make use of a preterm infant's gestational age and weight to determine an infant's immediate medical care needs. The multi-disciplinary team in the NICU would then be able to provide medical care and neurodevelopmental support that befit a specific infant.

Metha et al. (2022) postulate that if the obstetrician and neonatologist can establish an infant's gestational age (GA) prenatally and postnatally, they could provide specific medical care after birth while in the NICU. This information about the infant encompasses the level of maturity and development the specialists could expect from the infant. Singhal et al. (2017) mention that the New Ballard score, used within 24 hours after birth in most NICUs, is a practical measuring tool of the neonate's physical and neuromuscular maturity. Furthermore, according to Singhal et al. (2017), the apprehension of the preterm infant's GA would determine the level of care and the neurodevelopmental prognosis. An infant born at the gestational age of 30 weeks tends to look different than an infant born at the gestational age of 35 weeks, with features other than those of a 40-week full-term infant. Therefore, the relevance of the following.

2.3.1 Distinctive characteristics of the newborn preterm infant

Bergman (2010) explained that *preterm infants look* distinctively different from full-term infants.

Some of the characteristics are:

- Below average size and weight.
- Cranium: It is soft, long, thin, and too large compared to the rest of the infant's body.
- Face: Wrinkly.
- Ears: Pliable as they are still very soft due to cartilage immaturity.
- Eyes:
    - The eyelids of a highly premature infant (less than 26 weeks gestation) would still be fused.
    - Due to sensitivity to light, the eyes will be closed.
- Lungs: They are underdeveloped, which might lead to a need for ventilation, which coincides with numerous tubes and lines.

- Ribcage:
    - Caves in with every breath.
    - Ribs may appear protruded.
- Four limbs:
    - Appear very skinny and in extension, rather than flexion, due to low muscle tone.
    - Although mainly perfectly formed, the hands and feet are long and thin.
- Genitalia: underdeveloped if born before 34 weeks of gestation.
- Skin:
    - It is hypersensitive, delicate, and wrinkled.
    - Usually, the preterm infant's skin makes up 13% of the body weight.
    - This porous skin has a thin stratum corneum and an acidic PH, which leads to moisture evaporation through the skin.
    - The infant's skin colour may vary from pinkish to mottled or pale due to poor oxygenation.
- Lanugo:
    - Long, soft, dark body hair, especially on the upper arms and shoulders.
    - Extremely low birth weight (ELBW). Premature infants do not have lanugo yet and, therefore, cannot regulate their body temperature.
- Due to immature body systems, the following are inevitable:
    - Irregular heartbeat: this could be due to a patent ductus arteriosus (PDA), which is an opening between the two atriums of the heart, which is closed in

the heart of a full-term infant. A PDA, at birth, is ubiquitous within the preterm infant population.

- Inadequate release of the protein surfactant: the parathyroid hormone-related protein lowers surface tension, keeping the alveoli from collapsing after exhalation and making breathing easier. As a result of this inadequate release of surfactant, most *preterm infants* suffer from different levels of respiratory distress syndrome (RDS), which leads to them being intubated and connected to an oscillator or ventilator.
- Twitching: due to the central nervous system's immaturity.
- Necrotising enterocolitis (NEC): the cause of death for many a prematurely born infant is due to the underdevelopment of the gastrointestinal system, which must endure feeds at an immature stage.
- A mother's colostrum or foremilk would increase *the preterm infants'* immunity. Still, when the colostrum is available during these first days after birth, premature infants are kept nil per os (NPO) to prevent NEC.

When considering the immaturity mentioned above, preterm infants may face advanced medical challenges.

2.3.2 Complications, challenges, and impairments associated with prematurity

Gavin (2019) stated that short-term complications are due to the immaturity of a preterm infant's systems, which may lead to anaemia, apnoea, bronchopulmonary dysplasia, and intraventricular bleeding in the brain. In addition to these complications, Gavin (2019) mentions respiratory distress syndrome (RDS), which involves the lungs and heart. Hyperbilirubinemia and the likelihood of exiguous intestines in an immature liver translate to necrotising enterocolitis. Gavin (2019) also notes retinopathy of prematurity (ROP), auditory difficulties, and the inability to regulate the body's core temperature. Long-term complications might include cerebral palsy, low muscle tone, chronic health issues, impaired learning, problems with vision and hearing, as well as behavioural and psychological problems

(Zimmerman, 2018). The infant's structural brain organisation alters since the brain is exposed to the environment earlier than prepared. Brain bleeds might occur due to the disorganisation and developmental impairment of the infant's brain (Dubois et al., 2008).

According to Pappalardo et al. (2023), early life stress (ELS) could occur during the prenatal and postnatal periods, which relates to perinatal stress. ELS may remodel non-inherited cellular and molecular communication, leading to altered behaviour in mental and physical aspects (Pappalardo et al., 2023). Lammertink et al. (2020) state that due to the immaturity of the preterm infant's brain, postnatal stress may reform the programming of the brain and other critical systems, including the hypothalamic-pituitary-adrenal axis, as well as the autonomic nervous system. Accordingly, evidence suggested by Lammertink et al. (2020) demonstrated that the autonomic nervous system's (ANS) dysfunction caused by prematurity could continue into infancy and early childhood, leading to prolonged abnormal maturation of the ANS. More specifically, as was mentioned in the research of Yiallourou et al. (2013), the decreased reactivity of the ANS seems to have an interrelationship with higher exposure to neonatal stress.

Hanson et al. (2024) described N-methyl-D-aspartate receptors (NMDARs) as channels for ions. Together with ionotropic and G-protein receptors, these channels form glutamatergic synaptic transmission throughout the central nervous system. Hanson et al. (2024) mention that NMDARs are essential for creating postsynaptic density. NMDARs are present presynaptically and extrasynaptically and, therefore, play a role in regulating neuronal reactivity and arbitrating synaptic transmission. Hanson et al. (2024) state that these receptors need NMDARs to function fittingly. In the altered brain microstructure of the preterm infant's underdeveloped brain, there might be an inadequate production of NMDARs, which may lead to caspase-mediated cell death or apoptosis, which the body uses to rid itself of unused or dead cells (Hansen et al., 2024).

Mento and Bisiacchi (2012) explain that the type of sensory experiences in the NICU shapes the preterm infant's sensory system, which could compromise the integrity of cerebral white matter. Preterm infants in the NICU face many developmental challenges, including their inability to self-regulate. Individual pathways for self-regulation skills form through life

courses. Miller et al. (2007) recorded that when preterm infants in the NICU are in an environment where sensory over- and/or under-stimulation occurs, infants are at high risk of developing altered structural brain organisation, which could lead to sensory processing dysfunctions. Occupational therapists form part of the multi-disciplinary team in the NICU and specifically focus on providing neuro-developmental supportive care. Occupational therapists contribute to preventing prematurity-related complications, e.g., plagiocephaly, torticollis, extreme malalignment, and other musculoskeletal and neurodevelopmental difficulties. Over- and under-stimulation occur in the NICU of the private hospital in Bloemfontein despite having a Developmental Supportive Care Policy, 1.3 (Addendum A). It is impossible to single out any one complication, challenge, or impairment associated with prematurity as having more influence on a preterm infant than another (Ji et al., 2022). Firstly, the researcher presents an overview of the preterm infant's brain development.

2.3.2.1 Structural changes in a preterm infant's brain

Magnetic Resonance Imaging (MRI) shows the appearances and changes in the preterm infant's brain. As suggested by Madan (2005), while the preterm infant is in the NICU, the developing preterm infant's brain is prone to injury that causes ischemic episodes. These ischemic episodes, as mentioned by Maalouf et al. (1999), can cause inflammatory reactions and neurotoxins that alter the regular activity of the nervous system, eventually disrupting or altering its normal functioning. (Maalouf et al., 1999)To elaborate, Chelli et al. (2015) used gestational age to categorise preterm infants to determine their brain development in ex-utero. These authors mention that scanning the preterm infant's brain within 48 hours after birth and during their stay in the NICU appears to be different at term-equivalent age. Crucial to Chelli et al. (2015) is that during each following week, noteworthy changes developed in the preterm infant's brain.

According to Sólyom-Varga (2021) who mentioned, the germinal layer haemorrhage, intraventricular haemorrhage, and haemorrhagic parenchymal infarction could explain the prevalence of the morphometry incidence of white matter succeeding early life stress. In their study, Van Huis et al. (2014) also included very preterm infants at the corrected age of five years. Van Huis et al. (2014) linked the study's results to developmental motor

impairment, complex neurological dysfunction, hyperactivity, inattention, cognition, visuomotor coordination, low intelligence, slow processing speed, and behavioural problems to prematurity (Van Huis et al., 2014). Another essential point, as highlighted in the study by De Almeida et al. (2020), is that there is meaningful growth of white matter fibres from 20 to 40 weeks gestational age during foetal brain development. It could explain the considerable network strength and efficiency increases in the full-term infant's brain while absent in very preterm infant's brain development. Equally crucial, as was mentioned by De Almeida et al. (2020), is that preterm birth occurs during the critical period of brain development and impacts the standard topological network organisation by discomposing the formation of long-range structural connections of the white matter fibres.

The following illustrations are taken from the seminal article by Cowan (1979) to demonstrate the foetal brain's embryonic progression and developmental stages. Enlarging the first five illustrations of a typical infant brain's dimensions illuminates the formational characteristics. The five illustrations after that are approximately four-fifths of a life-size infant's brain. Cowan (1979) mentioned that the forebrain, midbrain, and hindbrain emerge as protruding bulges at the head-end of the neural tube. Also, according to Cowan (1979), the cerebral hemispheres in humans overgrow the midbrain and the hindbrain; therefore, the cerebellum in adults is not fully visible. Cowan (1979) postulated that the developing brain generates new neurons at an average rate of 250,000 per minute. Then, Cowan (1979:116) assumed that the fully developed human brain has over 100 billion neurons, and Cowan assumed that no new neurons develop after birth. Per these calculations, it is vital to note the significant volume and gyral complexity increase during the last ten weeks of gestation, as shown in Figure 2.1.

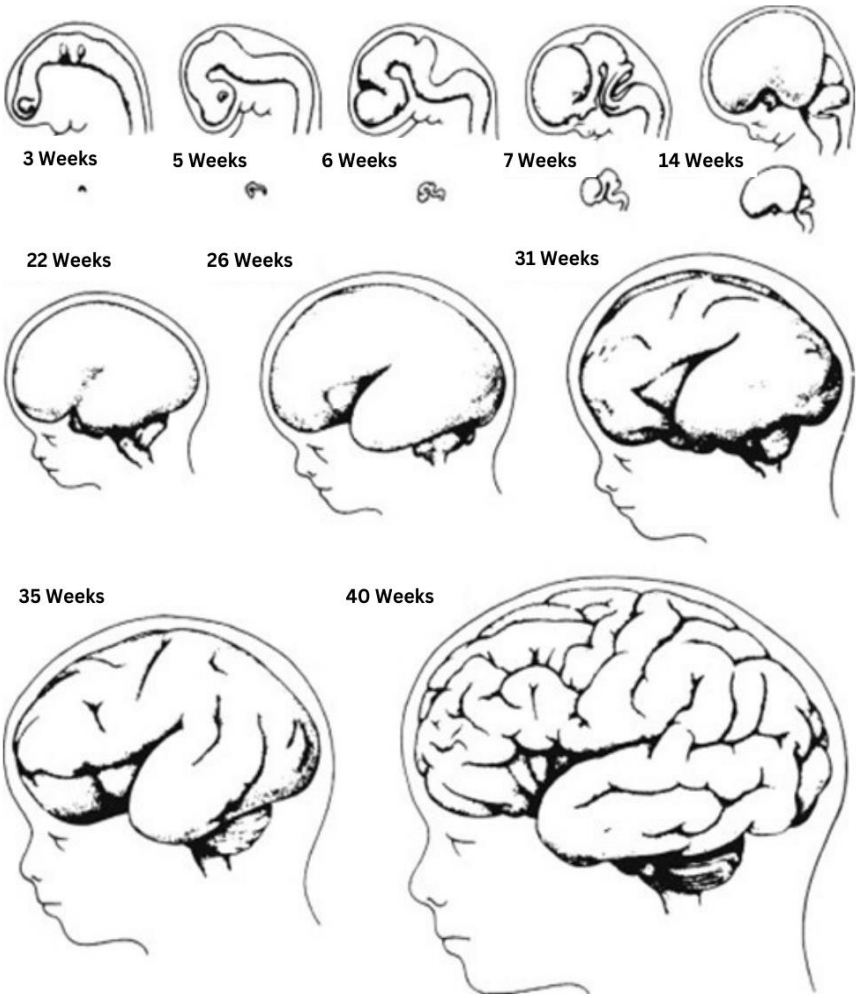

Figure 2.1 The gradual development of the human brain from three weeks to 40 weeks. Reproduced with permission. Copyright© 1997 SCIENTIFIC AMERICAN, Inc. All rights reserved. From the Scientific American Journal: The Development of the Brain, 241:1

Furthermore, the gestational age in weeks, as illustrated in Figure 2.1, can be translated into days as follows:

- Three weeks → 25 days
- Five weeks → 35 days
- Six weeks → 40 days
- Seven weeks → 50 days
- Fourteen weeks → 100 days

- Twenty-two weeks → Five months → Preterm infant → Incompatible with life
- Twenty-six weeks → Six months → Preterm infant
- Thirty weeks → Seven months → Preterm infant
- Thirty-four weeks → Eight months → Preterm infant
- Thirty-eight weeks → Nine months
- Forty weeks → Full-term infant

If one reconsiders the structural changes to the infant brain following the studies of Maalouf et al. (1999), Van Huis et al. (2014), and Chelli et al. (2015), as mentioned in paragraph 2.3.2.1, Cowan (1997) could be correct in his assumption that no new neurons form after birth and therefore there is a possibility that the brain of a preterm infant born at 30 weeks gestational age is incapable of forming new neurons. This information may explain why preterm infants suffer from developmental motor impairment, complex neurological dysfunction, hyperactivity, inattention, cognition, visuomotor coordination, low intelligence, slow processing speed, and behavioural problems (Van Huis et al., 2014).

In conjunction with Cowan's (1997) illustrations, the above research confirms that normal development in full-term infants differs from premature infant development. However, the research set out below will make it clear that prematurity affects the brain and other body systems. Following this, the researcher discusses the development of muscle tone and its long-term effects on the preterm infant.

2.4 MUSCLE TONE

In 2008, this researcher became interested in developing muscle tone and its long-term effects on the preterm infant while employed in a NICU in Bloemfontein. During that time, it was unclear to her why the muscle tone of full-term infants was not the same as that of preterm infants. The researcher also noticed that the differences in tone between these two groups persisted, even after the preterm infants' corrected age was 40 weeks. This interest increased when the researcher completed the Bobath Neurodevelopmental Therapy for

Paediatrics (NDT) course in 2010 and the Bobath/NDT Baby Course in 2012. The approach established an understanding of the relationship between tone, movement quality, postural control and coordination.

The researcher discusses muscle tone and its complications, challenges, and impairments associated with prematurity that may lead to an extended stay in the NICU. Complications due to deficient muscle tone, as mentioned by Gosselin et al. (2005), might cause an unhealthful life, which could lead to the death of preterm infants. More importantly, the noxious NICU, insufficient neuro-developmental supportive care, and malnourishment increase the probability of a preterm infant's neurological maturation being interrupted. The prolonged cohort study guided by Larroque et al. (2008) utilised "The Amiel-Tison Neurological Assessment at Term" to confirm that preterm infants risk developing neurological problems due to the harsh NICU environment. The findings of Farmania et al. (2017) confirm the research of Larroque et al. (2008). Both these studies showed the increased probability of the occurrence of cerebral palsy in preterm infants born before or on 34 weeks of gestation, with a 1% chance to occur before the age of five years. As mentioned by Farmaniea et al. (2017) and Larroque et al. (2008), the incidence may rise to 5%-15% in infants born before the gestational age of 32 weeks. As was further mentioned by Larroque et al. (2008), in an adverse perinatal incident, the medication given to the mother during the birthing process and critical illness of the newborn preterm infant is more likely to affect the active tone rather than the passive tone. Therefore, there is a need to discuss muscle tone as an intricate part of the development of the preterm infant.

Claudine Amiel-Tison already identified muscle tone in 1968. She divided the neurological characteristics of muscle tone into two categories: the active muscle tone and the passive muscle tone that exists in the axes and limbs of all humans. Amiel-Tison (1968) measured the passive tone while the infant remained passive at rest, while she measured a single joint's repetitive passive movements. In later years, Metha et al. (2022) stated that at 28 weeks of gestation, the muscle tone is entirely flaccid. That development follows a caudocephalic direction due to the distal segment development.

According to Amiel-Tison, a goniometer is a clinical tool for effectively measuring an infant's passive tone. This clinical tool assesses *preterm infants*' neurological status at 40 weeks postconceptional age. The New Ballard score, as mentioned by Boxwell et al. (2019) and Singhal et al. (2017), accurately measures these different limb angles, indicating that these angles tend to decline as the muscle tone increases. Sarnat's functional anatomic approach, as discussed by Farmania et al. (2017), explains caudocephalic maturation, as there are two pathways in controlling motor function: the corticospinal and subcortical spinal pathways. According to Farmania et al. (2017), the myelination of these two pathways may differ in the velocity of myelination, and the development order may vary in individuals. Expeditious adjustments are observed from the gestational age of 24 to 34 weeks in the subcortical spinal system's myelination in a caudocephalic order (Farmania et al., 2017). Of equal importance, as described by Farmania et al. (2017), is that by 34 weeks of gestation, fully myelinated medial pathways surface. The lateral pathways are only partly myelinated, while the lower system is antigravitational activity dependent. The findings of Allen and Capute (1990) and Metha et al. (2022) confirm that the caudocephalic maturation pattern is responsible for the direction of the development of passive tone. The authors, as mentioned above, stipulate that the order of the evolution of tone and reflexes develops from the gestational age of 25 weeks to 40 weeks gestational age. Allen and Capute (1990) also described that the first flexor tone is found in the lower extremity at 29 weeks PMA. The flexor tone appears in the upper limbs after two to three weeks. Equally important, Allen and Capute (1990) mention that *preterm infants* exhibit two patterns of normal development: caudocephalic tone and reflexes in the lower to upper extremities, and centripetal indicates the development from distal to proximal. Farmanie et al. (2017) revealed *that* preterm infants of the gestational age of 40 weeks exhibit a remarkably reduced flexor tone and adductor angle compared to full-term infants. Another study by Saint-Anne Dargassies, 1977, compared *preterm infants* at the gestational age of 40 weeks with full-term infants. The range of motion was substantially more comprehensive, muscle tone was lower, and range of motion and flexibility were more considerable in the group for preterm infants. To conclude, the study by Howard et al. (1976) claimed that preterm infants have lower responses when movement activities are involved,

especially regarding items involving muscle tone. Preterm infants have higher arousal levels but have more inadequate responses to items involving muscle tone.

As Farmania et al. (2017) suggested, internal and external factors have less influence on the preterm infant's passive tone, which postulates that the internal and external factors are less than they thought. Still, instead, the preterm active tone is more influenced by an unfortunate incident during the perinatal period, maternal medication during delivery, and acute affliction of the infant. An infant's active tone is examined segment by segment when held upright, and the righting reaction in the lower extremities is demonstrated (Metha et al., 2022). Furthermore, as mentioned by Metha et al. (2022), as maturation takes place and the infant can sustain his body weight, the righting reaction occurs in the trunk, and lastly, the righting of the head is conceivable. In conclusion, Robinson (1966) and Metha et al. (2022) agree that the grade of the primary reflexes is reliable on the standard of the active tone and that at 28 weeks, these reflexes are present but weak and difficult to elicit.

Another essential point that Tecklin (2008) established is that during the first year of a preterm infant's life, it is not only cerebral maturation that evolves but also vision, hearing, vestibular, tactile, and automatic systems. Similarly, according to Allen et al. (2009), expeditious growth occurs within the central nervous system, and the differentiation in the structure of the neurons takes place. Then, there is also the development of glial cells, myelination occurs, and substantial growth of the axons and dendrite is observed between the gestational age of 23 and 32 weeks (Allen et al., 2009). Almost all preterm infants spend indefinitely long periods in the NICU that entail more exposure to extrauterine surroundings. The abnormal environment of the NICE leads to preterm infants having difficulty moving into a flexed posture, as they prefer a more extended posture when compared to full-term infants.

In summary, the muscles become floppier and weaker, and due to this continuing extended posture, the preterm infant suffers from impaired motor development (Bodensteiner 2008). Kenner and Wright (2007) concluded that hypotonia in *preterm infants* is the effect of early maturation of the immature muscular system and the inability of the muscles to resist gravity. In addition, Joseph et al. (2014) state that the ability to resist passive stretch and uninterrupted passive tightening is needed to achieve optimal muscle tone. For the preterm

infant in the NICU, the probability of developing low muscle tone increases as this extrauterine environment does not encourage this essential movement-driven development (Teledevara et al., 2019).

Muscle tone, as described in the paragraphs, affects the muscle tone of all the muscles in the preterm infant's body. Therefore, the low muscle tone is assumed to affect the tongue muscles. Hence, an essential component of this study is an explanation of the normal development of the tongue and its relationship with other body systems.

2.5 THE SOMATOSENSORY REGION OF THE CEREBRAL CORTEX

The anatomical as well as neurological relationship of the tongue with the body system, which is relevant to understand the sucking process, is essential. Therefore, the researcher explains the somatosensory and somatomotor cortex through the homunculus diagram, indicating the different facial dermatomes in the diagram diagram.

2.5.1 The anatomical relationships of the tongue with the body system

According to Bordoni et al. (2018), the tongue has several anatomical connections, such as the combinative tissues and the circulatory systems, which stem from a group of cells that migrated from the neural tube to form the tongue. Bordoni, Marelli, and Morabito (2016) explain that the somite mesoderm forms the tongue's muscle cells, and the unsegmented somitomeres form the mastication muscles. Also mentioned by Bordoni et al. (2018) is that the tongue has a connection with the following three structures: the hyoid bone, the suprahyoid and the infrahyoid muscle. Complementary to this, Castro et al. (1999) describe that due to the hyoglossus membrane that ties up with the tongue and the lingual septum, a human can maintain its posture and keep its head in equilibrium with the rest of its body.

Similarly, Castro et al. (1999) found that the omohyoid muscle and the anterior belly of the digastric muscle assist the tongue, cervical track and the head/neck to move into flexion, extension and rotation, which is the first phase of the ability to swallow and start vocalisation. During the first phase of swallowing and vocalisation, Castro et al. (1999) mention that jaw and tongue movements help to coordinate the suprahyoid and infrahyoid muscles. All tongue

movements, except retraction, are assisted by the suprahyoid and infrahyoid muscles. The tongue muscles, which include the intrinsic – and extrinsic muscles, work in unison. What matters as well, as was mentioned by Zaidi et al. (2013), is that the posterior part of the tongue has a crucial function relating to respiration, while the anterior part of the tongue is indissolubly in non-respiratory activities. Bordoni et al. (2018) state that the tongue has a sturdy connection to the strap and sternocleidomastoid muscles. This connection warrants a thoracic outlet and fascial continuity. Bordoni et al. (2018) pointed out that the tongue needs to react on the contractile tonus from muscle groups that might be in direct or indirect contact with the tongue to promote proper functioning. The central and peripheral nervous systems control this complex organisation of muscle groups.

In conclusion, as Bordoni et al. (2018) explained, the tongue extends, bulges, and can be flattened, making it a hydrostat which acts as an apparatus that detects the presence of fluid as a preventative measure. In addition to Bordoni et al. (2018), Gilbert et al. (2007) mentioned in their article that the mammalian tongue falls into a class of organs known as muscular hydrostats. These muscle organs generate contractions and stabilise the musculoskeletal/locomotor systems. If an infant has body stability, it can transition into mobility and movement against gravity. Considering that all the muscle groups of the preterm infant can be affected by low tone, it would be reasonable to argue that the preterm might have difficulty going into rolling to be able to go into sitting and finally walking. Therefore, one can expect that *preterm infants* may show developmental milestone delays.

2.5.2 Neurological relationships

Studies by Picard and Olivier (1983) showed that the tongue is substantially represented in the brain. The cortex, medulla oblongata, limbic system and mesencephalon form an exceedingly organised part of the brain. The comprehensible somatotopic organisation, excessive specificity, and integration occur on a cortical level (Picard and Olivier, 1983). Due to the neuroplasticity of the brain's cortex, environmental stimuli can influence the activity of the tongue. According to Schmidt et al. (2009), physiological stimuli can improve the functioning of the tongue, whereas pathological stimuli may lead to functional disorders. The tongue against the hard palate will cause the parasympathetic system to reduce systematic

activity, including heartbeats, increasing the respiratory rhythm. Schmidt et al. (2009) added that when pushing the tongue against the soft palate, the sympathetic system causes a reduction in activity.

Bordoni et al. (2018) also mentioned that the tongue's placement and the strength of the voluntary or non-voluntary movement of the tongue influence the lung volume. Saboisky et al. (2015) debate that the pleural receptors are activated by a pulmonary stretch, inhibiting the hypoglossal nerve that controls tongue movement and the phrenic nerve that controls breathing; therefore, the posterior-lateral part of the tongue's movement or the lack thereof cannot activate the anterior cingulate cortex, which is instrumental in cognitive, motor, sensory, emotional information, and pain processing. Furthermore, according to Nicholson et al. (2017), Van Daele et al. (2011) and Sakamoto et al. (2010), the ACC is also associated with visceral sensation, while the amygdala influences emotions and mood regulation, as well as verbal behaviour, taste learning, and the forming of motor patterns during chewing. As Sbarbati and Osculati (2007) mention, the tongue's posterior and anterior areas have specific ganglia that open to the portal of the enteric system, which is the beginning of mastification or the chewing process. Mastification is the beginning of digestion, which increases the surface area in the mouth for the efficient breakdown of foods due to the efficient secretion of enzymes needed. Another essential point by Sbarbati and Osculati (2007) is that the tongue can modulate digestive functions and alert the stomach and intestines before the arrival of food.

2.5.3 Systemic relationships

2.5.3.1 Homunculus: Somatosensory and somatomotor cortex

Huang et al. (2009) mention that adenosine triphosphate switches type III cells when the taste stimulation is received to release serotonin and norepinephrine, as well as gamma-aminobutyric acid, while the synthesis of acetylcholine stimulates the secretion of saliva. A pilot study by di Vico et al. (2014) reports that the tongue influences control of the lower limbs and that subjects with postural impairments who had electrical tongue stimulation showed improved balance, gait, and posture. Changes in the tongue's position, as noted by

Kothari et al. (2014), could influence the tongue's myoelectric system, which can innervate the body's position using muscle activity and voluntary respiration increases notably while in supine, ensuring an open upper airway. An illustration of the homunculus in Figure 2.2 demonstrates that the tongue has greater tactile sensitivity than the finger. The tongue represents the sizeable primary motor and cortical sensory areas compared to other body parts. As mentioned in paragraph 2.5.1, the tongue is a muscular hydrostat that stabilises the musculoskeletal system (Gilbert et al., 2007; Bordoni et al., 2018). This fact matches what Barnett-Cowan et al. (2015) noted: that the tongue typically adopts a central position, and it could reinforce the position of the head. Postural dysfunction is directly related to how the tongue interacts with the body posture, as there is an association between the occlusal class and pathological postures (Bordoni et al., 2018). To add to this train of thought, Magliulo et al. (2018) stated that the tongue's morphology and non-physiological position discordantly influence the cognitive area, hearing, smell, and renal function. Figure 2.2 also shows that the tongue represents a larger primary motor and cortical sensory area than any other body part and has a greater tactile sensitivity to touch than the finger.

Somatosensory Motor sensory

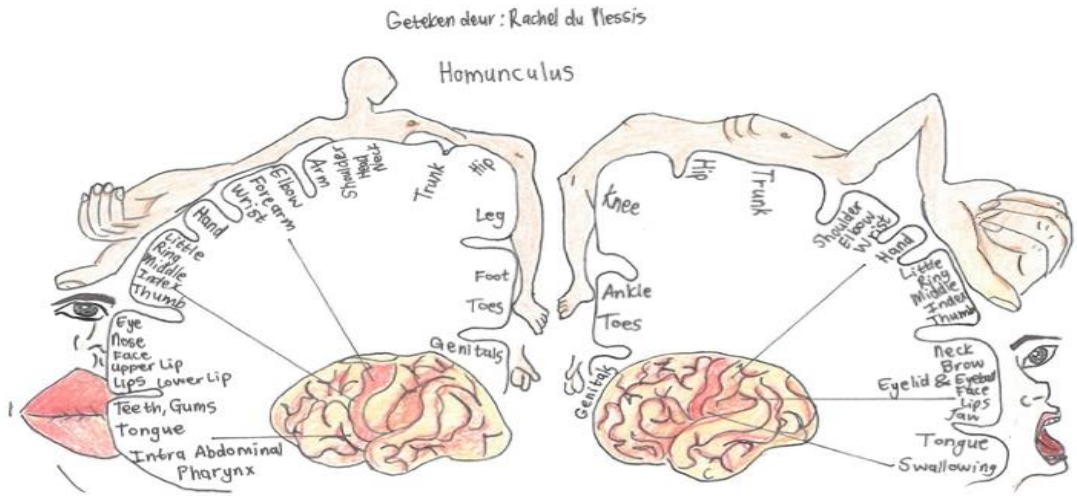

Figure 2.1 Homunculus (Artist: Rachel du Plessis 2024).

In conclusion, Bordoni et al. (2018) mention that dysfunction could lead to several local and systemic pathologies due to the tongue's countless connections with different body systems. In addition, when evaluating the tongue, according to Bordoni et al. (2018:5), it has to be kept in mind that connections with other systems of parts of the body, namely the lower limb, the temporomandibular joint, the neck, the respiratory system, the pelvic diagram, and the muscles of the thoracic outlet may also influence the physiological behaviour of a person. Thus, the multi-disciplinary team working with the preterm population in the NICU should consider all the aforementioned information during manual tongue evaluation to enable the best intervention and therapeutic results.

As previously stated, there are systemic relationships between the tongue and other body systems. The first discussion covered the homunculus and its relation to the somatosensory and somatomotor cortex. The following discussion will explain the facial dermatomes and the systemic relationship between specific nerves and the specific skin area they translate into.

2.5.3.2 Facial dermatomes

A systemic relationship exists between the cutaneous innervation by fibres of specific nerve relays and a particular skin area. The spinal nerve innervates most of a human's skin. In contrast, the face receives cutaneous innervation from the trigeminal nerve, also known as a cranial nerve. In addition, there are different dermatomes, as illustrated in Figure 2.3.

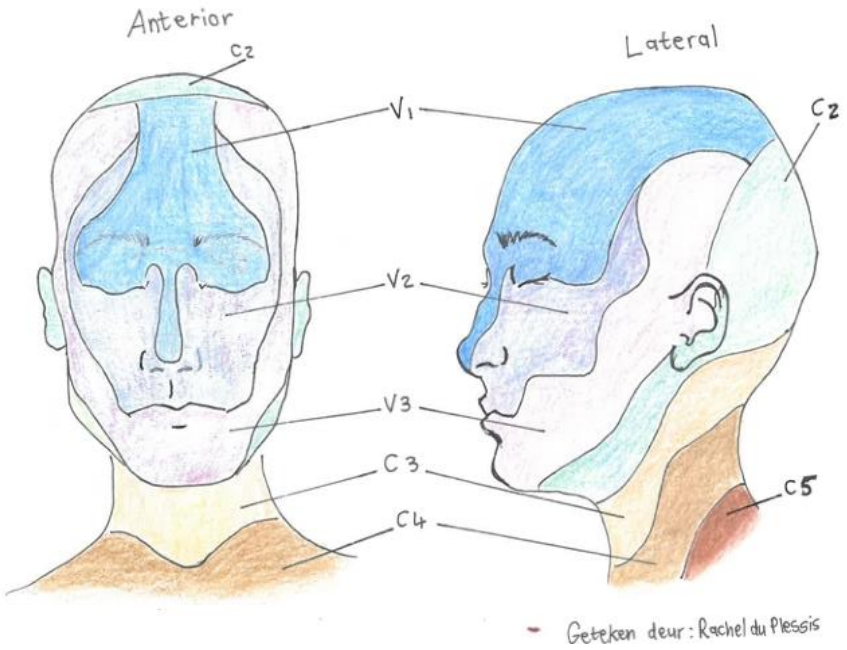

Figure 2.2 Facial dermatomes provides sensory innervation to different face parts. (Artist Rachel du Plessis,2024).

Table 2.2 Facial Dermatomes and the nerve that provides sensory innervation

Facial Dermatomes and the nerve that provides sensory innervation	
V1 **Ophthalmic nerve**	It carries sensation from the scalp, eyes, nose, forehead, and skin, as well as from mucous membranes of the upper face and scalp. It contains sympathetic nerve fibres to the pupillary dilation, iris, conjunctiva and cornea.
V2 **Maxillary nerve**	It carries sensation to the midface.
V3 **Mandibular nerve**	It carries sensation from the lower third of the face, from the floor of the mouth, jaw and tongue.
C2	It carries sensation from the upper and posterior parts of the scalp, from the skin on the front of the neck and the earlobes.
C3	It carries sensation from the side of the face and the back of the head.
C4	It carries sensation from parts of the neck and shoulders.
C5	It carries sensation from the upper part of the upper arm down to the elbow.

Figure 2.4 combines Figure 2.2 of the homunculus and Figure 2.3 of the facial dermatomes. It ventures to demonstrate the inter-relationship between the facial dermatomes and the

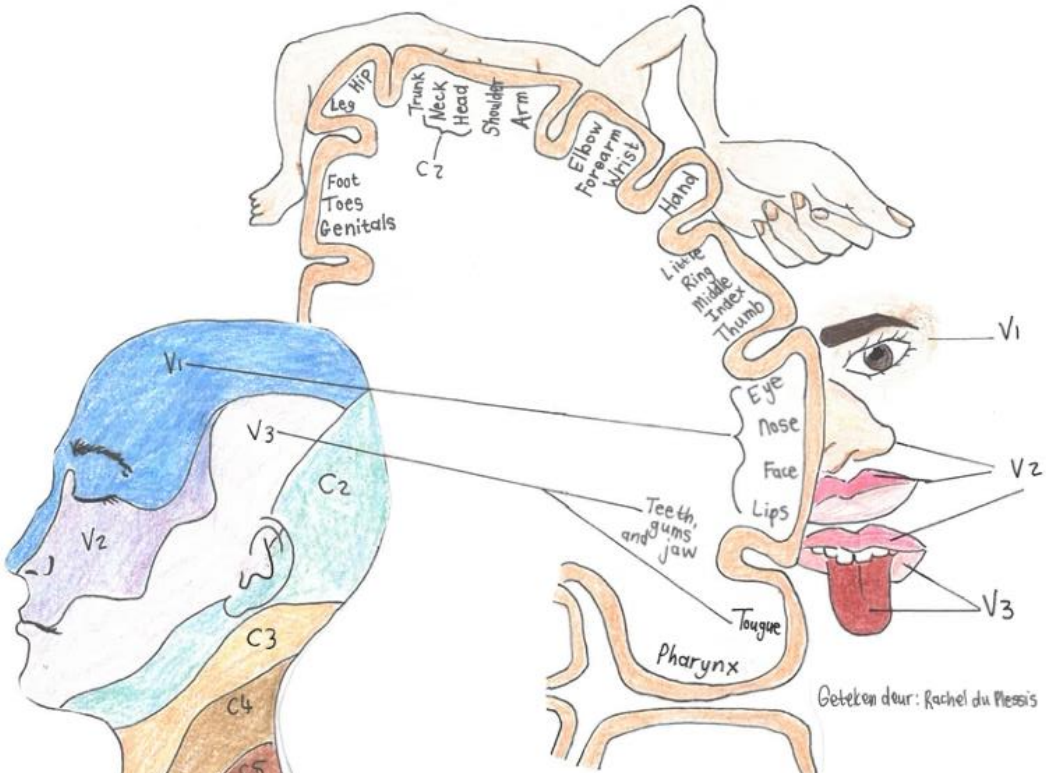

Figure 2.3 The inter-relationship between the facial dermatomes (Left) and the somatosensory cortex (Right) (Artist Rachel du Plessis 2024).

somatosensory cortex.

Subsequently, apart from the inter-relationship between the facial dermatomes and the sensory cortex, evidence by Ruiz et al. (2019) illustrates that low-birth-weight preterm infants might suffer from:

- long-term difficulties due to compromised health, growth and development,
- decreased well-being during the antenatal, newborn and postnatal phase,
- and alterations of orofacial structures might lead to morphological shortcomings.

Equally important, as was stated by Ruiz et al. (2019), is when the preterm infant and full-term infant's face dividing the face into three-thirds, it will show an upper-, middle-, and lower third. The middle- and lower-thirds way of development could impact the activities in the oral and nasal cavities. As a result of being born before the gestational age of 40 weeks, there might be other conditions directly caused by prematurity, such as poor posture and low

muscle tone. As described by Ruiz et al. (2019), these potential changes may cause the head and neck to be in non-alignment with each other or the body. This non-alignment influences how a preterm infant would suck-swallow-breath and how the lips, tongue, and orofacial muscles move and interact. From the information in Figure 2.5, Ruiz et al. (2019) concluded that the face of a preterm infant with a low birth weight might differ because of unforeseen circumstances. The malformation contributes to underdeveloped suck-swallow-breath synchronicity (Ruiz et al., 2019), which leads to difficulty in breastfeeding and bottle feeding. In the study by Ruiz et al. (2019), the researchers used descriptive characteristics of infants. They compared Group A, which has very low-weight preterm infant characteristics, with Group B, which has full-term infant characteristics. The following are the averages of both groups used in the study.

	Group A (n = 54)				Group B (n = 100)			
Variable	Mean	SD	Min	Max	Mean	SD	Min	Max
Birth Weight (g)	1,281	136	1,000	1,492	3,121	347	2,500	3,970
Gestational Age (wk)	30	2	28	35	38	1	37	41
Upper Third (mm)	30.2	3.5	23.3	37.0	31.1	3.2	24.1	40.0
Middle Third (mm)	24.2	1.4	20.3	26.9	25.9	1.5	22.7	29.0
Lower Third (mm)	27.6	1.8	24.2	31.6	29.9	2.3	25.2	35.1
Width Facial (mm)	64.8	3.9	60.0	74.9	81.4	4.3	74.2	89.8
Height Facial Total (mm)	82.0	0.6	71.4	92.1	86.9	0.49	76.3	98.9
Neonatal Total Facial Index	1.27	0.01	1.07	1.43	1.07	0.01	0.92	1.28

min, minimum; max, maximum; wks, weeks; Test, Student's *t*.
Group A, Group of very-low-birth-weight preterm infants.
Group B, Group of full-term newborns.

Figure 2.4 Orofacial characteristics of the very low-birth preterm infants. Reproduced with permission. Permissions form [241121-027607]. From the Jornal de Pediatria: Orofacial characteristics of the very low-birth-weight preterm infants, 96-102, by Ruiz et al.,2021 (Addendum J)

The abovementioned facts confirm that the facial characteristics of the anatomy of the preterm infant differ in more than one way from that of a full-term infant. This thought may previously have been pure speculation as to why preterm infants have difficulty sucking but considering the information provided by Ruiz et al. (2019), as set out in, it seems to be a highly probable reason for preterm infants having difficulty in sucking.

In brief, the researcher considered the homunculus, its somatosensory and somatomotor cortex in combination with the facial dermatomes, and the inter-relationship between them. The research by Ruiz et al. (2019) confirmed that low-birth-weight preterm infants have a higher risk of developing problems with breathing, sucking and swallowing. This hindrance may lead to difficulty gaining weight and being on oxygen for prolonged periods, leading to a more extended stay in the NICU.

In summary, the somatosensory region of the cerebral cortex has an anatomical relationship with the tongue, which is related to the body system. The researcher used the homunculus and the facial dermatomes to simplify the explanation of these systemic relationships.

The following section will comprise an analysis of the motor process of sucking through an explanation of the central pattern generators that control sucking. A narrative regarding the relationship between sucking and the limbic system will follow that. In addition, a clarification of the two different types of sucking, namely nutritive sucking and non-nutritive sucking will conclude the section.

2.6 SUCKING

2.6.1 Anatomy and Physiology

An ultrasound investigation by Crum et al. (1995) led the Dakota Department of Health to publish a booklet in which Crum indicates that a foetus of the gestational age of 20 weeks could suck its thumb. As Crum et al. (1995) mentioned, the foetus has the reflex to suck and grasp at this particular age. Therefore, the researcher presents an in-depth look at the activity of being able to suck.

Shandley et al. (2021) describe that the full-term neonate is born with the ability to suck successfully because the brain's neural network is already formed and functional. This network keeps on developing into adulthood. The complex neuronal network, as well as the brain's neuroplasticity, are prerequisites for the infant to obtain nutrition and to develop its ability to suck. Based on the ideas of Shandley et al. (2021), observing the neonate's skill of being able to suck or not being able to suck provides insight into the areas of the brain that

may have been damaged either before, during, or after the birth process. In the same way, Back (2017) mentions that observing the neonate's sucking as an evaluation method makes it possible to identify a brain injury. Before these recent studies, Wintermark (2015) claimed that an MRI was the sole predictor, and therefore unreliable, for determining clinical impairment or prognosis. The relationship between the brain's neuroplasticity and the infants' ability to suck may potentially repair the brain injury (Back, 2017).

The foetus begins to suck and swallow *in utero*, which develops into integrating breathing ex-utero. Sucking is a motor process controlled by central pattern generators (CPG), thus making it a complex sensorimotor process (Shandley et al., 2021).

- The CPG interneurons' first level is in the brainstem, specifically in the upper medullary and pontine areas. It generates a basic swallow without extra input (Barlow, 2009).
- The second level includes the subcortical structures such as the basal ganglia, hypothalamus, cerebellum, amygdala, and the tegmental area of the midbrain.
- The third level is the supra-bulbar cortical swallowing centre (Mistry and Hamday, 2008). Five cranial nerves, namely: V, VII, IX, X, and XII, and sensory or motor relay nuclei in the brainstem and their interconnections comprise the sucking neural circuit (Maynard et al., 2020).

Shandley et al. (2021) based their studies on the full-term infants' ability to suck. Unfortunately, the preterm infant does not have the privilege of repetitively practising this complex sensorimotor process of suck-swallow while in utero. Consequently, preterm infants have difficulty integrating breathing ex utero due to preterm birth. Therefore, during this research, it was deemed worthwhile to investigate the CPG and scrutinise the nerves involved in the formation of the CPG. The trigeminal nerve, or cranial nerve 5 or CN V, is the sizeable three-part nerve involved in the facial dermatomes, as shown in Table 2.2. Figure 2.6 shows that specialised networks of interneurons within the CPGs generate rhythmic motor patterns, such as sucking, which include the following nerves: CN V, CN VII, CN IX, CN X, and CN XII.

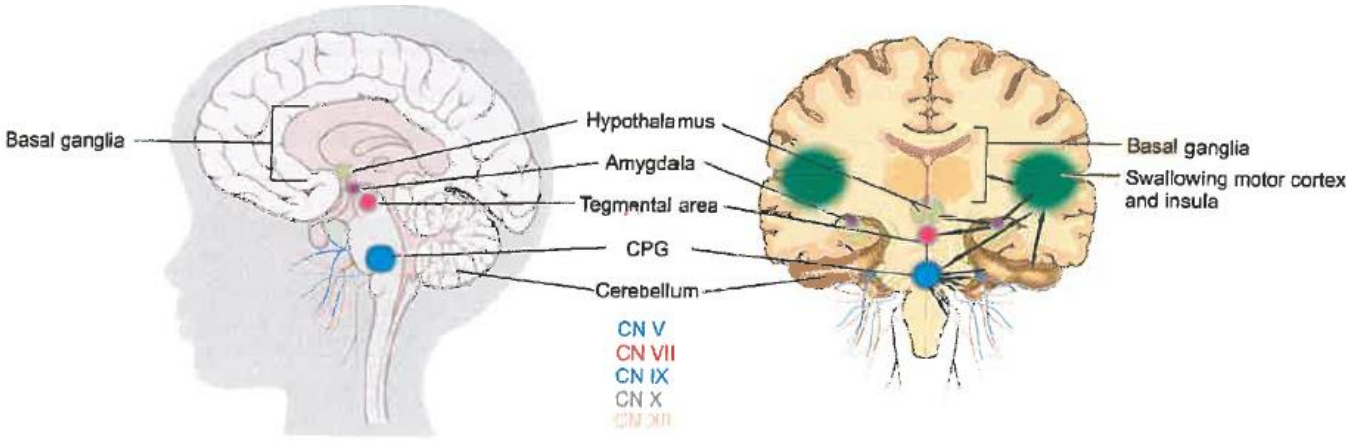

Figure 2.5 Central Pattern Generator. Reproduced with permission. Permission from Frontiers in Pediatrics in terms of the Creative Commons Attribution License (CC-BY 3,0). From the Frontiers in Pediatrics: Abnormal Nutritive Sucking as an Indicator

The central theme of the subsequent discussion is an explanation of the working of the CPG, as well as a description of some of the functions of the CPG that involves sucking. Barlow and Estep (2006) stated that one CPG function modulates orofacial reflexes by incorporating messages from the trigeminal sensory flow.

According to Finan and Barlow (1996) and Iriki et al. (1988), the suck Central Pattern Generators (sCPG)is a generator that consists of a bilateral patterning generator. This bilateral circuit of interneurons is in the brain stem reticular formation. Intrinsic burst-generating capabilities, according to Del Negro et al. (1998), Tanaka et al. (1999), and Zimmerman and Barlow (2008), can be observed within the Oro rhythmic generator circuits due to the interneuron's composition. When the brain stem transaction distorts the rhythm-generating circuits, they cannot receive descending input from the cerebral cortex for Oro rhythmic generation to occur (Barlow and Estep, 2006). Another essential point Barlow and Estep (2006) make is that while an infant is sucking on a pacifier, it produces sensory information from cutaneous and deep afferents. Barlow and Estep (2006) elaborated on the timing and number of efferent signals used to guide the facial, trigeminal, and hypoglossal lower motor neurons. Equally important, according to Truisson and Essick (2004), the two areas with high densities of low threshold and rapid conducting mechanoreceptive afferents

are the lip vermilion and the two areas at the tip of the tongue. The oral mechanoreceptors modulate the timing and immensity of the sCPG's output during infant development (Finan and Barlow, 1996). Equally important is the sCPG's ability to adapt to an unexpected change in the environment, e.g., a different pacifier, which would then influence the alteration of the Oro rhythmic activity of the jaw. A change in the environment would also affect the movements of the lips and tongue, as well as the Oro rhythmic behaviour, which includes the volume change of the bolus or mechanical properties of the nipple. The Oro rhythmic activity would change the coding via the primary trigeminal afferents to the jaw (Lund and Kolta, 2006a) (Lund and Kolta, 2006b). Neural activity along the trigeminal lemniscus enables an infant in developing develop and establish sucking actions when regular subjection to self-generated Oro sensory episodes is provided (Barlow and Estep, 2006).

To conclude, as was subsequently mentioned by Pascual et al. (1998) and Bosman (1973), preterm infants in the NICU are subjected to having nasogastric tubes, orogastric tubes, nasal cannula, and endotracheal intubation tubes inserted in either the nose or mouth. These tubes are removed and replaced every third day to prevent infection. In the same way, as mentioned by Barlow and Estep (2006), sensory deprivation has adverse effects on the mechanisms of cortical and cerebellar differentiation during the early postnatal period. Therefore, a preterm infant with a damaged central nervous system often shows less developed sucking patterns, according to Zimmerman and Barlow (2008). Subsequently, Barlow and Estep (2006), as well as Pascual et al. (1998), demonstrated that enhancing the sensorimotor activities by using a pacifier while the infant is in the NICU is the most advantageous for developing the brain and strengthening the sucking process.

The second level of the sCPG includes the limbic system (Mistry and Hamday, 2008). In the book titled "Waarom lewe ek" by Daniël J. Louw, based on the work of Viktor Frankl, the father of logotherapy, Louw mentioned that an abnormal reaction to an abnormal situation is normal behaviour (Louw, 2007: 30). In this situation the limbic system comes into play. As identified by Tyler and Abdijadid (2023), cells of the mesencephalon, diencephalon, and telencephalon that comprise the limbic system formation are formed during embryogenesis.

According to Sa de Almeida et al. (2020), this system is an accumulation of brain structures located lateral to the thalamus, underneath the cerebral cortex, and atop the brainstem.

A discussion about the significance of the different structures of the limbic system and the structures closely related to the limbic system follows here.

2.6.2 The limbic system

Catani et al. (2012) state that the limbic system is the part of the brain that involves behaviour, emotional responses, motivation driven by primitive drives, learning, and memory. The limbic system is fundamental to survival. Dysfunctions in any of these brain regions, or the connections between them, are believed to cause distress and difficulties suffered by individuals suffering from depression and anxiety (Bick and Nelson, 2016). As Sa de Almeida et al. (2020) stated, abnormalities in the limbic system could implicate developmental disorders. The amygdala and the hippocampus, as part of the limbic system, are discussed in the following section.

2.6.2.1 Amygdala

Recently, investigators have examined the effect of premature birth on the structure of the amygdala. According to Schmitz-Koep et al. (2021), due to increased stress levels of premature birth, the amygdala is compromised. However, accounting for the lifelong plasticity of the amygdala, it is unclear whether such structural changes persist into adulthood (Schmitz-Koep et al., 2021). This research found significantly lower whole amygdala volumes in premature-born adults. At the same time, premature-born adults had substantially higher T-scores for avoidant personality, reflecting the increased social anxiety trait. Results by Schmitz-Koep et al. (2021) demonstrate reduced amygdala volumes in premature-born adults. The data presented in this study suggest the lasting effects of prematurity on the amygdala structure.

2.6.2.2 Hippocampus

Long-term follow-up studies using quantitative magnetic resonance imaging (MRI) show that preterm birth is associated with long-term reductions in cortical surface area, volume and folding, and reductions in the volume of subcortical regions (Dean et al., 2014). Neurodevelopmental outcomes correlate independently with white matter injury and the magnitude of the grey matter deficits. Similarly, as was stated by Dean et al. (2014), decreased caudate, cortical, and hippocampal volumes were associated with lower intelligence quotient in preterm infants at seven to eight years of age. In the study of Strahle et al. (2019), the researchers mentioned that preterm infants are at high risk for brain injury during the perinatal period. Intraventricular haemorrhage and periventricular leukomalacia, the two most common patterns of brain injury in preterm infants, are associated with poor neurodevelopmental outcomes (Strahle et al., 2019). Very preterm infants with brain injury had smaller hippocampal volumes at term equivalent age compared to term and very preterm infants with no to mild injury, with the smallest hippocampi among those with grade III/IV intraventricular haemorrhage and post-haemorrhagic hydrocephalus. Furthermore, as was also mentioned by Strahle et al. (2019), larger ventricle size was associated with smaller hippocampal size. Smaller hippocampal volumes were related to reduced motor performance at age two years across all groups. In addition, smaller hippocampal volumes in infants with brain injury correlated with impaired cognitive scores at age two years, a relationship specific to this group. Stahle et al. (2019) demonstrate that perinatal brain injury is associated with hippocampal size in preterm infants, with smaller volumes related to domain-specific neurodevelopmental impairments in this high-risk clinical population.

Gimenez et al. (2004) compared the relationship between hippocampal and thalamic grey matter loss and memory impairment in adolescents by comparing the history of premature and full-term infants. These researchers observed significant differences between groups regarding verbal learning and verbal recognition but not visual memory. Their analysis showed significant left hippocampal and bilateral thalamic reductions in the preterm infants. The researchers observed correlations between left hippocampal grey matter reduction and verbal memory, learning, and percentage of memory loss in the premature group. Another point of interest is the correlation between verbal learning and the left posterior hippocampus. Gimenez et al. (2004) suggest that left hippocampal tissue loss may be

responsible for memory impairment and is probably related to the learning disabilities that preterm infants exhibit during schooling.

Dean et al. (2014) believe that advanced neuroimaging techniques now offer the opportunity to track the long-term impact on the preterm brain, assess neurodevelopmental outcomes, and provide novel opportunities for early interventions.

The amygdala and hippocampus are part of the limbic system structures. There are different opinions on whether the following structures are part of the limbic system or whether there is only close interaction between these structures forming the limbic system. The circuits within the limbic system show a prolonged after-discharge effect and a delayed reaction after the preterm infant experiences pain during a painful procedure (Cook et al., 2023). The emotional response will outlast the stimuli that initiate the reaction. Lately, anatomists tend to separate the limbic system from the hippocampal structures due to their involvement in encoding new memories.

2.6.2.3 Cerebellum, as well as limbic and paralimbic regions

As was mentioned by Limperopoulos et al. (2014), injury to the premature cerebellum is related to remote cortical development. Infants who are born prematurely are at a significantly elevated risk for neurodevelopmental disorders and delays, even in the absence of structural brain injuries (Cook et al., 2023). Notably, the affected cerebral cortical regions are contralateral cerebellar hemisphere projection targets in the mature brain. The observations by Cook et al. (2023) describe a significant association between these regional decreases in cerebral cortical volume and long-term neurodevelopmental outcomes in preterm infants. These researchers specifically show that there may be a risk of impaired cognitive functioning, language, and behaviour and that motor performance increases significantly with a decrease in regional volumes of the cerebral cortex. Another essential point is that the injured cerebellar hemisphere showed secondary underdevelopment of the cerebral cortical projection regions, which correlates with the long-term functional impairment in prematurity-related cerebellar injury (Limperopoulos et al., 2014).

These risks may be due to earlier-than-typical exposure to the extrauterine environment and its bright lights, loud noises, and exposure to painful procedures, given the relatively underdeveloped pain modulatory responses in preterm infants, as was discussed by Cook et al. (2023). Preterm infants in the NICU endure frequent pain exposure, which may confer the risk for later defects. Preterm infants exhibit pronounced hyperconnectivity within the cerebellum. Hyperconnectivity exists between the cerebellum, the limbic and paralimbic regions, correlating with the number of skin break procedures (Cook et al., 2023). Moreover, skin breaks are associated with autism and poor language scores at 18 months. These results have significant implications for the clinical care of preterm infants undergoing painful exposures during routine NICU care, which typically occurs without anaesthesia. Cook et al. (2023) also mentioned that repeated pain exposures appear to have an increasingly detrimental effect on brain development during a critical period and that the effects are still visible 18 months later.

2.6.2.4 Fronto-paralimbic limbic structural connectivity

Connections within the complete, spatial connectivity of neural pathways in the brain result in specific nodes possessing more connections than others, making them network hubs (Sa de Aleida et al., 2020). Brain network hubs play a central role in facilitating the integration of disparate neural systems by forming long-range connections (Van den Heuvel et al., 2015). As Van den Heuvel et al. (2015) mentioned, a "rich club" organisation refers to the presence of some hub regions that are particularly densely connected, more than expected by chance. Sa de Aleida et al. (2020) stated that preterm birth leads to impaired rich-club organisation and fronto-paralimbic/limbic structural connectivity. Brain network hub differences and impaired rich-club organisation were present in preterm infants. Structural hubs are present during the prenatal period and have a consistent spatial topography throughout development (Ball et al., 2014). Results from the study of Ball et al. (2014) confirm that by term age, both full-term infants' and preterm infants' brain networks demonstrate the presence of network hubs, comprising mainly subcortical (thalamus, caudate and putamen) and limbic (dorsal cingulate gyrus, insula and hippocampus) regions in both groups. The left praecuneus is a hub found in full-term infants. In contrast, the bilateral superior temporal gyrus, left Heschl gyrus,

and amygdalae are hubs only found in preterm infants. Moreover, Van den Heuvel et al. (2015) stipulate that this diminished connectivity might contribute to the reduced integration capacity observed in preterm infants' brain networks.

2.6.2.5 Thalamus

The thalamus, as a subcortical hub, has been shown to present a rich-club connectivity pattern involved in large-scale integration of neural signals (Alexander et al., 1986; Van den Heuvel and Sporns, 2011) and in essential higher-order cognitive functions (Bressler and Menon, 2010). An impaired thalamocortical structural connectivity at term-equivalent age, following preterm birth, has been shown to correlate with impaired cognitive performance in premature infants at two years of age (Ball et al., 2015). Additionally, when preterm infants reached school-going age, alterations in the corticobasal ganglia-thalamo-cortical loop (namely prefrontal-subcortical circuits) were associated with poorer social behaviour, recognition of social context, and simultaneous information processing at school age (Fischi-Gomez et al., 2015). Thalamocortical connections are established during the late second and third trimester of development when preterm birth occurs (Kostovic et al., 2014). Therefore, prematurity and its associated events, such as inflammation, hypoxia/ischemia, stress, and essential environmental changes, may affect the establishment of these connections. Preterm infants presented a significantly diminished thalamic connection compared to full-term infants. Previous literature evidence diminished thalamic-cortical connectivity and reduced network capacity of deep grey matter following preterm birth (Ball et al., 2014). From all detected network hubs, the left and right thalamus were the regions with the highest nodal degree in both preterm and full-term infants.

2.6.2.6 Praecuneus

The limbic precorneal region is closely related to the posterior cingulate/retrosplenial region, which connects to the limbic medial temporal region, including the Para hippocampal gyrus and hippocampus (Al-Ramadhani et al., 2021). The left praecuneus, a hub observed in the full term but not in preterm infants, has already been shown to be a network hub in the newborn brain (Huang et al., 2015). In the human brain, the praecuneus has wide-spread connections.

The praecuneus plays a significant role in the association area, supporting various behavioural functions, including memory retrieval, reward monitoring, emotional processing and mediation between task and rest states (Li et al., 2019). It plays a role in the default mode network, functionally linked to self-consciousness, social cognitive functions (Mars et al., 2012), and the regulation of attentional states and cognition (Leech and Sharp, 2014), which are known to appear later in the development of preterm infants (Smyser et al., 2011). Interestingly, MRIs showed that the left praecuneus plays a central role in integrating systems in newborns and also belongs to the nodes hierarchically. Then, as mentioned by Padilla et al. (2020), more neural activity was noted in the brain regions of full-term infants and not in the brains of preterm infants when they were ten years old.

The limbic system, all adjacent structures, and their multiple connections are still not fully explained and understood, and more research is needed. With the advances in neurosciences, there are still ways of discovering more informative details.

In summary, the somatosensory region of the cerebral cortex, which included the anatomical relationship of the tongue with the body system, was discussed. In addition, the researcher revised the anatomy and physiology of sucking, and the importance of the sCPG, as mentioned by Barlow and Estep (2006), was addressed, which led to the discussion of the limbic system. The researcher seeks to clarify the sucking activity, as it is part of the self-regulatory behaviour, which is central to this research project.

2.6.3 The sucking activity

Customarily, healthy full-term infants are born with the essential skill of performing nutritive sucking. On the other hand, the preterm infant does not have full-term development experience while *in utero.* As was identified by Shandley et al. (2021), an infant of the postmenstrual age (PMA) of 28 weeks seems able to suck and swallow adequately to start with oral feeding but experiences excellent difficulty with breathing simultaneously until 32 weeks PMA, and by 34 weeks PMA, there seems to be a substantial improvement. It is commonly necessary for the preterm infant to develop in two areas, namely maturation/gestational age and gaining experience in the suck-swallow-breath (SSB) activity

(Shandley et al., 2021). Subsequently, age is not the only indicator of readiness to feed without harm.

Lau (2015) mentions an ever-increasing rate of preterm births and accentuates its negative impact on a country's health system due to preterm infants' lengthy stay in the NICU, caused mainly by preterm infants' inability to suck-swallow-breath. This inability to SSB causes the infant not to gain sufficient weight. A preterm infant in the NICU of the private hospital in Bloemfontein discharge date depends on whether or not the infant weighs 2kg, and the primary caregiver can provide 3-hourly feeds. The feeds should then not take longer than 30 minutes. If the feeds take longer, the preterm infant expends too much energy and does not gain weight. According to Gilson et al. (2019), another reason for not gaining weight is that between 40% and 70% of premature infants display immature and atypical feeding skills. The infants who depended on respiratory support for lengthier periods and showed delays in starting with oral feeding were most affected.

There is substantial evidence that the pathophysiology of desaturation in preterm infants is due to diaphragmatic fatigue (Kwon et al., 2018). According to Kwon et al. (2018), the chest wall of preterm infants is amendable. A deficiency of the respiratory mechanism leads to desaturation during feeds. Kwon et al. (2018) also mention that erratic breathing leads to the contortion of the chest wall, which is noticeable as desaturation on the monitor connected to the preterm infant while it remains in the NICU. This contortion increases the volume displacement of the diaphragm during inspiration. Diaphragm displacement requires additional effort and significant calorie expenditure, inducing diaphragmatic fatigue and desaturation (Kwon et al., 2018). Furthermore, Gewolb and Vice (2006) mention a link between frequent hypoxemic incidences, which differ in severity and duration. Equally important, as discussed by Gewolb and Vice (2006), is that after the mechanical ventilation of preterm infants, there is an increase in the number of concurrent abdominal muscle contractions. Subsequently, this leads to a constant delay in lung inflation after the contraction of the abdominal muscles, which evolves into decreased lung volume (Kwon et al., 2018). After discharge, a substantial segment of preterm infants ceaselessly show feeding problems. These preterm infants have a two- to three-time higher rehospitalisation rate than

term infants, where 16% is related to feeding problems (Gilson et al., 2019). The rhythmic nature of sucking requires SSB synchronicity, which has two distinct types: non-nutritive sucking (NNS) and nutritive sucking (NS).

2.6.4 Nutritive sucking

Preterm infants should be able to perform NNS after birth. With maturity, neurodevelopment would improve NS. Maturity would render the suck, swallow, and breath synchronicity more coordinated. NNS sucking paves the way for NS, according to Lubbe (2021), who also describes that this sucking process consists of shorter sucking bursts. Neonatal NS is an intricate human action that includes the interaction of multiple systems. Abnormal nutritive sucking may be an indicator of neonatal brain injury. It is uncertain if a mature NS pattern will surpass long-term neurocognitive functioning and developmental outcomes for infants with brain injury. However, taking a prematurely born infant who can successfully orally feed at home would considerably reduce their stress (Shandley et al., 2021).

One must consider that the window of opportunity to train an infant to suck with a mature NS pattern is likely short, probably a few weeks while in the NICU before being discharged (Shandley et al., 2021). Therefore, using a conventional pacifier enhances NNS and NS while the infant is in the NICU. A pacifier also supports self-regulation. After discharge, the parent uses the same pacifier to continue this NNS, NS, and self-regulation process. Subsequently, one needs to consider other therapeutic activities in the NICU.

2.6.5 Non-nutritive sucking

Goldson (1987) states that an infant's first Oro motor activity after birth is to coordinate the burst-pause pattern with respiration, whether done with a feeding nipple or pacifier. According to Oston (2020), synchronous rhythmic activity occurs within the human brain and coordinates two types of neural processes.

- The first neural process occurs in a small group of cells within the thalamus, which is seen as an internal cellular activity when a single cell fires rhythmically without external influence. This rhythmic firing is called the pacemaker process. As soon as

there are connections between the excitatory and inhibitory thalamic cells, it sends a message to a larger group of cells within the cortex. This group of cells acts as a pacemaker for cortical cells within a broader range.

- Secondly, another rhythmic activity occurs due to the conjoint behaviour of cortical networks. The speed and efficacy of processing information during intricate and executive functions are called synchronised rhythmic activity (Oston 2020).

Timing and rhythmicity reveal themselves during infancy when feeding time and interaction occur between the infant and caregiver (Bundy et al., 2020). Miller et al. (2003) and Humphrey (1964) reported that as early as 15-18 weeks of gestational age, sucking starts in utero. When the ontogenesis of the timing mechanisms occurs, the interactive synchrony comes into play before birth at around 30 to 34 weeks of gestational age (Oston 2020).

NNS is an automatic, predictable, rhythmical, and involuntary response elicited when given a tactile input in or around the mouth (Sohn et al., 2011). According to Pineda et al. (2019), NNS is an essential infancy skill for oral feeding and self-regulation. Foster et al. (2016) add to this by claiming that using a pacifier affords NNS, which provides calmness and psychological stability to an infant by enabling self-regulation. At 28 weeks of gestation, the ability to suck and swallow is present but not fully coordinated until 32 to 34 weeks (Neiva et al., 2014). At 32 weeks of gestational age, according to Zimmerman and Barlow (2008), the classic burst-pause pattern can be observed due to the central nervous system (CNS) maturity. The preterm infant at the gestational age of 37 weeks and in the NICU should be able to suck like a full-term infant (Wolff, 1968).

Equally crucial, as stipulated by Mizuno and Ueda (2005), is that the CNS's integrity could be compromised at the gestational age of 32 weeks, as also highlighted by Barlow and Estep (2006) and based on Lau and Schanler's (2000) findings, preterm infants, compared to full-term infants, often present with immature sucking skills and delayed patterning. Another essential point made by Medoff et al. (1989) is that these preterm infants generate fewer suck, followed by shorter bursts and then a longer pause between bursts, which cause lower suck pressure. Several researchers, like Cowett et al. (1978), agree by reporting that the

physiological distress these preterm infants endure while in the NICU is associated with broader variability in suck patterns. During the neonatal period, NNS can be affected by preterm birth and low birth weight, which might influence the ability to suck successfully due to poor muscle strength (Pineda et al., 2019). Being born too soon results in the infant prematurely being denied the opportunity to practice its sucking and swallowing skills *in utero*. By affording the infant the opportunity to NNS while in the NICU, the infant is encouraged to gain this valuable skill, which in turn provides the opportunity to self-regulate (Reed, 2019).

Lubbe (2021) describes NNS as health-giving since it leads to physiological stability, higher levels of oxygenation, and a decrease in heart rate. Other benefits of NNS are that it protects the infant from aspiration, as sucking inhibits swallowing and improves glucose usage as insulin secretion follows NNS, Lubbe (2021). In addition, Lubbe (2021) mentions that NNS could intensify the absorption of feeds due to an escalation of gastrin secretion, decreased somatostatin secretion, and enhanced gastrointestinal tract functioning.

Grassi et al. (2018) postulate that NNS may not influence the primary outcomes of sucking, such as speech and developmental delay later in life. More importantly, as mentioned by Lubbe (2021), when it comes to secondary outcomes such as reduced hospital stay due to an acceleration in maturation, the conversion from feeding with a tube/gavage feeding makes the transition to bottle feeding more successful. Infants introduced to NNS can handle increased milk volume and daily oral feeds (Forster et al., 2017) (Tian et al., 2015). Another essential point, according to Lubbe (2021) and Jenik and Vain (2009), is that NNS is advantageous for self-consolation, soothing, and pain relief. A study by Bingham et al. (2010) described that the introduction of NNS to preterm infants had higher NNS organisation scores than preterm infants without previous exposure to NNS. These scores predicted an improved transition to oral feeds, in some cases, three days earlier than preterm infants who had not been exposed to NNS and exhibited more chaotic patterns of suck bursts. NNS proves advantageous for modulating self-regulation, increasing levels of alertness, extending the duration of quiet and deep sleep, and enhancing coordination and muscle tone (Pinelli and Symington, 2005).

Furthermore, while NNS takes place, the nerves required to perform NNS involve the sCPG, which will form an essential NNS pathway using the preeminent strategy that when neurons fire together, they will entwine (Tian et al., 2015). Therefore, when using the Occupational Therapy Practice Framework: Domain and process (2020:74), "intervention approaches may address sensory processing, which promotes emotional stability in preparation for executive functioning to support engagement."

In summary, the sucking activity consists of two phases, namely non-nutritive sucking and nutritive sucking. Due to prematurity, infants in the NICU have difficulty performing these activities. This research aims to find reasons for these malfunctions and propose possible solutions. The infant's active participation is recommended and vital, together with a technological, occupational treatment component that simulates NNS, which may lead to improved NS in the NICU and after discharge.

The researcher will address the factors contributing to the negative influence on the neurological and physical development of the preterm infant in the NICU environment.

2.7 EXPERIENCING THE NICU AS A SENSORY HARSH ENVIRONMENT

Due to premature birth, admission to the NICU is inevitable. Mento and Bisiacchi (2012) describe the NICU as a stressful environment, which is caused by sensory overstimulation due to bright lights, noise, repetitive painful procedures like heel pricking, nasal suctioning, and inflammatory pain, experienced as ceaseless invasive care procedures. The relationship between sensory overstimulation and repetitive pain activates the central afferent pain pathways, which causes excitotoxic damage (Anand and Scalzo, 2000). Another essential point Lynn et al. (2011) made is that an infant's brain needs adequate physiological protection and biological ontogenesis to enable higher-order cognitive functioning. Thus, it is improbable that the NICU can replicate the *in-utero* experience that the preterm infant would have had if it had not been born prematurely. However, when the infant-carer relationship occurs in a secure and supportive environment, it assists the infant in its self-regulation behaviour (Lynn et al., 2011). Fortunately, on a global scale, there is a tendency to bring change to improve infant care in the NICU. According to Sarapuk et al. (2017),

neurodevelopmental care is an approach that aims to reduce the mismatches between the extra-and intra-uterine environment by decreasing the stress of preterm newborns in the NICU and promoting the optimal neurobehavioural development of these infants. In the private and public sectors, the NICUs in South Africa incorporate the NIDCAP of Prof. Heidelise Als and Little Steps® and the Neurodevelopmental Supportive Care of Prof. Welma Lubbe (2019).

Due to these recent developments, particularly in South Africa, it is necessary to elaborate on the effect of the NICU on the vital sensory systems of preterm infants, namely auditory, olfactory, visual, and tactile.

2.7.1 Auditory

According to the American Academy of Paediatrics and Pineda et al. (2019), the noise levels in the NICU should not be higher than 45 dB. As Pineda et al. (2019) reported, sound intensities were as high as 68 dB in certain NICUs.

2.7.2 Olfactory

Lubbe (2021:13) explains that at 28 weeks of gestation, the preterm infant's olfactory senses are fully functional, but the olfactory neurons develop much earlier. For this reason, the toxic smell of alcohol and powerful chemicals used during procedures in the NICU are harmful to an infant's olfactory senses, as well as its respiratory system.

2.7.3 Visual

2.7.3.1 Visual development

According to the research by (Stanley et al., 2008), the gestational age of 28 to 30 weeks marks the beginning of more organised sleep states. Organised sleep states evolve in the rapid-eye-movement state or REM sleep and the non-REM sleep. It is also the stage when infants get admitted to the NICU. When the REM sleep state is interrupted, pons-geniculate-occipital waves in the pons and hippocampus and synchronous waves of ganglion cells become delayed. The spontaneous development of these waves can only be active during

REM sleep, thus in the dark. The NICU's environment interferes with the infant's sleep cycles. Interrupted sleep will alter the development of the visual system.

2.7.3.2 Lighting in the NICU

The AAP recommends that the ambient lighting in the NICU should be <646 Lux (60 FC). Diverse lights in the NICU environment, such as dim, bright, or cycling lights, are described in the literature by Pineda et al. (2019). Cycling light suggests that lights should be on for 12 hours and off for 12 hours in a 24-hour cycle. However, these studies recommended that a preterm infant born at 28 weeks should remain in a dim environment until 32 weeks of gestational age. It isn't easy to maintain in the private sector, let alone in the public sector. Most of the NICUs in South Africa have one or two rooms to accommodate extremely ill infants or extremely premature infants in a 12-bed unit. The other 10 – 13 infants lay side by side. Switching on the bright light at one infant's bed exposes the infants in adjacent beds.

2.7.4 Tactile

2.7.4.1 Premature infants experience pain while in the NICU

A research article by Sarkaria and Gruszfeld (2022) mentions the work done by Anand et al. (1987), published 35 years ago. Anand et al. (1987) postulated that neonates' immature central nervous system prevents this population from experiencing pain. However, based on the definitive findings of Anand et al. (1987), preterm infants who received insufficient anaesthetic during painful procedures exhibited more noticeable metabolic stress reactions and showed signs of instability postoperatively. Furthermore, as explained by Sarkaria and Gruszfeld (2022), the research by Craig et al. (1993) demonstrated that premature infants displayed behavioural and physiological reactions to induced painful procedures. As described in an article by Xie et al. (2021), regular painful procedures may result in short-and long-term complications suffered by the infant, such as hyperalgesia and late neurodevelopmental dysplasia. One of the recently confirmed and defined informative details by Sarkaria and Gruszfeld (2022) is the NICU pain experience. Consequently, more than 40 pain scales with proven validity and reliability were created, including the Premature Infant Pain Profile and Behavioural Infant Pain Profile (Sarkaria and Gruszfeld, 2022). Based on Elliot

and Coventry's (2012) findings, pain is one of the eight vital signs mentioned. Therefore, the pain scales could be helpful to monitor the pain levels of a preterm infant in the NICU, as they cannot verbally communicate this type of information.

Furthermore, premature infants that are born before 37 weeks gestational age usually have a birth weight of 1 500g – 2 500g, low birth weight (LBW), and extremely premature infants that are born ≤28 weeks of gestation typically weigh <1 000g, extremely low birth weight (ELBW). During the stay of an ELBW preterm infant in a NICU, up to 12 repetitive pain procedures can occur daily (Mokhnach et al., 2010). As a result of the quantum leap in the development of medical technology, more preterm infants are surviving. Still, according to Mokhnach et al. (2010), the extent of daily exposure to invasive, painful, and tissue-damaging procedures has multiplied. "Early pain might disrupt the development of regions involved in somatosensory processing," according to Duerden et al. (2018:878). In the same way, Dueren et al. (2018) concluded that it is unavoidable for preterm infants in the NICU to have below-par functional outcomes.

Essential points, as presented by Duerden et al. (2018), are:

- This vulnerable population is developmentally sensitive, and continuous exposure to pain shows subcortical structural damage.
- One of the regions affected is the thalamus, which communicates with the nociceptive pathways, which may lead to discontinuous thalamocortical projections due to untimely pain.
- The region of the somatosensory thalamus shows a decrease in volume.
- It led to a decline in thalamic metabolic growth and thalamocortical pathway maturation.
- Findings suggested that thalamic development was associated with poor cognitive and motor outcomes at three years of corrected age.

Therefore, the thalamus is intricate in precipitating repetitive pain and necessitous neurodevelopment.

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The following are procedures that cause pain and discomfort to the preterm infant while in the NICU, according to Alison Kendrick, Clinical Nurse Educator at the Royal Children's Hospital Melbourne (2018):

- Blood tests: heel pricks, venepuncture, or arterial stab,
- Lumbar puncture,
- Eye examination, e.g., to detect retinopathy of prematurity (ROP-screening),
- Line insertion,
- Removal of adhesive tape and sutures when doing wound/stoma dressings,
- Insertion of NGT or OGT,
- Treatment of IV extravasation excoriates or breaks the skin, to name a few.

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The following images are examples of different ways to draw blood from infants in the NICU:

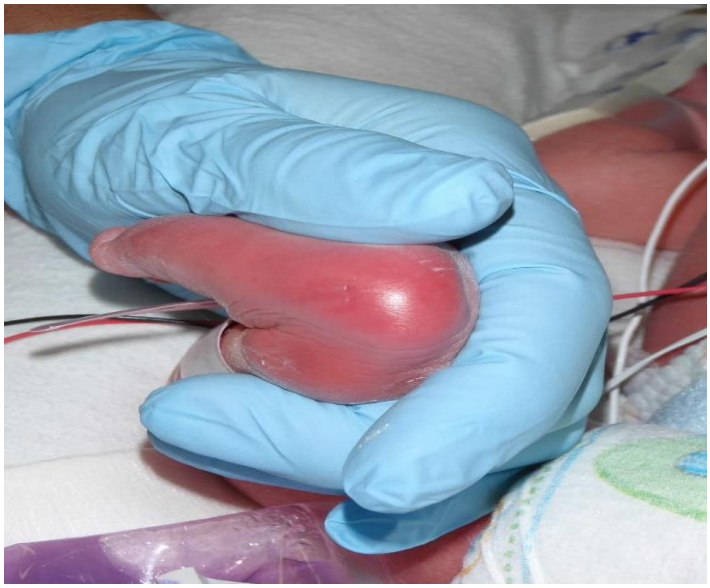


Figure 2.6 The RN prepares the infant's heel by pressing down on the ankle to draw blood

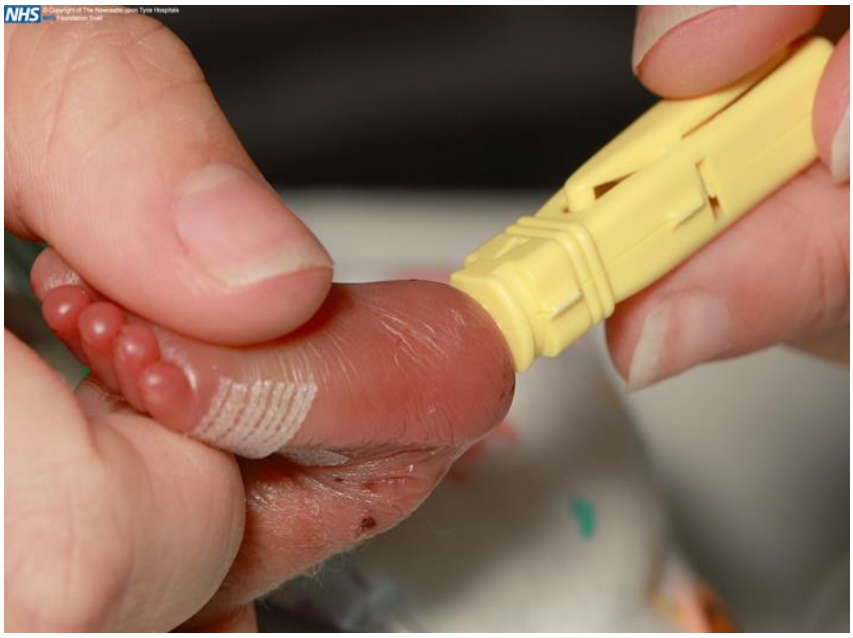


Figure 2.7 Venous sampling from the heel using a lancet to cut a linear opening into the infant's flesh

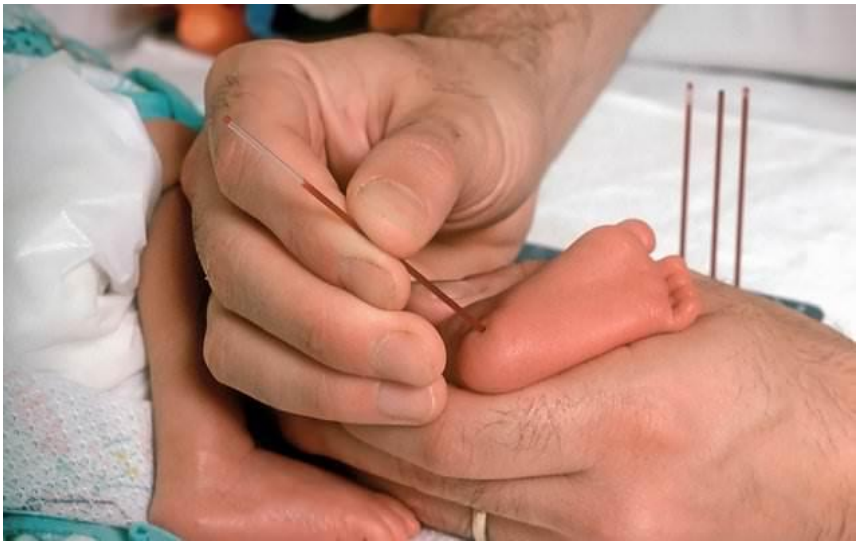


Figure 2.8 A capillary tube is used to draw venous or deoxygenated blood to measure the blood gas of the preterm infant

Figure 2.9 Newborn screening is done on the heel of the premature infant using a needle. This procedure risks going too deep into the infant's flesh, which might lead to nerve damage

In the following pictures, stress cues during these painful procedures are shown in Figure 2.11, Figure 2.12, Figure 2.13 and Figure 2.14

Figure 2.10 The skin turns from healthy pink to mottled left leg (above)

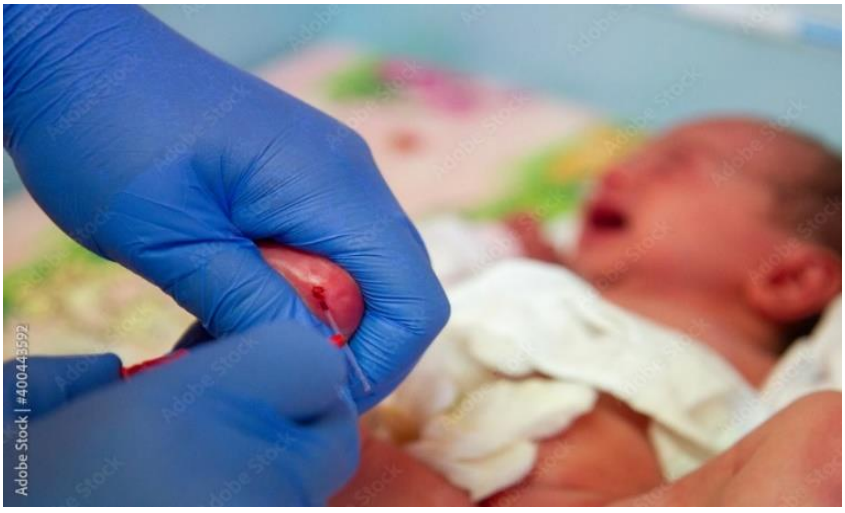


Figure 2.11 Behavioural state: The infant cries during the heel prick procedures

Figure 2.13 A preterm infant experiencing a painful procedure

Figure 2.12 The site where blood collection occurred is on the right forearm. Stress cues are frowning, eyes shut, and a stop sign shown by the left hand, the skin is mottled

One must examine the tongue to gain insight into pain and pain relief. The tongue has countless connections with different body systems, and dysfunction within one of these systems might lead to various local and systemic pathologies (Bordoni et al., 2018).

It is important to note that, despite the negative and painful actions that need to take place in the NICU to save the preterm infant's life, there exists a positive impact of neuro-developmental care on infants while in the NICU.

2.8 SEEING THE NICU IN A MORE POSITIVE LIGHT

Based on the findings of Séassau et al. (2023), as described in their article "Neonatal Care Unit Interventions on Preterm Development", the NIDCAP enhanced neurobehavioral and neurological development in preterm infants in the NICU. The NIDCAP intervention reduces the need for respiratory support and the length of hospital stay. Unfortunately, the NIDCAP program is not readily available to all NICUs because it requires extensive training and a significant time investment by caregivers.

The study "Developmental care advantages in preterm infants' management" conducted by Pavlyshyn et al. (2023) showed that it is possible to improve early outcomes in extremely and very preterm infants using developmental care techniques. Developmental care is associated with fewer late-onset sepsis, retinopathy-of-prematurity, periventricular leukomalacia, and feeding intolerance. These researchers reported that preterm infants spent fewer days on ventilator support, needed less antibiotic therapy, and parents were more involved with feeding their infants. These positives lead to better daily weight gain and growth parameters at discharge. Breastfeeding support, Kangaroo mother care with skin-to-skin contact, stress and pain management, and parental involvement in daily care are the most critical components of developmental care and should be routine neonatal practice.

"Maternal experiences of caring for preterm infants in a vulnerable South African population" is a study by Buys and Gerber (2021:1). Their findings indicate that there are many risk and protective factors affecting a mother's experience of having, caring for, and feeding a preterm infant. While most of these experiences appear universally shared, others are more context specific. Significant context-specific findings involve cultural beliefs and traditions

surrounding preterm birth. Non-standardised approaches to maternal education regarding the use of traditional medicines with preterm birth illustrate a gap in the understanding thereof, as only some preterm infants receive information regarding the dangers of using traditional medicines. Furthermore, misunderstandings of the risks of tube feeding suggest poor maternal education in the neonatal wards and point to a vital opportunity for occupational- and speech therapists to intervene and assist in easing maternal stress. Reduced maternal stress may lead to lower parental perception of childhood vulnerability, a known risk for poor infant developmental outcomes.

NICUs around the globe are aware of the possible negative influence the NICU could have on preterm infants. These known negative factors contributed to the research that established the NIDCAP programme used in many first-world countries. In many developing countries, multi-disciplinary teams work together to accomplish primary developmental care like Kangaroo Care/skin-to-skin contact. Dr Nills Bergman and his wife, Jill, are the pioneers of this life-changing way to take care of a preterm infant. Subsequently, Bergman and Bergman (2010) state that having a preterm infant in the NICU is overwhelming for the infant's parents and life-threatening for the preterm infant. Therefore, all the multi-disciplinary team members should be knowledgeable about the structural changes that might occur in a preterm infant's brain and how they affect the infant's behaviour when provided with adequate supportive neuro-developmental care.

Another programme utilised in South Africa is the "Little Steps" ® - a developmental care programme developed by Dr Welma Lubbe. In addition, the research of Buys and Gerber (2021) in South Africa highlighted the necessity of informing the parents of preterm infants of the importance of developmental care.

In summary, the document explains why the NICU has a negative connotation. Furthermore, it defines the vital sensory systems, namely the auditory, olfactory, visual, and tactile systems of preterm infants, and the effect of the NICU on these systems. In conclusion, it emphasises that research could improve the care preterm infants receive in NICUs in South Africa today. As mentioned, that could have more positive long-term effects on premature infants.

In the following discussion, the researcher aims to explain self-regulation and how Mrs Jean Ayres's lifelong work led to the development of the "Sensory integration-informed intervention," trademarked as Ayres Sensory Integration® (ASI). The researcher also discusses how the absence of the SSB synchrony could lead to difficulty performing self-regulation.

2.9 SELF-REGULATION

Self-regulation is fundamental to developing skills needed to accomplish adaptive developmental tasks in the different stages of life (Geldhof et al., 2010). However, as Geldhof et al. (2010) mentioned, diverse perspectives contribute to understanding the concept of self-regulation. Notwithstanding, researchers agree that self-regulation has significant implications for individual trajectories of development, health, and well-being throughout life (Halfon et al., 2017). Various factors contribute to successful self-regulation, e.g., genetic predisposition, internal- and external motivation, caregiver support, and the environmental context, as described in the Duke Centre for Child and Family Policy for the Administration for Children and Families (2015). From a developmental perspective, no single theory sufficiently explains all aspects (Lynn et al., 2011).

2.9.1.1 Frame of reference

The Sensory Integration (SI) frame of reference focuses on how the interaction between the sensory systems, including auditory, vestibular, proprioceptive, tactile, and visual, provides integrated information that contributes to an infant's learning and adaptive behaviours (Schaaf et al., 2010). The critical consideration is that preterm infants in the NICU might not have the ability to make adaptive responses to constantly changing sensory environments. The sensory integrative abilities include sensory modulation, discrimination, postural-ocular control, praxis, bilateral integration, and sequencing. In the SI frame of reference, the outcomes of the sensory integrative process consist of:

Short-term goal

- The ability to modulate, discriminate, and integrate sensory information from the body and the NICU environment.

Medium-term goal

- Self-regulation to regulate and maintain their arousal level to focus on a task, e.g., sucking a pacifier, breastfeeding, bottle feeding.

Long-term goal

- Maintenance of postural control, ocular control, bilateral coordination, and laterality,
- Praxis and organising behaviour for tasks and activities, and
- Development of self-esteem and self-efficacy.

Although only the short-term- and long-term goals focuses on in the NICU environment, all three goals aim to lead to successful participation in daily occupations. Interventions using the SI frame of reference in the NICU environment include therapeutic equipment, such as pacifiers and nests, to provide preterm infants with sensory opportunities with at least two of three sensations (tactile, vestibular, and proprioceptive). Sensations are provided in a structured environment, graded to a greater or lesser intensity depending on the infant's needs. The outcome of successful sensory integration is participation in daily life activities. It will enhance the fulfilment of the infant's roles, such as being able to play on a playground, which includes constantly changing sensory information (Adapted from Frames of Reference for Paediatric Occupational Therapy: A frame of reference for sensory integration (Schaaf et al., 2010)).

2.9.2 Sensory Modulation

Ayres (1979) defined modulation as the CNS regulation of its activity. When in the NICU, the preterm infant is subjected to ongoing changes in the sensory information, leading to alterations in the arousal state that is no longer optimal. To have an optimal level of arousal, according to Lane et al. (2010), it is necessary to filter through the different sensations and attend to those that are relevant. The preterm infant might find it difficult to filter these different sensations, which could result in the infant's over- or under-responsivity to sensory input.

2.9.3 Arousal State

Arousal is the underlying theory of the Alert Program®, and Ayres (1972, 1979) proposed that it is the state of the nervous system, which describes how alert an individual is (Williams et al., 2020). Williams and Shellenberger (1996) mention that self-regulation is "the ability to attain, maintain, and change one's arousal appropriately for a task or situation". Bigsby (2020) states that "the infant's ability to transition from one state of arousal to another is one of the most reliable expressions of an infant's tolerance for a particular sensory experience." Cortical activation is a function of the reticular formation depending on the sensory input. Sensory input comes through individual pathways. Therefore, the reticular formation must activate the cortex, thereby changing the receptivity of cortical sensory neurons (Lane, 2020).

2.9.4 Tactile Stimulation

Blackwell's literature review (2000) states that "there remains little doubt that tactile stimulation is an important factor in the social, emotional, physiological, and neurological development of infants and young children. Consequently, it is one of the essential elements in the nurturing and healing environment of the infant and child."

According to Ayres (Lane, 2020), tactile defensiveness occurs when the discriminative dorsal column medial lemniscus system fails to exert normal inhibitory influence over the anterolateral system. Therefore, light touch evoked protective, escape-like (fight-or-flight) behaviour and intense emotional responses. Ayres (1972) states that the tactile defensive responses to nociceptive perception or pain sensation qualities in sensory stimuli represent insufficient inhibitory components in a functional system designed to monitor a specific type of impulse control. Thus, the behavioural response system, designed for protection and survival, predominated over a system designed to allow the organism to respond to the spatial-temporal qualities of the tactile stimuli.

Furthermore, Ayres believed that providing specific, discriminative tactile and proprioceptive stimuli would activate the DCML system to "close the gating mechanism" to block the protective response to touch and diminish associated increased levels of activity and distractibility (Lane, 2020). Ayres thought that previous defensive eliciting tactile stimuli (Lane, 2020) could influence the DCML system and result in gate cell inhibition, allowing for

the transmission of defence-eliciting stimuli. When deep touch pressure, mediated by the dorsal column, was applied during this study, it could activate the gated cell, decreasing transmission of defence-eliciting stimuli and diminishing the defensive response.

2.9.5 The Vestibular and Auditory Systems

The vestibular and auditory systems are situated in the bony structure of the inner ear and send impulses to the eight cranial nerves. The CNS receives these neurological impulses and transmits impulses where they "cross paths and exchange information at multiple junctures in the cerebellum, brainstem, and cortex" (Frick, 2020).

According to Boboshko et al. (2023), prematurity is one of the most crucial risk factors that negatively affect the maturation of the auditory system. Preterm infants demonstrate high rates of hearing impairments. Auditory processing difficulties in preterm infants might result from disturbances in the central auditory system development and sensory deprivation due to peripheral hearing loss (Boboshko et al., 2023).

- **Vestibular**

The vestibular system is multisensory. The hair cells in the ear act as peripheral vestibular receptors in the inner ear and respond to linear and angular movement. Thus, it also responds to the movement of the head in space. According to White et al. 2023, the cochlear hair cells consist of one row of inner hair cells and three rows of outer hair cells. The inner hair cells are the actual sensory receptors. As Lane (2020) mentioned, cochlear hair cells are involved in head translation and changes in head position relative to gravity. All movements automatically influence activity on both sides of the head (Lane, 2020).

- **Auditory**

Equally important, Lane (2020) states that the hair cells in the ear, found in the organ of Corti, act as the mechanism of transduction and receptors in the auditory system and function similarly to the hair cells in the vestibular system. The organ of Corti in the inner ear reacts to sound waves of the tympanic membrane, which separates the middle ear and outer ear.

2.9.6 Proprioception

In 1906, Sherrington defined proprioception "as the perception of joint and body movements as well as the position of the body, or body segments, in space" (Bundy and Lane 2020). Up until now, the literature description of proprioception has not changed. It is, however, crucial to understand the difference between proprioceptors→proprioceptive receptors proprioception→proprioceptive feedback, and the perception of joint and body movements.

The vestibular and proprioceptive sensations interact, as both relate to the control of posture and movement. Rose et al. (2009) also aligned arousal with proprioceptive input. Ayres (1972) theorised and showed deep touch pressure and proprioceptive information to have a clinically calming effect. Therefore, arousal and proprioceptive input are linked, as both are carried to the CNS via the dorsal columns, according to Lane (2020c).

2.9.7 Deep Pressure

Bundy and Szklut (2020) mentioned that infants find deep pressure touch, proprioception, and slow, linear vestibular input most accessible and tolerable.

2.9.8 Smell

The ability to smell depends on two chemical senses: gustation and olfaction. Lane and Reynolds (2020) identified that medications, respiratory infections, and peripheral nerve damage could cause olfactory (smell) or gustatory (taste) processing disturbances. Paediatricians describe different medicines daily to the preterm infants in the NICU, and most often, preterm infants' secondary diagnosis is respiratory distress caused by infection in the lungs. Therefore, NICU infants might have difficulty identifying smell and taste accurately.

2.9.9 Therapeutic Positioning

Therapeutic positioning includes placing the preterm infant in a prone, supine, or side-lying position (King and Norton 2017). Containment hold with deep pressure would be when the researcher places her hands on the infant's head and around their feet to provide consolation or use boundaries such as a "nest". According to King and Norton (2017), therapeutic positioning immediately affects the infant's arousal state and provides physiological stability to the preterm infant. Subsequently, Als' Synactive theory (1982), which is specific to the care

of infants in the NICU, describes the infant's self-regulatory capacities as a dynamic system that includes the autonomic, motor, state, and interactive subsystems.

The Alert Program®, grounded in Ayres's theory of Sensory Integration, contends that arousal is when the nervous system is in a particular state; it could describe how alert an individual is. On the other hand, self-regulation is "the ability to attain, maintain, and change one's arousal appropriately for a task or situation" (Williams et al., 2020).The Alert Program® emphasises the importance of self-regulation and motivates the use of sensorimotor strategies to direct arousal states to aid optimal functioning.

2.10 SENSORY INTEGRATION INFORMED INTERVENTION

Sensory integration-informed intervention, trademarked as Ayres Sensory Integration® (ASI), is based on the lifelong work of Jean Ayres, an occupational therapist and a neuropsychologist (Lane et al., 2019). Ayres (1972) defined sensory integration as "the neurological process that organises sensation from one's own body and the environment and makes it possible to use the body effectively within the environment." Although Ayres focused on the contribution of the tactile, vestibular, and proprioceptive systems to development and learning, she included the visual and auditory (Miller and Parham, 2020). In occupational therapy, ASI implies an intervention to improve function, skill, and behaviour as a basis for everyday activities (Lane et al., 2019). Sensory integration intervention is based on neural plasticity as it allows the brain to process and integrate sensory information, enabling development and learning. Sensory integration helps the individual to perceive the world more accurately and respond more effectively to the environment. A South African study by Lecuona, van Jaarsveld, Raubenheimer, and van Heerden (2017) investigated the effects of ASI intervention on the development of premature infants. The key takeaway message was that early ASI intervention significantly enhances premature infants' developmental progress. In the NICU, a calm and alert state is necessary for an infant to engage purposefully in meaningful daily activities, including social contact and sleep. In this discussion on sensory integration, it will become clear that sensory experiences and environments play an essential role, specifically self-regulation, in the development of an infant. The NIDCAP and the Neonatal Therapy National Certification Board have the same stance, namely the importance of self-regulation by the

preterm infant in the NICU. Furthermore, Lubbe's Little Steps® program (2021) mentions that when preterm infants can self-regulate, it promotes a regular respiratory pattern and a consistent heart rate. As contextualised by Lane et al. (2019), playful sensorimotor activities paired with active engagement, tailored to the individual, provide a positive challenge. It promotes adaptive behaviours for neuroplasticity in response to these experiences. Therefore, following an ASI approach can assist infants in the NICU in self-regulation.

The discussion of the somatosensory region of the cerebral cortex, the tongue's relationship with the body, the neurological- and systemic connection, and the anatomy and physiology of the tongue as imperative for sucking was discussed earlier in this chapter. A common characteristic of the study population under discussion is the difficulty to perform the suck, swallow, and breath synchrony. Neiva et al. (2014) stated that these infants have trouble with the suck, swallow, and breath synchrony by 28 weeks of gestation and that poor synchrony still exists until 32 to 34 weeks. In addition, Mohr et al. (2019) stated that preterm infants have immature self-regulatory capacities. Difficulty with early regulatory behaviour signals increases the infant's need for assistance with self-regulation. Therefore, these infants require external regulation to modulate negatively affected states and physiological needs. Subsequently, when these preterm infants gain assistance with the suck, swallow, and breath synchrony during the period of 28 weeks of gestation to 36 weeks of gestation, there could be an improvement in their ability to self-regulate.

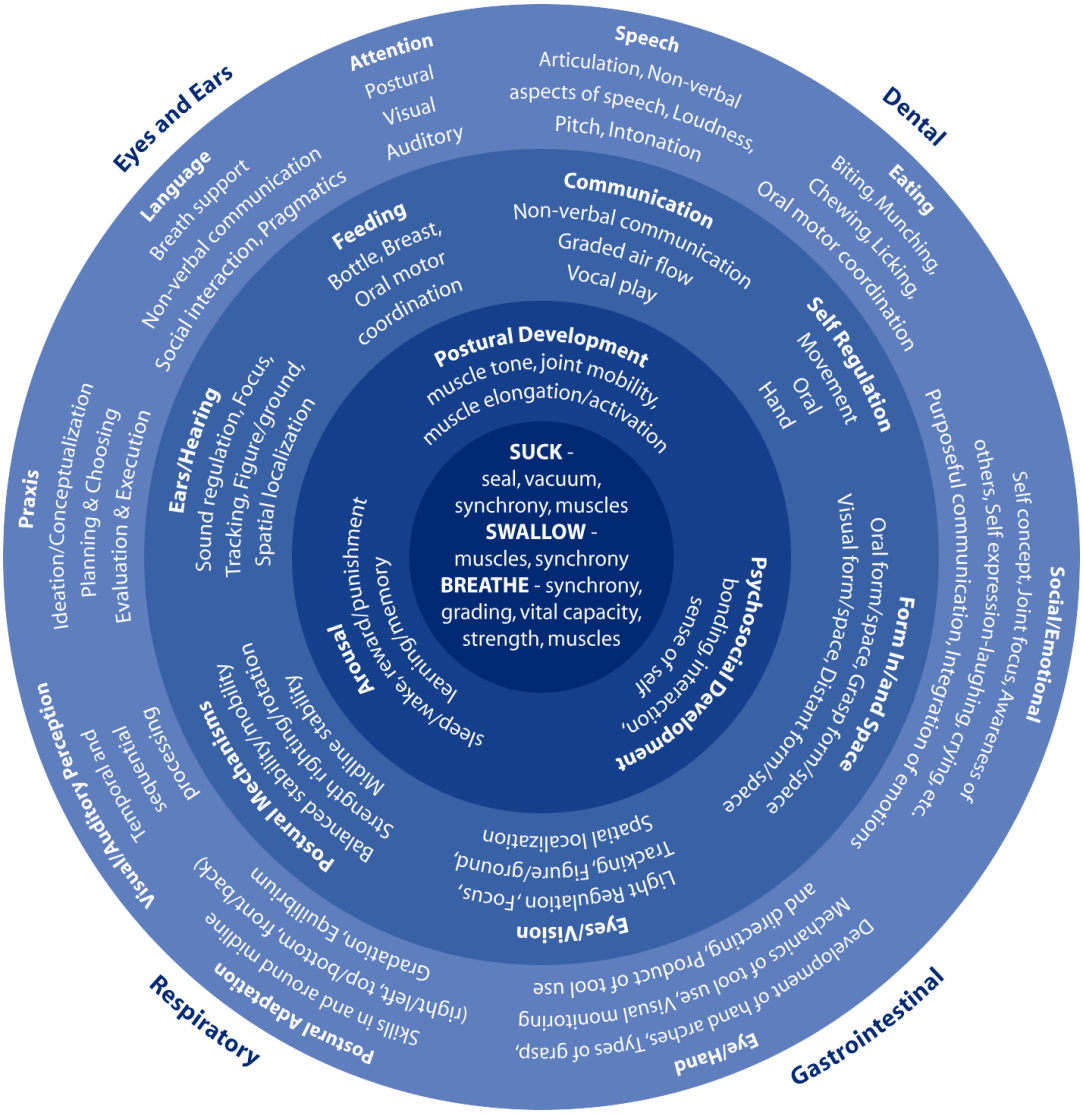
2.10.1 Difficulty in Performing Self-regulation

In the late 1970s, Jean Ayres informed Patti Oeter that SSB synchrony "was the seat of sensory integration" and that SSB is a field of study that needs investigation (Oetter and Richter, 2020). The survival nature of SSB synchrony and the immense presentation of SSB synergistic behaviour in infancy led to the in-depth study of SSB from embryonic development throughout life. Oeter, Richter, and Frick developed the MORE program in 1993 and used this guide to grade the oral motor activities, after which addressing deficits takes place (Oetter and Richter 2020). Although the term motor, oral, respiratory, and eyes model "Integrating the Mouth with Sensory and Postural Function (MORE) is accepted, it is better known as the SSB synchronicity Model, and during their research and clinical observations of typical and

atypical SSB synchronicity, Oeter, Richter, and Fick (Oetter and Richter 2020) stipulated discreet interventions. The infant should be able to have an activity (sucking) to form a vacuum (around the mouth) and a way to seal this vacuum (by sucking on a pacifier or its mother's breast or the teat of a bottle) to obtain active sucking.

The MORE – SSB Synchrony model, as described by Oeter, Richter, and Fick (Oetter and Richter 2020), will be discussed via the illustration in Figure 2.15. This model indicates the suck/swallow/breathe synchrony as it would evolve as a normal development in a full-term infant.

Relationship of Development of the Suck/Swallow/Breathe Synchrony



Patricia Oetter, MA, OTR/L, FAOTA© 1989
Oetter, Richter, Frick, revised 1993, 1998
Oetter, Richter, revised 2004

Figure 2.14 Integrating the mouth with sensory and postural functions. Reprinted with permission. From the book M.O.R.E.: Integrating the Mouth with Sensory and Postural Function by Oetter, P., Richter, E., Frick, S., 1993. Therapro, NJ, (Addendum L).

Oeter et al. (1993) based the model on the neural construct that structures the drive's function, and function refines and elaborates on structure, which refines and elaborates function. The suck/swallow/breathe synchrony lies at the centre of this structure/function

paradigm for many sensorimotor and developmental functions. Each ring in the diagram represents more terrific refinement and elaboration of earlier functions.

Most of the population of NICUs is preterm infants. The long-term goal of this research is for these infants to achieve activities in the outer circle, probably after discharge. Therefore, the researcher utilises the MORE circle as true north and starts with early intervention as soon as the infant demonstrates readiness for these interventions. Consequently, concerning Figure 2.15, the researcher will discuss the MORE model in detail:

- Control in this process would emerge from proximal to distal, as indicated in the MORE, from the inner blue circle to the outer blue ring.
- Development progress as the preterm infant moves to early childhood, thus starting in the inner blue circle while active sucking occurs. These researchers expected that the quality of sucking will increase, as will endurance. In early childhood, the infant sometimes needs to revisit the inner circle briefly to confirm previous learning. An example is the infant sucking on the feeding cup, the inner orange circle and then returning to sucking on the sports water bottle, the outer blue ring.
- SSB strategies in the inner dark blue circle are more functional in the outer blue ring. Systems would flow over in active eating of more solid foods, facial expressions, self-regulation by chewing gum, smoking if already an adult, and vocalisation.
- Self-regulation improved through tongue, jaw, and cheek proprioception. Sucking, biting, and chewing is used to address active facial musculature.
- In the preterm infant, respiration is automatic if the brain is unscarred after being born too soon—however, learning is required for controlled respiration. Learning will occur in the outer blue ring if the preterm infant has frequent, functional, and repetitive opportunities to practice this activity.

Of equal importance is optimal respiratory function and improvement of posture in early childhood, as was published in 1993 by Oeter, Richter, and Frick (Oetter et al., 2020).Specific interventions include manual techniques to release fixed muscles of the tongue, cheeks, jaw,

shoulder girdle, trunk, and diaphragm. In these situations, the knowledge of the multidisciplinary team is of considerable importance.

Frick, Oetter, and Richer (1996) mentioned that benefits of the SSB synchronicity are the ability to increase and maintain alertness, focus attention, support posture, enhance communication and promote stability to perform "power" tasks (Oetter et al., 2020) such as:

- Graded breathing would support typical sleep patterns, physical activity, and verbal and nonverbal communication.
- Sucking is imperative to obtain better control and function of the extraocular muscles and the inner ear.
- Sucking can activate facial musculature for articulation and the demonstration of emotional facial expressions, as well as increase core muscle strength for posture (Kolar et al., 2012).

Improving sensory and motor processing should be implemented throughout early childhood development. When incorporated into activities of daily living, the SSB concepts and strategies can improve self-regulation, oral motor (eating skills), articulation, and postural muscular stability/mobility. Therefore, it builds a foundation for positive sensory experiences throughout infancy. According to Rosemary Bigsby (Bigsby, 2020),awareness of an infant's behaviour, arousal patterns, and facial expressions makes it easier for the multidisciplinary team to prevent stressful interventions.

Furthermore, in their study, White-Traut et al. (2002) stated that multisensory interventions, as mentioned by Ayres (1979), improved the behavioural changes during wake/sleep cycles, quicker progression to oral feeding, enhanced development, and earlier discharge from the hospital. White-Traut et al. (2002) also confirmed that preterm infants with these sensory integration-informed interventions displayed less irritability during painful procedures. The sensory integration-informed intervention takes place when:

- The infant sucks on a pacifier → oral sensory,
- Deep pressure/massage is performed → tactile sensory,

- someone talks to and makes eye contact with the preterm infant → multisensory.

Through the information in the discussion mentioned above and the researcher's personal experience, it is essential to acknowledge the magnitude of self-regulatory behaviour in the NICU and how to promote it the following:

- Non-nutritive sucking: by giving the infant a pacifier.
- Foot bracing: placing the infant in a "nest" made of linen, which mimics the uterus. It also establishes the infant's position in space by providing tactile and proprioceptive input.
- Hands to the face/chin and thumb sucking: by positioning the infant into the midline, flexion, and side-lying. Eliminating gravity provides tactile and proprioceptive input and benefits preterm infants with low muscle tone.
- Positive touch and massage techniques provide deep pressure instead of a feathery touch, as the infant's skin encodes light touch as pain.
- Positive touch also includes containment hold and head cupping.

The researcher utilises the following strategies to enhance early caregiving:

- ✓ Move into the infant's boundaries by speaking in a soft, gentle voice and resting hands.
- ✓ Swaddling to improve postural containment.
- ✓ Promotes skin-to-skin/kangaroo mother care when parents are visiting.
- ✓ Encourages the mother to place the preterm infant's mouth close to the nipple of the breast so that nuzzling can take place as the forerunner for breastfeeding/sucking.
- ✓ Slow movements and containment are necessary.

In the following section, the researcher aims to explain the therapeutic approaches currently used in the NICU of a Bloemfontein's private hospital.

2.11 THERAPEUTIC APPROACHES IN THE NICU

During the first months of life, full-term infants use sensory information to alter their postural control and movement. At the same time, preterm infants spend their first weeks in the NICU, where the environment dispenses sensory demands on their auditory, visual, and tactile systems. Posttraumatic stress interconnected mental health concerns and autonomic nervous system activation in critically ill infants may be experienced by infants admitted to the NICU, accordingto Als, Picouto, and Hau (2015). These taxing demands during critical brain development might lead to potential difficulties with sensory modulation. Thus, providing neuro-developmental care less harmful to a premature infant is of utmost importance. As it is wise to build a foundation with positive sensory experiences throughout the stay of the preterm in the NICU, the following guidelines are imperative:

2.11.1 Infant baby massage as part of neuro-developmental care

The skin, which comprises 2 500 square centimetres in the preterm infant, is described by Bond (2002) as the body's largest sensory organ. The term "positive touch" was coined by Cherry Bond (2002) in her booklet "A Silent Dialogue." Bond derived this technique from Dr Federick Leboyer's book, "Loving Hands," which he wrote after seeing a young Indian mother massaging her baby in the streets of Calcutta(Bond, 2002). Bond (2002) obtained her qualification from "The International Association of Infant Massage", which led to the introduction of the NIDCAP programme.

Meanwhile, "positive touch" is now perceived as a "developmentally sensitive philosophy" (Bond, 2002) administered to the youngest of infants in the NICU. The researcher performed infant massage during the sensory integration-informed intervention. These interventions occur daily, contingent upon the infant's capability to tolerate the intervention at that specific moment. Research by Hutchon et al. (2019) has shown that infant massage enhances electron-cephalogram-based surrogate markers necessary for brain maturation. Furthermore, therapeutic infant baby massage for critically ill infants in the NICU is not uncommon. In the study by Lambert et al. (2017), physical therapists did passive range of motion (ROM) stretches, comparable to the researcher's massage during her therapeutic

interventions. As Lambert et al. (2017) mentioned, avoiding scar tissue sites during stretching is essential.

The researchers, Hutchon et al. (2019), concluded that performing these interventions for 15 minutes per day is safe and workable. The researcher adheres to these guidelines in the intervention approach used in the study.

2.11.2 The regulation of sleep-wake rhythms using massage as part of neuro-developmental care.

In the following section, the researcher will explain why she uses infant baby massage as part of the therapeutic occupational intervention.

Preterm infants sleep up to 18 hours of the 24 hours in the NICU (Helping Your Premature Baby Settle in at Home, 2022). In the NICU, the term "cluster care" is used by the multi-disciplinary team. This team strives to perform patient care by providing medication and changing diapers, linens, and lines. Then, feeds need to be delivered, either by gavaging, cup feeding, or bottle feeding, depending on the infant's needs. It is then that the researcher applies infant massage, which differs from session to session according to the infant's capability to handle input and medical stability. These activities occur at three-hour intervals so the infant can return to a quiet, deep sleep as soon as possible. The researcher performs this activity twice daily after the medical personnel's activities.

A study that Goldstein Faber et al. (2003) conducted at the Department of Nursing, University of Haifa, Israel, found that the massaged infants, versus the control infants, managed propitious supportive modifications in their rest-activity cycles at the age of eight weeks. The experimental group measured a higher nocturnal melatonin production in the twelfth week, meaning the melatonin level was higher at night. This study also mentions the circadian rhythm, the 24-hour internal clock in the brain that regulates cycles of alertness and sleepiness by responding to light changes in the environment. Hence, Goldstein Ferber et al. (2003) concluded that massage might positively affect the development of sleep-wake cycles in infants by using infant massage in the early stages of life.

2.11.3 The regulation of sleep-wake rhythms using swaddling and nesting as part of neuro-developmental care.

As mentioned by Abdeyazdan (2016:552) in their article "The effect of nesting and swaddling on the sleep duration of preterm infants hospitalised in the NICU," it becomes clear that this kind of intervention has a positive outcome on preterm infants in the NICU. Furthermore, Abdeyazdan (2016:552) acknowledged that sufficient sleep is beneficial, as it influences the growth and "development of the sensory systems, the structure of the hippocampus, pons, brainstem, middle brain, motor system, limbic, long-term memory, thermoregulation, and appropriate responses to environmental stimulation."

2.11.4 Sucrose and NNS as part of neuro-developmental care

The key aspect discussed by Liu et al. (2017) is the effect of the combination of oral sucrose and NNS on the procedural pain suffered by preterm infants in the NICU. According to Dilli et al. (2014), when given orally, sucrose affects the gustatory receptors that release endogenous opioids in the central nervous system. Therefore, when the preterm infant performs NNS during a painful procedure, combined with orally given sucrose, Liu et al. (2017) confirm that it triggers the nonopioid mechanism, which amplifies the analgesic effect on pain.

Using NNS and sucrose implies considering better practices to protect the immature brain of the preterm infant during painful procedures.

2.11.5 Expressed breast milk, supported with NNS as part of neuro-developmental care.

In the nursing guidelines by Kendrick (2018), she mentions that expressed breast milk (EBM) has a sweet taste. This milk is an analgesic for the preterm infant when given 5 minutes before a painful procedure. Kendrick (2018) also postulated that providing EBM before giving oral sucrose is preferable. NNS was also beneficial when EBM was delivered orally with a syringe on the anterior part of the preterm infant's tongue.

2.11.6 The pacifier for NNS without sucrose or EBM

Based on the findings of Liu et al. (2017), NNS, an analgesic, can actuate the tactile receptors through the gate control mechanism of pain inhibition and thus diminish the effect of pain during painful procedures. Therefore, a pacifier aids in managing pain even when an infant is NPO. An example of this could be in the case of infants whose mothers are HIV^{+}.

To conclude, pacifiers have other medical benefits, as Lubbe and Ten Ham-Baloyi mentioned (2017). Giving comfort and promoting neuro-behavioural organisation might reduce the risk of sudden infant death. This knowledge would make transitioning from the NICU to home more manageable for parents/caregivers, including the infant.

Therefore, enhancing sleep and assuring undisturbed sleep using cluster care is beneficial, as well as the positive interventions mentioned previously. The researcher uses these positive interventions during her standard daily intervention with premature infants in the NICU.

2.11.7 Crochet octopi in the NICU as part of neuro-developmental care

In February 2013, volunteers in Denmark started to bring colourful crocheted octopi to the NICU. According to these volunteers, the reason for using these octopi in the NICU was that the tentacles resemble the umbilical cord and would remind the infants of being in utero. On 22 August 2013, reporter Marc Chaksfield of news@thelocalsweden reported that Swedish doctors had banned these crocheted octopi from their hospitals, as hospital staff were concerned that these octopi might be a breeding ground for bacteria. According to an article in the Irish Medical Journal (Smith, 2020), there are only anecdotal reports that when infants hold onto these octopi tentacles, they remain calmer. The Irish Neonatal Health Alliance of 16 May 2018 encouraged further research on the crocheted octopi to obtain objective and evidence-based data, after which it could be decided whether these crocheted octopi should be part of family-centred care for preterm infants in the NICU.

In November 2017, the Rotunda Hospital Dublin, Ireland, initiated its pilot project, “The Tentacles for Tinies” (Smith, 2020). The study aimed to use a specific new tool designed for use in the NICU on pre-term patients, namely an octopus. This multi-disciplinary project included microbiology physicians and infection control officers responsible for compiling protocols for the practical as well as safety aspects of the project. Smith (2020) mentioned

that this observational study included 28 infants <34 weeks or when out of humidity. The study found that infants had fewer desaturations while holding the octopi, with a median of one desaturation [0-4] versus three [0-7] desaturations while not holding an octopus. However, this did not reach statistical significance (p = 0.162). Furthermore, as stated by Smith (2020), there were no differences between the median heart rate and oxygen saturation measurements between the two epochs during the instances where the octopi were employed. However, according to the survey conducted among parents with preterm infants included in the study, 100% reported that they liked the programme and that it could benefit babies in the NICU (Smith, 2020). According to the Nation Health Paper Alliance (2018), further research on crocheted octopi is pivotal to obtaining objective and evidence-based data to decide whether introducing these crocheted octopi should be part of family-centred care for premature babies in the NICU. The researcher experienced first-hand that these crocheted octopi are not used during the supportive developmental care of infants in the NICU of the private hospital in Bloemfontein. Octopi are handed from volunteer to volunteer and then given to a registered nurse (RN) who randomly places them next to the infant after admission to the NICU. There is no quality control regarding the type of wool/cotton or stuffing used to fill the octopi. There are no cleaning instructions for this soft

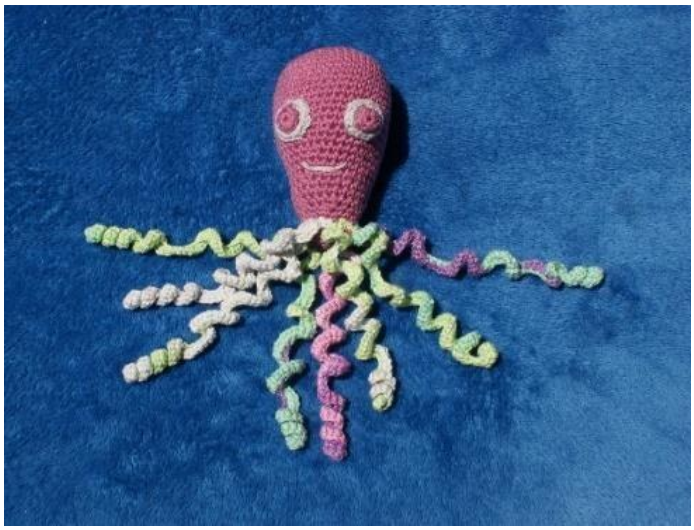


Figure 2.15 Crocheted Octopus (Photo: Researcher).

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2.12 OCCUPATIONAL THERAPY INTERVENTION

2.12.1 The researcher's qualification.

The researcher is qualified as an International Association of Infant Massage (IAIM) instructor. She obtained this qualification in 2004. She did the Little Steps® program in 2008 and again in 2018. This program by Prof. Welma Lubbe emphasised neuro-developmental supportive care of the preterm infant in the NICU, emphasising protecting the immature infant's brain. This program pays attention to the infant's behavioural state by correctly reading the infant's stress cues and providing self-regulation methods. The researcher completed the "Basic Paediatric Bobath/Neurodevelopmental Therapy Course" in October 2010. The researcher did a follow-up course for infants, the "Advance Level II Baby Course", in 2012. In March 2010, the researcher did the "Sensory Integration Theory Course", the first step to becoming an occupational therapist trained in SI. In April 2011, the researcher completed the second course nl. "Sensory Integration Test Administration Course". After that, in 2012, the researcher completed the "Sensory Integration Interpretation Course" as the third step in becoming SI-trained. Due to unforeseen circumstances, the researcher could not complete the fourth step in becoming an SI-qualified occupational therapist. The researcher did, however, complete the "Infant Sensory Integration Training" in 2015, presented by Megan Faure. In 2017, the researcher completed the "Building Blocks for Sensory Integration Course" offered by Sheila M Frick. Following this course, the researcher attended "The Diversity of Sensory Integration", presented by SAISI, in 2019. In addition, the researcher qualified as a Certified Neonatal Therapist (CNT) in 2021. The Neonatal Therapy National Certification Board, based in the United States of America, is a multi-disciplinary organisation committed to ensuring that occupational therapists have the knowledge and experience to practice independently in the NICU. Earning recognition as a CNT through the Neonatal Therapy National Certification Board, based in the United States of America, is a rigorous process and includes documentation and certain verifications. Worldwide, there are 800 CNTs and only five in South Africa.

2.12.2 Occupational therapy intervention for self-regulation in the NICU

The occupational therapist in the NICU specifically uses the therapeutic principles from the ASI frame of reference during the intervention to enable the infant's self-regulation. Facilitating an adaptive response leads to engagement in developmentally and contextually relevant activities (Schaaf and Davies, 2010). Self-regulation of infants in the NICU is the focus of this study and based on the background information and the reviewed literature, self-regulation plays an important role. Evidence exists on the value of sensory integration-informed occupational therapy intervention for developing self-regulation (Williams and Shellenberger, 2020).

As part of a multi-disciplinary team, the occupational therapist can address the self-regulation challenges infants in the NICU experience using the sensory integration frame of reference. Self-regulation as a child-rearing occupation forms an important part of child-rearing as a parent occupation and thus includes parental guidance in terms of "parent sensitivity to infant behaviour, parent participation in care and collaboration with NICU therapists" (Bigsby, 2020:483). Although using a sensory integration frame of reference focuses on the touch-, proprioceptive-, and vestibular systems, it does not exclude other systems, namely visual, auditory, taste, and smell. As executed by the researcher, an intervention session starts at the end of cluster care, between 10:00 and 11:00, when the infants display signs of disorganisation due to overstimulation. When the premature infant's posture and behavioural state demonstrate confusion, the occupational therapist incorporates "nesting", using a rolled towel to contain the infant in a foetal position. The nest supports the infants' prone, supine, or side-lying postures. Then, by using the "containment hold"-positioning, the occupational therapist would apply deep pressure by cupping the infant's head with one hand and cupping both feet with the other by using gentle pressure toward the median plane of the infant's body. The occupational therapist's soft, low-pitched voice encourages the infant to re-organise. The goal is to get the infant into a quiet, deep sleep as soon as possible. In such a behavioural state, an infant tends to use less energy due to slower and deeper breathing and a slower heart rate. This results in weight gain, ultimately shortening the infant's stay in the NICU. The occupational therapist needs to use both hands to assist the infant in self-regulating, which is quite a challenge. If she removes her hands too quickly, the infant will likely change back into its former behavioural state. However, the occupational

therapist often releases a hand to place a pacifier in the infant's mouth to initiate self-regulation, assisted by the sucking mechanism. Some infants do not have the strength or ability to keep the pacifier in their mouth, resulting in the pacifier continuously slipping out. Such a vexing repositioning of hands is frustrating for therapists and infants alike. There is no single solution to the problem of assisting infants to self-regulate while attempting NNS.

The researcher used the following as part of the occupational therapy intervention with the control- and experimental groups.

2.12.3 Infant massage as part of the occupational therapy intervention

2.12.3.1 Infant massage

Holbrook stated in 1979 that the anatomical and functional characteristics of the skin as a barrier begin to develop in utero. The development of the skin is visible around 34 weeks gestational age in utero and is functionally capable of acting as a barrier (Mancini 2004). The skin is a vital and the largest organ of the human body, according to Walker (2022). Walker (2022) also mentions that the skin's sensory properties influence temperature regulation and immunological functions. While performing infant massage on preterm infants in the NICU, the researcher touches as much skin as possible using the palms of her hands and fingers. Massage techniques are utilised to "attenuate physiological and behavioural responses to stress and pain, decrease cortisol levels, accelerate the maturation of electroencephalograph and visual acuity, and improve developmental scores"(Peterson, 2018:68). In the same way, Peterson (2018) mentions that massage may reduce pain and anxiety, as these two elements are triggers of posttraumatic stress disorder and might also cause the activation of the autonomic nervous system. Another essential point is that infant massage includes passive stretching, providing proprioceptive input and passive range of motion movements (Peterson 2018), which the researcher used during the daily intervention sessions. Peterson (2018) also mentioned that infant massage may positively influence somatic growth. Therefore, infant massage of preterm infants while in the NICU might enhance the formation of the different skin layers.

2.12.3.2 Massage oil

Massage with oil ensures a smooth, gliding surface without friction. Therefore, the preterm infant is more likely to accept touch (Bond, 2002). When choosing an oil for preterm infants in the NICU, the researcher had to determine the qualities of the different oils. Bond (2002) recommends plant-based oils, as they are easily absorbed into the dermis, whereas mineral-based oils may cause a skin occlusion film on the skin's surface. From experience, the researcher knew that the oil needed to be odourless. The olfactory system of the preterm infant might be overwhelmed by all the unknown odours. Ultimately, the researcher decided to use pure grapeseed oil. Extracting oil from grape seeds is done by using the cold-pressing method. This method does not involve heat or chemical treatment; therefore, it is safer and more consumer-efficient, according to Garavaglia et al., 2016. Grape seed oil contains high levels of Vitamin E, which may be a potent pro-oxidative agent that suppresses inflammatory responses. Pure grape seed oil does not have a specific smell or taste. It is also safe for preterm infants to put their hands into their mouths after massaging, as one may use the same oil for food preparation.

2.13.4 NICU and assistive technology

2.13.4.1 Supporting non-nutritive sucking development by using a pacifier

Feeding maturity depends on neurological maturity and indicates that the mother of the preterm infant should start with skin-to-skin care to produce milk from the breasts. According to Krol and Grossmann (2018), human milk given to an infant instantaneously after birth could aid neurological maturity. It may also contribute to the physical process of myelination of the nervous system, thus leading to neurological maturity. Neuro-developmental care includes the use of a pacifier to simulate the activities performed by the foetus while in utero and activities displayed after birth, like thumb and fist sucking.

2.13.4.2 The ideal pacifier

Early Oro motor stimulation plays a crucial role in the development of the preterm infant while in the NICU (Zimmerman and Barlow, 2008). According to Shandley et al. (2021), therapeutic approaches involve pacifiers, and these pacifiers should have certain qualities, as they may predict how an infant will suck on them. The debate about what the perfect pacifier

should look like is long-standing, even more so a pacifier for low-birth preterm infants. According to the article, “Development of a pacifier for low-birth-weight infants’ non-nutritive sucking,” published by Engebretson and Wardell (1997), the pacifier should be made from a medical-grade plastic that is odourless and tasteless. Furthermore, according to Lubbe (2017), it should be a cylindrical one-piece pacifier to ensure tongue cupping while non-nutritive sucking occurs. The bolus at the end of the teat, also called the pacifier bulb, should be as big as the thumb of a preterm infant born at the gestational age of 32 weeks and younger. Meanwhile, for preterm infants older than 32 weeks gestational age, the teat should be the size of a mother's nipple (Lubbe, 2017). The ideal length of the teat “should reach the ridge between the soft and hard palate to stimulate the limbic system of the brain” (Lubbe, 2021: 138)

As illustrated in Figure 2.17, the smaller circle indicates the ridge between the soft and hard palate, while the bigger circle indicates the limbic system.

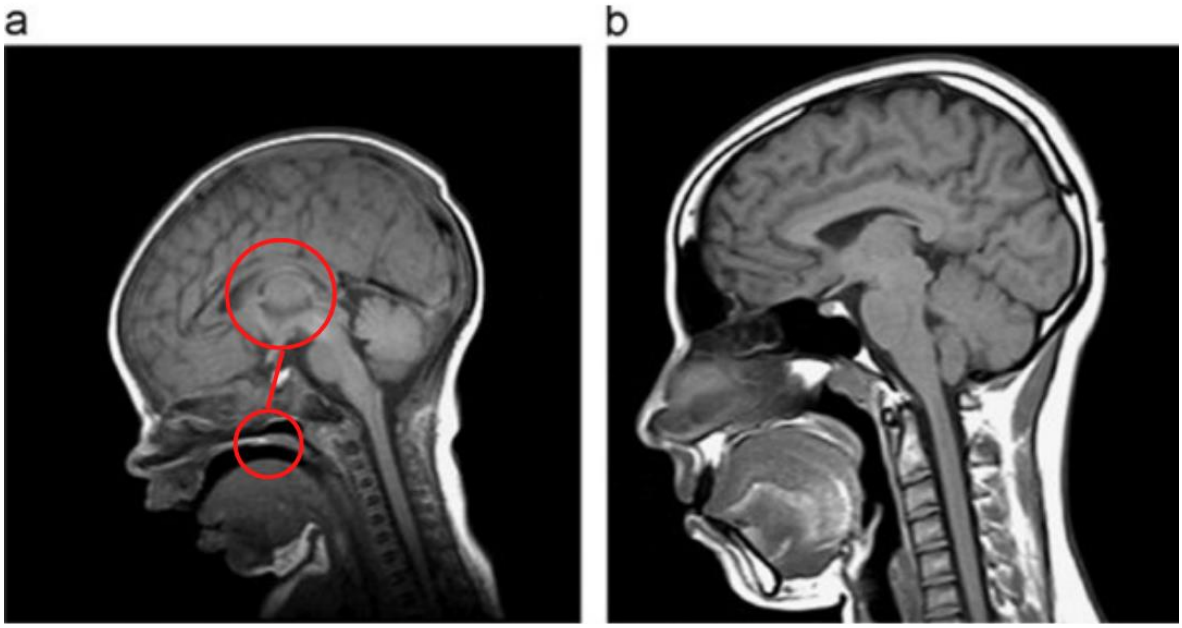

Figure 2.16 (a) Mid-sagittal T1 MR images of an infant’s brain at the age of 39 weeks, five days, GA at birth, that was one day old at the time of the scan. (b) An adult brain. Reprinted from Computers in Biology and Medicine, Volume 64, Chelli N. Devi, Anupama

The thickness of the pacifier will influence the stiffness, as stiffer pacifiers will "elicit fewer sucks per burst, up to half as many, and also the strength, or amplitude of each suck, is decreased" (Zimmerman and Barlow 2008:81). Similarly, the shape and texture of the pacifier will influence the NNS pattern of the preterm infant (Oder et al., 2013). According to Engebretson and Wardell (1997), the mouth shield should be big and soft to stimulate nerve endings around the mouth and prevent aspiration. The pacifier should have a handle on the shield for hand-to-mouth, grasping, self-soothing and midline positioning. These concepts describe the ideal pacifier to be used in the NICU to introduce nutritive sucking to the preterm infant.

2.13.4.3 Standard pacifier used in the NICU, the private hospital in Bloemfontein

Figure 2.18 shows the standard pacifier given to the infant after admission to the NICU. Parents of infants are allowed to bring the pacifier they purchased for their infant. The infant shown in Figure 2.18 is unable to continue sucking the pacifier when the occupational therapist removes her hand. The standard pacifier does not have an indent, which would have enabled the infant to suck while being on synchronised inspiratory positive airway pressure (SIPAP).

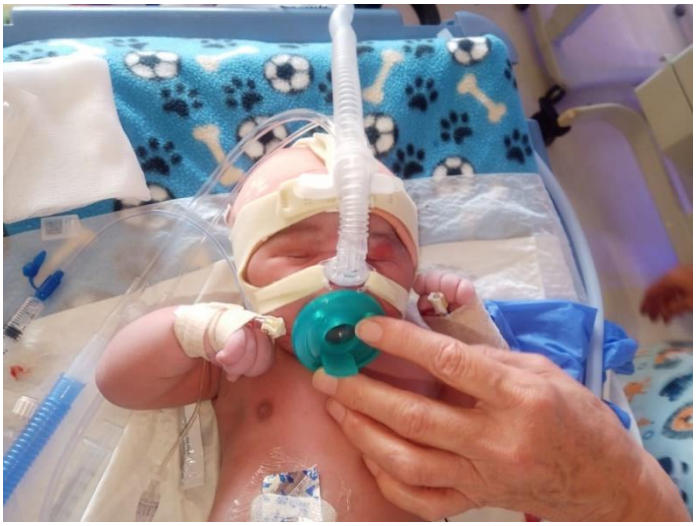

Figure 2.17 Standard pacifier without indent given after admission (Photo Researcher, with parent's consent, (Addendum N)

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2.13.4.4 Description of the Octo-Sense

Considering information and knowledge of infants' need in a NICU to self-regulate, the researcher and the inventor used an existing concept, a crocheted octopus. This design and concept were adapted to develop the Octo-Sense as assistive technology to support the infant's self-regulation during occupational therapy intervention. The assistive technology device called the “Octo-Sense” aims to enhance the outcomes of self-regulation therapy. The Octo-Sense device was designed, manufactured, and introduced as part of the sensory integration-informed intervention in the NICU. During the 17 years that the researcher worked in the NICU, positive and negative modes of handling the preterm infant came to light. The researcher observed first-hand the importance of a preterm infant having a pacifier to enable the infant to inaugurate NNS and NS. In some NICUs, an infant receives a pacifier after birth. These pacifiers often get lost in the soiled linen, and the parents must replace them. The size of the Octo-Sense, with the tentacles, makes it easy to notice.

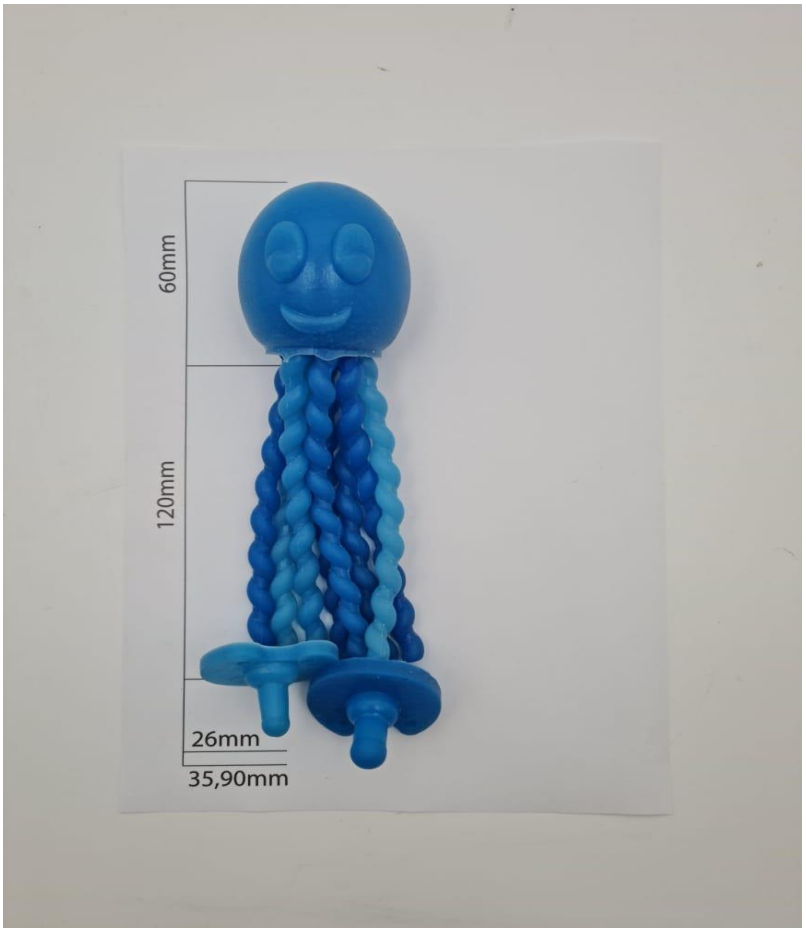

Figure 2.18 Octo-Sense. (Photo: Researcher).

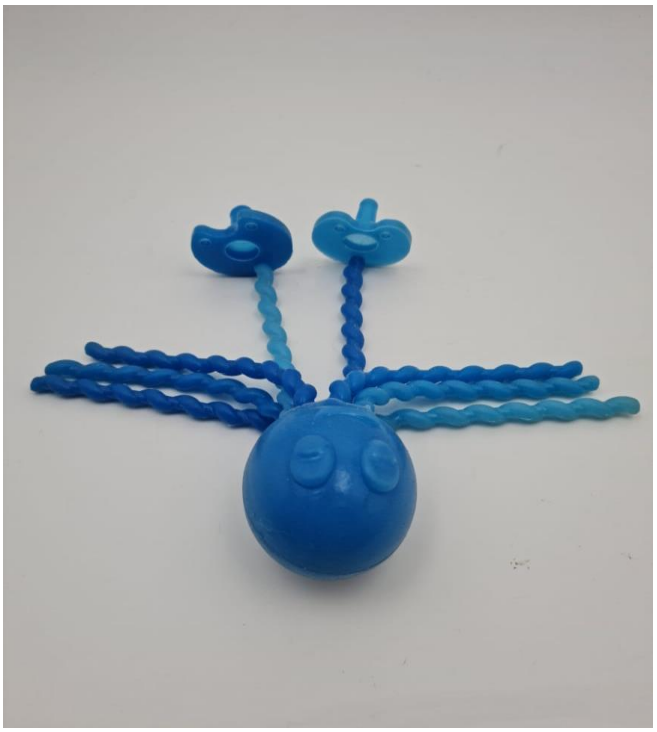

Figure 2.20 The Octo-Sense pacifiers. (Photo: Researcher).

Figure 2.19 Octo-Sense, showing the two pacifiers of different sizes. Both of the Octo-Sense's pacifiers have an indent. This indent allows the infant to suck while being on SiPAP. (Photo: Researcher).

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The Octo-Sense resembles an octopus with a rounded head and eight tentacles weighing 244g. According to Bundy and Lane (2020), the afferent part of the Autonomic Nervous System (ANS) consists of two parts: the sympathetic, which gives the warning of fight or flight, and the parasympathetic, which functions to restore energy by telling the infant's body to "rest and digest" (Bundy and Lane 2020:63). All the bodily organs receive signals from both these pathways so that the body can be in a constant dance, ensuring the continued regulation of the flow of different signals in the body (Bundy and Lane 2020). The use of the Octo-Sense can be explained as follows: When a preterm infant in the NICU feels a feathery touch, it elicits a fight-or-flight reaction. Showing how dysregulated the preterm infant becomes in the NICU. The sympathetic part of the ANS activated this overreaction or tactile defensiveness. If the Octo-Sense is placed partially on the preterm infant while the pacifier is in the infant's mouth, the parasympathetic ANS takes over as deep pressure calms the activated sympathetic response down. When the preterm infant feels his body's resistance against a solid object, he can adjust his own body to ensure that proprioception aids in diminishing his discomfort. The reason for partially positioning the Octo-Sense on the preterm infant is that the amount of deep pressure applied by an object should be 10% of the preterm infant's body weight(Noyed, 2024). Therefore, if a preterm infant weighs 2 000 g, the deep pressure applied should be 200g. Therefore, the researcher must establish the preterm infant's weight before therapy. The ability to adjust the deep pressure of the Octo-Sense according to the preterm infant's weight makes the Octo-Sense unique. The tentacles are twirled, resemble an umbilical cord, and could be placed into the infant's grasping hands or added to apply deep pressure.

The Octo-Sense is manufactured from Dragon Skin™ silicone, blasted into a mould designed according to specifications. This silicone can stretch and return to its original form without tearing or permanent distortion. A specific non-poisonous pigment colours the Octo-Sense. This blueish colour resembles the bluish-white umbilical cord while in utero. In an email to the researcher (Addendum O), a fellow researcher at the School of Psychology, University of Sussex, England, Alice Skelton, wrote that the colour vision in premature infants is difficult to unpick. However, Skelton wrote that all infants could see high contrasts, such as black-and-white images, and infants could not distinguish between blue and white light. The development of the visual system in utero occurs in the absence of visual stimulation,

according to Stanley et al. (2008). However, the NICU environment significantly impacts the development of the visual stimuli of the preterm infant. Thus, the colour of the Octo-Sense should not add to the visual stimuli of the preterm infant. As mentioned, the ideal silicon pacifier is manufactured from medically graded plastic that is odourless, tasteless, and, therefore, non-toxic. The silicone is safe to be placed into the mouth of the preterm infant. The reason for having two different sizes of Octo-Sense pacifiers is that, according to Lubbe (2017), preterm infants of the gestational age of 32 and younger should have a smaller pacifier than those infants born at 34 to 36 weeks of gestational age. Therefore, one tentacle has a smaller pacifier according to the mouth size of a 32/0 to 33/6 preterm infant. The larger pacifier is attached to another tentacle for a 34/0 to 36/6 preterm infant. Equally important, as also mentioned by Lubbe (2017), is that the pacifier needs to be cylindrical to ensure tongue cupping while NNS takes place. It should be a one-piece pacifier.

The design of the Octo-Sense meets all the requirements mentioned already. When placed into the infant's hand/hands, the added value of the pacifier is that the tentacles would prevent the infant from pulling on the NGT, OGT, or other nearby lines. Preterm infants tend to seek something to hold onto, as the umbilical cord is always close while in utero. Therefore, the tentacles may provide for hand-to-mouth positioning, grasping, self-soothing, and midline positioning. The indent within the shield of the pacifiers of the Octo-Sense makes it possible for the preterm infant to suck on these pacifiers even when ventilated, is on CIPAP or SiPAP, or has a nose cannula inserted. Some infants do not have the strength or ability to keep the pacifier in their mouth, meaning it will continue to slip out. The head of the octopus prevents the pacifier from slipping out of the infant's mouth when positioned correctly.

A container filled with water and a disinfectant like Precept/Milton is beside the infant's bed. The Ocoto-Sense silicone is water-resistant. The RN would submerge the standard pacifier in a container filled with water and disinfectant. The researcher submerged the Octo-Sense in a container filled with water and disinfectant. The Octo-Sense, manufactured from water-resistant silicone, is cost-effective for cleaning and disinfecting. Another benefit of the Octo-Sense is that it does not get "lost" in the infant's bedding, as it is bigger than the current pacifiers. Many pacifiers end up in the laundry with soiled linen. Currently, there is no

evidence to support the use of Octo-Sense technology as part of a sensory integration-informed occupational therapy intervention to improve/facilitate/support self-regulation. The researcher asked the following question: What would the self-regulation responses of an infant in the NICU be during the sensory integration-informed intervention, with or without the support of Octo-Sense assistive technology?

2.13 CONCLUSION

Chapter 2 presented an in-depth literature review of aspects related to premature infants in the NICU. The researcher presented epidemiological information regarding preterm infants and discussed the characteristics and the development of a preterm infant. Furthermore, the researcher noted the structural changes in the brain of a preterm infant and specifically mentioned the clinical significance of the limbic system. In the same way, the researcher provides reasons why the NICU can be a sensory harsh environment.

Therefore, the researcher took a closer look at the development of the preterm infant's brain, muscle tone, the somatosensory region of the cerebral cortex, and the anatomy and physiology experience that the preterm encounters in the NICU, which foresee harmful interventions. The sucking activity was described in detail, which included NNS as well as NS.

The researcher aimed to explain self-regulation and how the lifelong work of Dr Jean Ayres led to the development of the ASI. The researcher also discusses how the absence of the SSB synchrony could lead to difficulty performing self-regulation.

The researcher examined the relevant theory of infants in the NICU's ability to achieve self-regulation and the influence it might have on the overall development of the preterm infant. The key aspects the researcher explored were the self-regulation responses of infants in the NICU during sensory integration-informed interventions.

The circumstances in the NICU, the private hospital in Bloemfontein, led to the researcher's search for modes to assist preterm infants. Preterm infants need proper positioning and proper pacifiers to perform self-regulation, which includes sucking. It led to the development

of assistive technology, the Octo-Sense, used during occupational therapy interventions. Chapter 3 presents the research methodology used in this research study.

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CHAPTER 3: RESEARCH AND METHODOLOGY

3.1 INTRODUCTION

Due to premature birth, admission to the NICU is inevitable. The literature revealed that preterm infants in the NICU, though in a supporting environment, face traumatic and potentially life-threatening interventions after birth. Chapter 2 presented literature on the risk that premature infants face for possible sensory integration and developmental delays in the attempt to reach infancy.

The research problem arises as preterm infants in the NICU face many developmental challenges, one of them being their inability to self-regulate. Working as part of the multi-disciplinary team in the NICU, occupational therapists specifically focus on providing developmentally supportive care and preventing prematurity-related complications. Over- and under-stimulation also occurs in the private hospital in Bloemfontein despite the implementation of the developmental supportive care policy of the private hospital in Bloemfontein (Addendum B). As a result, this paper aims to describe and compare the self-regulation responses of infants in the neonatal intensive care unit (NICU) of the private hospital in Bloemfontein during a sensory integration-informed intervention with or without the support of assistive technology. Furthermore, the researcher will compare the self-regulation responses of infants who received the sensory integration-informed intervention with the standard pacifier with the self-regulation responses of infants who received the sensory integration-informed intervention with the Octo-Sense assistive technology. In addition, the researcher will describe the affordances of Octo-Sense assistive technology, which the infants engaged with during sensory-integration-informed intervention sessions.

To summarise, this study focuses on Octo-Sense as an assistive technology used in conjunction with sensory integration-informed occupational therapy intervention and its potential to assist preterm infants in their diligent efforts to self-regulate.

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This chapter aims to elucidate the study design and outline the research methodology employed in this investigation. To aid the reader, the researcher has included a diagram that provides a visual overview of what to expect while exploring Chapter 3.

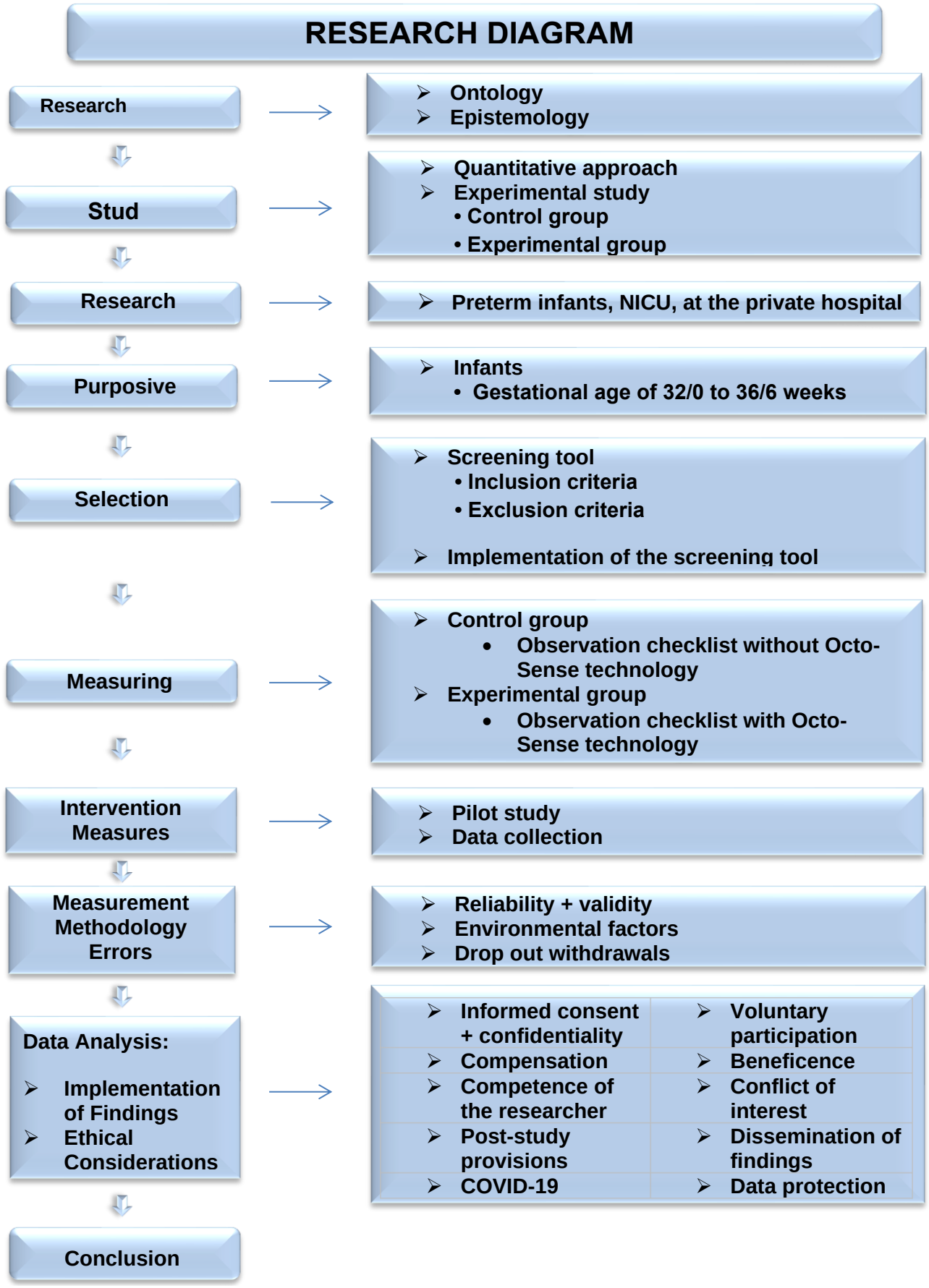

Figure 3.1 Schematic Presentation of Chapter 3

3.2 RESEARCH PARADIGM

A research paradigm is a philosophical and theoretical framework of a scientific school or discipline within which theories, laws, generalisations, and experiments are formulated to support them (Nicolopoulou, 2022). During the period that the researcher worked in the NICU as an occupational therapist, she witnessed the ongoing struggle preterm infants must overcome due to the hardship of being born too early. The researcher conducted a study on the performance of a newly developed assistive device. This research paradigm based on positivism led to the use of a quantitative data analysis study. The researcher based the research on the pillars described by Alele and Malau-Aduli (2023).

3.2.1 Ontology

Gilani et al., 2020) described ontology as a mechanism that can define, capture and standardise information, making seamless sharing in an area of interest straightforwardly. The researcher based this study's ontology on the description of the logic that allows machine readability and reasoning on data, as Chokwitthaya et al. (2023) mention in their article. As was also mentioned by Chokwitthaya et al. (2023), ontologies have been developed and effectively used to support knowledge sharing in various research domains.

3.2.2 Epistemology

Epistemology forms the basis of the philosophy of studying different beliefs and what people view as general knowledge (Alele & Malau-Aduli, 2023). The researcher applied the positivist outlook to gain understanding through objective observation and measurement. According to Godwin et al. (2021), a researcher could rely on statistical methods that use the means of groups to determine significant results by adopting this postpositive point of view. This outlook enabled the researcher to determine averages and trends in the datasheets and attempt to minimise the trend variations so that the results could apply to a larger population. Another essential point is that the researcher could conduct a randomised controlled trial to measure its impact on the infants' self-regulating ability whilst engaging in a sensory integration-informed intervention with and without Octo-Sense technology.

3.3 STUDY DESIGN

The researcher used a quantitative, experimental research design to answer the research question. This design was employed since it provides a systemic and objective way of using numerical data from a selected population subgroup to generalise the findings to the studied population (Maree et al., 2020). Regarding an experimental design, the researcher included the Octo-Sense as assistive technology (AT) as an independent variable during the standard occupational therapy intervention process (De Vos et al., 2020). The researcher provided the infants in the control and experimental groups with standard occupational therapy, which included sensory integration-informed interventions. The control group had access to the private hospital's standard pacifier, or the pacifier given to the infant by the parents. The intervention of the experimental group included the variable of the Octo-Sense as AT. Therefore, the researcher investigated the uses and effects of self-regulation by introducing an independent variable, i.e. the Octo-Sense.

Since the researcher's intervention is sensory integration-informed, the researcher compiled the questionnaires using the SI framework as a guideline.

In the following paragraphs, the researcher will discuss the typical research population for a NICU.

3.4 RESEARCH POPULATION

By referring to the *Checklist for possible inclusion* (Addendum P) as the screening tool mentioned in paragraph 3.6.1, the study population consisted of all moderate to late preterm infants meeting the inclusion and exclusion criteria, born between 32/0 to 36/6 at the private hospital in Bloemfontein, between 23 October 2021 and 31 May 2022. The researcher's data collection took place during COVID-19. The pandemic necessitated new regulations regarding who was allowed into the NICU. The researcher had difficulty contacting the infants' parents/guardians to sign the necessary documents. Fewer infants were born during this period, which is the reason for the small sample size. The Vermont Oxford Network is a voluntary organisation that strives to improve care for newborns by providing a data-driven, coordinated program (Edwards et al., 2019). The researcher consulted this network since the

most recent information is available and updated daily by different individuals globally. According to the Vermont Oxford Network (Table 3.1), 424 infants between the gestational ages of 32/0 to 36/6 were born at the private hospital in Bloemfontein between 2019 and 2022. The NICU of the private hospital in Bloemfontein is an eight-bed unit. If the need arises to admit a ninth preterm infant, it would be in the PICU, the private hospital in Bloemfontein. The research included these infants if they complied with the study's inclusion criteria.

The following table depicts the preterm infants admitted to the NICU of the private hospital in Bloemfontein from 2019 to 2022.

Table 3.1 Preterm births at the private hospital in Bloemfontein, January 2019 to December 2023

Infants gestational age	Infants born in 2019	Infants born in 2020	Infants born in 2021	Infants born in 2022	Infants born in 2023
32/0 – 32/6	14	9	9	18	9
33/0 – 33/6	16	21	9	10	8
34/0 – 34/6	26	46	16	25	15
35/0 – 35/6	45	27	21	21	31
36/0 – 36/6	27	14	30	20	32
TOTAL	128	117	85	94	95

3.5 SCREENING PROCESS

The researcher used the characteristics of preterm infants admitted to the NICU after birth to compile the self-developed checklist, *Checklist for possible inclusion* (Addendum P, as the screening tool. The screening tool is discussed in the following section.

3.5.1 Screening tool

The screening tool consists of the inclusion and exclusion criteria, which will be discussed in the following paragraphs.

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3.5.1.1 Inclusion criteria

For inclusion, the infants:

- Should have had a primary diagnosis of moderate to late preterm, born between the corrected age of 32/0 – 36/6 weeks,
- had to be medically stable within the acceptable range value for age, according to physiological parameters: Heart rate (HR), respiratory rate (RR), and oxygen saturation (Sp02) had to be within acceptable parameters for gestational age (Addendum P),
- could have a PDA,
- had to breathe room air spontaneously,
- or could be on non-invasive ventilation or nasal cannula,
- could be without a feeding tube,
- could still be on tube feeding, whether nasogastric or orogastric,
- must have a parent or legal guardian's consent to introduce the pacifier,
- have the informed consent of a parent or legal guardian (Addendum Q).

3.5.1.2 Exclusion criteria

The researcher used the following criteria to exclude infants who were not suitable to form part of the study. These were infants that:

- had been diagnosed with congenital abnormality or syndromes according to the secondary diagnosis,
- had been in isolation – thereby, the researcher prevented contamination from one infant to the next, as well as cross-contamination between the researcher and the next infant or,
- had been on invasive mechanical ventilation (intubated and mechanically ventilated).

After establishing the inclusion and exclusion criteria, a discussion about implementing the screening tool follows.

3.5.2 Implementation of the screening tool

The researcher participated in the ward round of the NICU daily at 8:00. Permission was obtained from the Unit manager (Addendum F) to access the list of new admissions. The information gained from this list was the infants' primary diagnosis, name, surname, gender, and contact details of the parent/legal guardian. Following this, the infants were screened for inclusion or exclusion from the study. The researcher contacted the parent/legal guardian for an appointment after the screening process. The researcher explained the reason for the study, the ethical considerations, and the introduction of a pacifier/Octo-Sense pacifier. The parents gave written consent and acknowledged that the researcher had sufficiently explained the study. Similarly, the parents acknowledged that they are aware that their infant might suck on a pacifier during their stay in the NICU. It was unnecessary to provide reasons for excluding any infants. The private hospital in Bloemfontein permitted a Sotho-speaking Registered Nurse (RN) in the NICU and PICU to explain the study in Sotho to the Sotho-speaking parents if they had trouble with the English version (Addendum D). Upon receipt of the written consent, a number was obtained from the randomisation list compiled by the biostatistician (Addendum R).

The sampling process is discussed in the following section.

3.6 SAMPLING, SCREENING AND RANDOMISED LIST

3.6.1 Purposive sampling

The research sample was determined by purposive sampling. According to Nikolopoulo (2022), purposive sampling refers to a group of non-probability sampling techniques, which should be used to select individuals due to the shared characteristics required for the sample. By way of explanation, the researcher intentionally selected preterm infants from the NICU and PICU in the private hospital of Bloemfontein, as permission had been granted to access these Units (Addendum D). In addition, the selected infants form part of the broader global population found in NICUs. The researcher used the information derived from the *Checklist for possible inclusion (*Addendum P) to identify the eligible sample.

The researcher, as According to Pindea et al. (2019:268), NNS is a "foundational skill of infancy that is important for oral feeding and self-regulation", which led to the conclusion that premature infants of the gestational age of 32 weeks to 36 weeks six days might be able to perform NNS. The authors also mention that NNS occurs as early as 15 weeks while in utero (Pindea et al., 2019). More importantly, "by 20 weeks, the rhythmical NNS was observed of the foetus regularly opening and closing its mouth in a series of organised bursts with pauses between compressions" (Pindea et al., 2019:268). The primary diagnosis of a preterm infant in NICU would be the indication of the gestational age at birth. Subsequently, the first criterion would be the primary diagnosis of the preterm infant born at a gestational age varying between 32 weeks and 36 weeks six days; therefore, the intention of the following five groups:

1. 32 weeks to 32 weeks, six days
2. 33 weeks to 33 weeks, six days
3. 34 weeks to 34 weeks, six days
4. 35 weeks to 35 weeks, six days
5. 36 weeks to 36 weeks, six days

The researcher screened the new admission list provided by the NICU daily. After screening the list of infants who might qualify for the study, the Checklist for possible inclusion (Addendum P) was used. The researcher would use the randomised list compiled by the biostatistician to select the specific number for a particular infant.

3.6.2 Randomised list

A biostatistician from the University of the Free State created a randomised list. The researcher used the randomised list to allocate an infant to either the control- or experimental group, as described in the following paragraphs.

The biostatistician created 70 groups to accommodate all the characteristics mentioned earlier in the randomised list (Addendum R). For example, if the randomised number is 26.2.1, it would indicate that the infant in question is part of the 26th group where the gender is male, the gestational age is 33/0 to 33/6 weeks, delayed oral feeding due to prolonged null

per os (NPO) is relevant, the infant was on prolonged invasive ventilation, and lastly, the infant was not diagnosed with a PDA after birth. Digit 2 indicates it as the second preterm infant in group 26, and digit 1 refers to the specific group. This infant forms part of the control group. If the number ends on the digit 2, it will indicate that the infant forms part of the experimental group. When the registered nurse working with this specific infant declared the infant as medically stable, the researcher would indicate it on the *Checklist for possible inclusion* (Addendum P) by marking it as "Yes". Subsequently, the researcher produced the first video of the intervention of infant 26.2.1.

The following section explains how the measuring instrument and the Observational checklist during Sensory integration - informed intervention WITHOUT Octo-Sense Technology and the Observational checklist during Sensory integration - informed intervention WITH Octo-Sense Technology (Addendum S) for the control and experimental groups were compiled.

3.7 MEASURING INSTRUMENT

3.7.1 Observational checklist during Sensory integration - informed intervention WITHOUT Octo-Sense Technology and the Observational checklist during Sensory integration - informed intervention WITH Octo-Sense Technology (Addendum S)

The researcher developed the Observational checklist during Sensory integration-informed intervention WITHOUT Octo-Sense Technology and the Observational checklist during Sensory integration - informed intervention WITH Octo-Sense Technology (Addendum S) after an investigation of the available literature concerning the Sensory Integration frame of reference, the NIDCAP program (Als & McAnulty, 2011) as well as programs from Little Steps® (Lubbe, 2018), and the Neonatal Behavioural Assessment Scale (Brazelton and Nugent, 1955). According to Maree et al. (2020), the researcher should pay attention to the following when compiling a questionnaire:

3.7.2 Discussion of the different questionnaires

The researcher designed two different questionnaires, one for each group. The researcher used Part A of the Observational checklist during Sensory integration - informed intervention

WITHOUT Octo-Sense Technology and the Observational checklist during Sensory integration - informed intervention WITH Octo-Sense Technology (Addendum S) in both groups. The researcher compiled a Part B for the control group and a different Part B for the experimental group. In Part C, the researcher asks specific questions regarding the Octo-Sense that only applied to the experimental group.

Table 3.3 describes Part A, which applies to the control and experimental groups. The observers had to indicate the selected answer directly with an "X" in one of the ten time-in-minute boxes on the Observational checklist during Sensory integration - informed intervention WITHOUT Octo-Sense Technology and the Observational checklist during Sensory integration - informed intervention WITH Octo-Sense Technology (Addendum S).

Table 3.2 presents an example of the block on the Observational checklist during Sensory integration - informed intervention WITHOUT Octo-Sense Technology and the Observational checklist during Sensory integration - informed intervention WITH Octo-Sense Technology (Addendum S), Part A, in the top right-hand corner on the first page of the Observational checklist during Sensory integration - informed intervention WITHOUT Octo-Sense Technology and the Observational checklist during Sensory integration - informed intervention WITH Octo-Sense Technology (Addendum S).

Table 3.2 Identification block

Number: 7.1.2		
Date: 2022-05-03		
Video: 1		
Observer	X A	B

The following is a description of Part A of the Observational checklist during Sensory integration-informed intervention WITHOUT Octo-Sense Technology and the Observational checklist during Sensory integration-informed intervention WITH Octo-Sense Technology

(Addendum S) that was used during the sensory integrated-informed intervention, which was used for both the control and experimental groups.

Table 3.3 Part A of the Observational checklist during Sensory integration - informed intervention WITHOUT Octo-Sense Technology and the Observational checklist during Sensory integration - informed intervention WITH Octo-Sense Technology (Addendum S) during sensory integrated-informed intervention for the control- and experimental groups (Developed: Researcher).

The Observational checklist during Sensory integration - informed intervention WITHOUT Octo-Sense Technology and the Observational checklist during Sensory integration - informed intervention WITH Octo-Sense Technology (Addendum S) used for the control and experimental group during the Sensory Integrated-informed intervention - Part A (The length of the videos was 10 minutes. The researcher used time increments of zero to ten minutes for Part A. The Observers marked the specific time slot with an X)	
Data	The checklist provided space at the top right-hand corner for the preterm infant's randomised number, the date when the researcher took the video, and whether it was video one, two, three, four, or five. Lastly, the observer would identify herself by crossing either A or B. See Table 3.3.
Behavioural state/Arousal state	The behavioural state was described/indicated by pictures of infants in different behavioural states. The behavioural states include crying, active wake, quiet awake/ open face, drowsy, active sleep, and deep sleep. The least desirable state, namely crying, was listed first, and the most desirable behavioural state, quite deep sleep, was listed last. An infant usually moves between these behavioural states for 24 hours. The observers used the Likert scale and time intervals to indicate the infant's behaviour for the duration of the intervention.
Colour	The four skin colours, jaundice, pink, pale, and mottled, determined whether an infant might be experiencing discomfort during the intervention. The colour would change from pink to mottled, which indicated stress. If needed, the researcher ended the intervention and sought the assistance of the RN.

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Visceral (Stress ques)	Spit-ups, gags, burps, sighs, and hiccups are signs of stress. If the researcher notices any stress cues, the intervention ends, and the researcher calls for the RN's assistance.
Face	Tongue extension, hand-to-face, mouthing, suck search, and sucking of hand/finger/pacifier indicate that the infant might be ready for NNS and self-regulation.
Attention	Fuss, yawn, sneezing, open face, and averting are signs of distress.
Head	Head positioning: -right, left, or in the middle, in relation to the infant's body.
Location	The observers indicated with an "X" whether the infants were in a crib, open incubator, or closed incubator.
Posture	Does a "nest" support the infant? Yes or no marked with an "X". Was the infant positioned prone, supine, left or right side-lying? Marked with an " X".
Motor	Infant's extremities: The observer noted flaccid arms, flaccid legs, extended arms, extended legs, and flexed arms. Flexed legs for the duration of the intervention. Signs of distress: arching neck, arching back, twitch of the body, a twitch of the face, a twitch of the extremities. The researcher ended the intervention and sought the assistance of the RN if the researcher noted signs of distress.
Extremities	The observers noted the following: Finger splay, stop signs, grasping, and fisting were signs of distress. When reported, the RN took the necessary actions.
Gastric tube (GT) feeding	An infant was included in the study irrespective of the kind of feeding, whether via the nose (NGT), mouth (OGT), cup, bottle, or breast. The position of the GT might influence the suck, swallow, and breath synchronicity of the infant, as noted by the researcher. The observer would mark with an "X" whether a GT is present.

For Part B, in Table 3.4, the researcher used the *Sensory integration-informed intervention without the Octo-Sense Technology checklist* (Addendum S) using the standard pacifier for the control group. The observers would indicate the applicable answer with an "X" in one of the ten time-in-minute boxes on the Observational checklist during Sensory integration - informed intervention WITHOUT Octo-Sense Technology and the Observational checklist during Sensory integration - informed intervention WITH Octo-Sense Technology (Addendum S).

Table 3.4 Sensory integration - informed intervention without the Octo-Sense Technology checklist for the control group (Developed by the Researcher).

Sensory integration - informed intervention <u>without</u> the Octo-Sense Technology checklist – Part B **(The Observer used time intervals to indicate the infant's actions for the 10-minute intervention)**	
Holding the pacifier in the mouth	The observers checked whether the infant held the standard pacifier in its mouth and, if so, marked the correct time increment. It would also indicate how long the infant had the pacifier in its mouth.
Actively sucking the pacifier	The observers checked whether the infant held the standard pacifier in its mouth and, if so, marked the correct time increment. It would also indicate how long active sucking took place.
Comments	Observers would write additional information in the space provided.

Table 3.5 pays special attention to Part B of the *Sensory integration-informed intervention with the Oct-Sense Technology checklist* (Addendum S) for the experimental group, where the researcher used the Octo-Sense as assistive technology. The observers would indicate the applicable answer with an "X" in one of the ten time-in-minute boxes on the Observational checklist during Sensory integration - informed intervention WITHOUT Octo-Sense Technology and the Observational checklist during Sensory integration - informed intervention WITH Octo-Sense Technology (Addendum S).

Table 3.5 Sensory integration - informed intervention with the Octo-Sense Technology checklist for the experimental group (Developed by the Researcher).

Sensory integration - informed intervention <u>with</u> the Octo-Sense Technology checklist – Part B	
Time increments	The researcher used time intervals to indicate the infant's action/s for the 10-minute intervention.
Holding the pacifier in the mouth	Whether the infant held the Octo-Sense's pacifier in its mouth, by which time increments would also indicate the length of time.
Actively sucking the pacifier	Whether the infant actively sucked on the Octo-Sense's pacifier, by which time increments would also indicate the length of time.
Holding on to tentacle/s with one hand	Whether the infant could hold onto tentacle/s with one hand.
Holding on to tentacle/s with both hands	Whether the infant could hold onto tentacle/s with both hands.
Comments	Observers would write additional information in the space provided.

The researcher Added Part C, shown in Table 3.6, to the *Sensory integration-informed intervention with the Oct-Sense Technology checklist* (Addendum S). The questions explicitly aimed to answer whether the Octo-Sense had any affordances and benefits. More importantly, this part of the questionnaire enabled the researcher to answer objective Four, namely, to describe the affordances of the Octo-Sense assistive technology that the infants engaged with during the sensory-integration-informed intervention sessions. The observers would indicate the applicable answer with an "X" in the YES or NO box on the Observational checklist during Sensory integration - informed intervention WITHOUT Octo-Sense Technology and the Observational checklist during Sensory integration - informed intervention WITH Octo-Sense Technology (Addendum S).

The researcher developed Part C of the questionnaire for the experimental group to assess the possible affordances of the Octo-Sense, as seen in Table 3.6.

Table 3.6 Affordances of the Octo-Sense – Part C

Affordances of the Octo-Sense – Part C	
Touch-able	Whether the infant touched the Octo-Sense
Hold-on-able	Whether the infant holds onto any part of the Octo-Sense
Grab-able	Whether the infant grabbed hold of any part of the Octo-Sense
Comments	Observers could write additional affordances of the Octo-Sense observed during the session in the space provided.

3.7.2.1 A checklist should appear user-friendly, and instructions should be clear

Part A consisted of the different behavioural states: crying, active wake, quite awake (also called open face), drowsy, active sleep and quite deep sleep. The researcher used photos to demonstrate the various behavioural states and described the behaviour in that specific photo. The Observational checklist during Sensory integration-informed intervention WITHOUT Octo-Sense Technology and the Observational checklist during Sensory integration-informed intervention WITH Octo-Sense Technology (Addendum S) developed by the researcher contained time increments of zero to ten minutes. The observed behaviour would then be indicated by an "X" in a checkbox. The researcher also used time increments of zero to ten minutes that had to be marked by an "X" for the sub-sections of Part A. Also, in Part A, there are three sections where the researcher indicated that the observers either must mark "Yes" or "No".

3.7.2.2 The researcher should order the question sequence so as not to confuse the observers

The researcher used two separate Observational checklists during Sensory integration - informed intervention WITHOUT Octo-Sense Technology and the Observational checklist during Sensory integration - informed intervention WITH Octo-Sense Technology (Addendum

S) to avoid confusion among the observers. The questionnaire for the control group consists of Part A, which includes all observations regarding the infant's noticeable responses. Part B consists of the responses from the observers when the researcher used the Octo-Sense. The experimental group questionnaire comprises Part A, which includes all observations regarding the infant's noticeable responses. Part B consists of the responses from the observers when the researcher used the Octo-Sense. The observers could add extra comments. Part C includes specific affordances of the Octo-Sense and comments about the Octo-Sense as assistive technology.

3.7.2.3 The researcher makes use of open-ended as well as closed-ended questions

Close-ended questions are answered with predefined multiple-choice options, like Yes/No responses, or scaled, e.g., "On a scale of 1 to 10, how happy are you?". The researcher compiled close-ended questions using the Lickert scale to gather quantitative data that is easy to analyse and compare on a spreadsheet. Open-ended questions gave observers the opportunity and space to reply in as much detail as they liked. Additional detail qualifies and clears up their responses, yielding more exact data and noteworthy understanding. In both questionnaires, Part A consists of closed-ended answers. The researcher designed Part B of the control group and Part B of the experimental group's questionnaire. The first part contains close-ended questions, and the second part has open-ended questions. The researcher designed Part C exclusively for the experimental group. Part C consists of closed and open-ended questions.

3.7.2.4 The time increment scale

For the close-ended questions, the researcher created ten-minute videos using time increments of zero to ten minutes for Part A and B.

3.7.1.5 Instructions should be simple, straightforward and concise

Using the randomised list, the researcher loaded the preterm infants in numerical order, according to the number given (Addendum R). The researcher chronologically loaded all

footage of a specific preterm infant based on the video's creation date. For instance, if clicked on Preterm Infant 7.1.2, the folder would display the following information:

- 20220503-7.1.2 Video 1
- 20220504-7.1.2 Video 2
- 20220505-7.1.2 Video 3
- 20220506-7.1.2 Video 4
- 20220507-7.1.2 Video 5

Electronic access to a specific video enabled the observer to watch it anytime. The observers used this information to complete the block on the *Sensory integration - informed intervention WITHOUT the Octo-Sense technology* or the *Sensory integration - informed intervention WITH the Octo-Sense technology* Observational checklist during Sensory integration - informed intervention WITHOUT Octo-Sense Technology and the Observational checklist during Sensory integration - informed intervention WITH Octo-Sense Technology (Addendum S) top right-hand corner of the first page (Addendum S). This information identifies the preterm infant, the date when the researcher created the video, and whether it was the first, second, third, fourth or fifth video. The observer would mark the A or B to identify herself.

3.8 DATA COLLECTION AND INTERVENTION PROCEDURES

Data collection took place from 11 February 2022 to 31 May 2022. According to Maree et al. (2020:105), observation is the systematic process of recording the behavioural patterns of preterm infants without directly questioning or communicating with the preterm infant. Maree et al. (2020) mention that having more than one observer benefits the observers. Therefore, the researcher used two observers to ensure their reporting was unbiased, as observation includes all senses and intuition, which may influence the observers' responses (Maree et al., 2020). The researcher decided to make use of video recordings of interventions instead of the observers being present during the taking of videos. In hindsight, this was a very good decision to take. Data collection took place from 11 February 2022 to 31 May 2022, which was during the COVID-19 period. The video recordings made it possible for the researcher to continue with the research. The strict COVID-19 hospital policy made it difficult

for the researcher to obtain informed consent from the parents, as some parents were in isolation and could not visit their preterm infants. Another dilemma arises: if the mother of a preterm infant tested positive for COVID-19, the preterm infant would be treated as COVID-19 positive. Even if the preterm infant was medically stable and qualified to be included in the study, the researcher had to wait for the COVID-19 test results to be negative before including the infant.

The researcher defined the purpose of the observations and the study's focus, which made it easy for the observers to focus on specific aspects. Before the commencement of the study, the researcher explained the intervention procedures to all paediatricians admitting infants in the NICU/PICU. The paediatrician gave written consent (Addendum E) that the infants they treated could form part of the study when declared medically stable (Addendum P). The researcher explained the involvement of nursing personnel in the NICU/PICU during the study to the NICU staff before the commencement of the investigation.

The researcher used the randomised list to allocate a specific number to an infant as soon as the researcher received the consent form from parents/caregivers. The researcher initiated the intervention once an infant was medically stable. The researcher conducted the intervention and data collection daily between 10:00 and 11:00. The researcher used a video camera on a tripod to record 10-minute interventions. The researcher aimed to have five interventions per infant over five consecutive days. When the RN declared an infant medically unstable for a specific day's intervention, the infant remained part of the study until it was perceived to be stable for the rest of the interventions.

In summary, Table 3.7 explains Part A of the intervention procedures used for both the control- and experimental groups.

Table 3.7 The intervention procedures using Part A of the Observational checklist during Sensory integration - informed intervention WITHOUT Octo-Sense Technology and the Observational checklist during Sensory integration - informed intervention WITH Octo-Sense Technology (Addendum S) during sensory integrated-informed intervention for the control and experimental group

Control Group and Experimental Group – Part A	
1	The researcher will use the standard pacifier or the Octo-Sense, depending on the preterm infant's unique number. If the preterm infant's number ends with 1, e.g., 7.1.1, indicating the control group. The researcher will use the standard pacifier the private hospital provides. In the same way, the researcher will use the Octo-Sense if the preterm infant's number ends with 2, e.g., 7.1.2, indicating the experimental group.
2	Before the standard SI intervention commences, the researcher will use a 1 ml syringe to draw pure grapeseed oil. The grapeseed oil ensures the smooth, gliding movement of the researcher's hands on the infant's premature skin. After use, the researcher discards the syringe in a medical waste container in the NICU. The researcher uses a new syringe for each preterm infant.
3	The researcher will ensure she has one syringe of grapeseed oil and one with either EBM or syrup simplex. Syrup simplex is only available if prescribed by the paediatrician. If the pacifier/Octo Sense is in the infant's nest, it will dry due to the heat of the overbed heater. The infant's mouth may also be dry, and the fluids make it easier for the infant to start sucking. If the pacifier/Oct-Sense was in the bucket with Percept for sterilising, it should not be dried. The fluid on the pacifier/Octo-Sense is not toxic but might taste unfamiliar. Therefore, the researcher will administer a few drops of EBM or syrup simplex to the infant's mouth and then hand over the pacifier if the infant indicates the need to suck. According to research by Beker et al. (2017), sweet smell and taste might increase gut motility, insulin secretion, and the release of appetite and digestive and metabolic hormones. The preterm infant in the NICU needs to have the opportunity to smell and taste EBM, even during tube feeding. The role of regular smell and taste of EBM might improve enteral nutrition and growth in preterm infants (Beker et al., 2017). Based on the ideas of Sawleshwarkar et al. (2022),oral sucrose is a safe and effective mild analgesic that decreases short-term

	pain and distress. Oral sucrose is a sweet solution that provides taste stimulation to the cellular membrane receptors in the brain, located in the endogenous opioid system (Sawleshwarkar et al., 2022).
4	The researcher stands next to the open incubator/closed incubator/crib, facing the infant. She rubs her hands with half of the oil from the syringe. Rubbing her hands together warms them, as one does not touch an infant with cold hands. A cold touch elicits the startle reflex, changing the infant's level of arousal.
5	The researcher considers that each infant has limits and an optimal tolerance range. Lane describes the modulation of sensation as follows (Bundy & Lane 2020:157): "Behavioural outcome of cellular modulation reflected in activity; adequate cellular modulation supports our ability to respond to sensation behaviourally in a manner that promotes adaptive environmental interaction and facilitates engagement in meaningful occupations." Therefore, it is incumbent on the researcher to do the following: ✓ The researcher should read the infant's chart to determine the course of events before the session. ✓ The researcher evaluates the infant's state of arousal by thorough observation. ✓ With the guidance of the NIDCAP Program, developed by Dr Als (1982), the researcher attends to visual cues from the infants' self-regulatory behaviour, such as hand-to-mouth, hand clasping and sucking fingers/hand/pacifier. ✓ As described in the NIDCAP Program (Als, 1982), distress signals include over-extended limbs, finger splaying, agitation, and respiratory pauses. ✓ Instead of using light touch, the researcher touches the infants "harder/deeper" to apply deep touch pressure to the muscles and joints underlying the skin by massage (Bundy and Lane 2020;305). ✓ For the researcher to use vestibular input, she must assist the infant in remaining in the "just right" arousal state while challenging movement, as Bundy and Lane (2020:292) mention.

	✓ When turning/rolling the infant from either supine or prone, the researcher should use one hand to hold the infant's head, neck and back. The other hand has the abdomen and legs. The researcher uses this containment hold to control the vestibular input speed, direction and rhythmicity. Rhythmicity and timing contribute to predictability and assist the infant in anticipating movement (Bundy and Lane, 2020). ✓ Preterm infants display low muscle tone (Teledevara et al., 2019); therefore, the vestibular movement against gravity might be challenging (Bundy & Lane, 2020). ✓ The auditory environment of the NICU is complex and affects the preterm infant's hearing. The researcher's voice is also an essential aspect of the auditory environment. The pace and rhythm of language are significant, as slow rhythmic vocalisations or verbalisations promote calming, timing, and sequencing within an activity (Bundy & Lane 2020). Therefore, during the SI interventions, the researcher uses her voice to synchronise with the movement of her hands.
6	After the intervention, all four limbs should be in the midline, thus flexed, while side-lying or prone. The researcher positions the infant in the foetal position using the "nests". The nest is an aid that works against gravity to benefit the preterm infant with low muscle tone.
7	When in the foetal position, the hands are in the midline and close to the face, and the infant can start self-soothing.
8	Following the above, the researcher uses deep pressure by cupping the infant's head and buttocks. She applies deep pressure from both sides at the same time. She holds her hands in this position for one to two minutes to ensure the infant is calm and contained. Usually, the infant's behavioural state moves from drowsy to active sleep and then deep sleep.
9	If the infant shows signs of wanting to suck, the researcher will immediately give the pacifier, regardless of the stage of therapy or state of arousal.

The researcher provided an overview of using the standard pacifier with the control group when conducting the study.

Table 3.8 The standard pacifier used with the control group – Part B

The standard pacifier used with the control group – Part B	
1	The hospital supplies one pacifier for an infant. If the infant were born at 28 weeks gestational age, it would receive the small standard preterm infant pacifier. This pacifier's shield diameter is 47mm, and the nipple length is 23mm.
2	The infant would need another pacifier at the gestational age of 32 weeks to 34/6 weeks. If the hospital had already provided a pacifier to the infant, a second pacifier of a different size would not have been issued. The parents would buy another pacifier at a general baby store or chemist. Another option is to order a hospital pacifier whereby the parents could claim costs from their medical aid.
3	The personnel change the linen twice in 24 hours but would need to adjust it sooner if it gets soiled within 24 hours. The personnel often unintentionally discard the pacifier with the soiled linen.
4	Preterm infants have low endurance and, therefore, cannot control the pacifier in their mouth between breathing and sucking periods. The pacifier continuously falls out of the infant's mouth.
5	The infant might be able to practice NNS during the sensory-integrated intervention; however, if the pacifier falls from the infant's mouth, this opportunity is lost. One of the characteristics of preterm infants is low endurance. This behaviour might change rapidly from active sleep to active crying.
6	The researcher cannot keep the pacifier in the preterm infant's mouth for an extended period.
7	The researcher had no tool to contain the grasping reflex except her finger.

Subsequently, Table 3.9 provides an overview of how the researcher used the Octo-Sense with the experimental group.

Table 3.9 The Octo-Sense used with the experimental group – Part B

The Octo-Sense used with the experimental group – Part B	
1	The researcher uses the knowledge and experience gained by working in the NICU and the infant's gestational age to choose the correct size pacifier. If the infant's gestational age is between 32/0 and 34/6, the miniature pacifier, with a shield diameter of 5 cm and a nipple length of 25 mm, is used.
2	The researcher uses the more oversized pacifier, with a shield diameter of 5cm and a nipple length of 26mm, connected to another tentacle for infants between the gestational ages of 34/0 and 36/6.
3	The infants tire easily and cannot control the pacifier in their mouth between breathing and sucking periods. The "head" of the Octo-Sense is immediately placed behind the pacifier to aid the infant in keeping it in its mouth.
4	If the pacifier remains in the infant's mouth, a significant change in the behavioural state may occur, such as going from active to deep sleep.
5	The Octo-Sense enables the infant to practice NNS during therapy and continue to suck after the researcher removes her hands after treatment.
6	If the infant demonstrates the grasping reflex, the researcher will place one of the Octo-Sense's tentacles in one or both hands.
7	If the infant shows a grasping reflex and accidentally grabs one of the tubes, the researcher will remove the tube from the infant's hand and replace it with a tentacle.

3.9 PILOT STUDY

The researcher executed the pilot study as per the approved final study protocol. The pilot study should be conducted in the same manner as planned for the primary investigation (De Vos 2020). The pilot study took place from 25 September 2021 to 5 October 2021. The pilot study included four infants. The researcher used the randomised list to determine whether the infant would be in the control- or experimental group. The pilot study assessed the technical accuracy of the self-developed assessment instruments, *Sensory integration-informed intervention without the Octo-Sense Technology checklist* for infants in the control group and the *Sensory integration-informed intervention with the Oct-Sense Technology*

checklist for the pilot study (Addendum T), as well as the *Checklist for possible inclusion* (Addendum P). Yegidis and Winbach (Maree 2020) state that a pilot study is a way to improve the primary investigation. Testing the measuring instrument leads to using a more accurate instrument in the main study. Furthermore, these authors mention that feedback from the persons administering the research tool is vital. The researcher should ask for as much feedback as possible. As was also mentioned by Yegidis and Winbach (Maree 2020), there should be ample space on the checklist to report uncertainties, which is imperative during feedback. Testing the measuring instruments should also assist the researcher in discarding confusing and poorly worded questions.

The researcher also had to take into consideration the time constraints that everybody working in the NICU had to adhere to, which was that no activity may occur between 12:00 and 14:00 to ensure better sleep quality for the preterm infants. The researcher did not foresee how time-consuming the planning of each intervention would be. The researcher went to the NICU at seven o'clock to be more time efficient, as the researcher could then review the night shift events and the procedures for that specific day. The summaries the researcher made for each preterm infant assisted the researcher in determining the day routine and, therefore, could better estimate the time of cluster care. Collecting the data before visiting hours was imperative: the researcher then minimised the possibility of the parents being present during data collection as the NICU was noisier during visiting hours.

In addition, the researcher needed to find the admission forms to determine each infant's medical history and -condition at birth and gestational age. This information would include whether the infant was diagnosed with a PDA and whether the infant needed mechanical ventilation. The researcher acquired the length of time the infant was on the ventilator and whether the infant required other breathing devices, such as the CIPAP or nose-canula. It was also crucial for the researcher to note whether the infant was NPO at some stage. The researcher had to go through different registers to obtain all this information. These registers are kept in locked cabinets, as it is personal information of the parents and the preterm infant, protected by the POPI-Act. The Unit Manager granted the researcher access to these registers. The researcher then compared the birth history to the infant's medical condition

on a specific day for possible inclusion. When a preterm infant is declared medically stable by the registered nurse attending to the infant, the researcher could include the preterm infant in the study. The researcher then included the first video recorded in the study. Unfortunately, the same infant might be unstable for the next few days. This event led to the infant's corrected age being no longer within the accepted age range acquired for the study, namely 32 weeks and six days to 36 weeks and six days on a specific day. Additionally, the paediatrician might have discharged the infant before the researcher could record five videos. However, the researcher included all videos taken up to discharge.

Following the pilot study, a lengthy discussion took place between the researcher and observers. These discussions between the researcher and the observers, as well as the discussions with the supervisors, proved beneficial for the study. The researcher adapted the Observational checklist during Sensory integration-informed intervention WITHOUT Octo-Sense Technology and the Observational checklist during Sensory-informed intervention WITH Octo-Sense Technology (Addendum S). The result was the implementation of two checklists, one for the control group and one for the experimental group. The observers' main concern was that the time increments did not afford enough time to observe a specific reaction from the infants. The pilot study's time increments were 0 - 1 minute, 1 – 2 minutes, 3 - 4 minutes, and up to 9 – 10 minutes, resulting in six-time increments. The researcher changed the time increments to 0 – 1 minute, 1 – 2 minutes, 2 – 3 minutes, and up to 9 – 10 minutes, thus ten increments to represent the ten-minute video. The researcher found that printing the Observational checklist during Sensory integration-informed intervention WITHOUT Octo-Sense Technology and the Observational checklist during Sensory integration-informed intervention WITH Octo-Sense Technology (Addendum S) on both sides of one A4 paper was impractical if she wanted a cost reduction. Therefore, the researcher changed the *Sensory integration - informed intervention WITHOUT the Octo-Sense technology,* with the heading printed in red, or *the Sensory integration-informed intervention WITH the Octo-Sense technology* with the heading in red so that information was printed on one side of three A4 pages (Addendum S). Page one consisted of Part A of the questionnaire, which applied to both groups. Both checklists had a space where the observers could write the preterm infants' unique number, the date the researcher shot the video and the number of the video

they were about to watch. In addition to Part A, the observers had to indicate the different behavioural states by looking at photos of infants in the various behavioural states. Part A included the specific observations regarding the infants:

- behavioural state,
- skin colour,
- change in visceral reaction,
- the observation of facial expressions,
- if the infant was sucking his hands or fingers,
- attention should be given to whether the infant is:
    - fussing,
    - yawning,
    - sneezing,
    - frowning,
    - if the eyes were opened or closed,
- the positioning of the head,
- the infant's posture,
- if the infant was in a "nest",
- the observation of a regulated or dysregulated change in the motor system,
- the location of the infant,
- and lastly, if the infant was tube feeding.

Part B was different for the two groups. It was either the *Sensory integration-informed intervention WITHOUT the Octo-Sense technology, with the heading printed in red, or the Sensory integration-informed intervention WITH the Octo-Sense technology*, with the heading printed in green, used (Addendum S). Part C applied to the experimental group. The researcher constructed specific questions regarding the Octo-Sense. Also, on page three, the observers could note their comments on the general sections of the Observational checklist during Sensory integration - informed intervention WITHOUT Octo-Sense Technology and the Observational checklist during Sensory integration - informed intervention WITH Octo-Sense Technology (Addendum S) and particular comments regarding the pacifier or the Octo-Sense.

The subsequent changes to the questionnaires were valid and necessary. Still, unfortunately, they led to the exclusion of the four preterm infants of the pilot study from the final data set.

In conclusion, the researcher considers a pilot study a much-needed part of an experimental study.

The researcher will now discuss the data collection process detail.

3.10 DATA COLLECTION

According to (Maree et al. 2020), observers should ensure their reporting is unbiased, as observations include all senses and intuition, which may influence the observators' responses. The researcher defined the study's focus during the discussions on the data collection procedure. The researcher used video recordings of interventions, making it possible for the researchers to watch the video more than once if unsure of a specific movement or action. Maree et al. (2020) mention that having more than one observer is beneficial, hence, the two observers. Data collection took place from 11 February 2022 to 31 May 2022.

3.10.1 Data collection procedure

The following Table 3.10 explains the data collection procedure and the transfer of information from hard copy to electronic form.

Table 3.10 Data collection procedure

Differentiation between observers	**The researcher named observers A and B to identify which observer completed a specific spreadsheet.**
Determining the infant's specific number	The researcher used the randomised list to assign each preterm infant a specific number; therefore, the infant's number was the name of the video.
Numbering of videos	The researcher used the infant's unique number and indicated whether it was the first, second, third, fourth, or fifth video and the date on which the researcher recorded it (See Table 3.2).

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Access to data	The researcher downloaded the video recordings from the cell phone to One-Drive using the laptop. Thus, giving the observers instant access to the latest video recording.
Which checklist to use?	The observers used the *Sensory integration-informed intervention without the Octo-Sense Technology checklist for the control group, which had unequal numbers (Addendum S). The researcher highlighted this heading in red. The observers used the Sensory integration-informed intervention with the Octo-Sense Technology checklist for preterm infants, with equal numbers for the experimental group.* The researcher indicated this heading in green (Addendum S).
Watch the video	When the observer determined which Observational checklist during Sensory integration - informed intervention WITHOUT Octo-Sense Technology and the Observational checklist during Sensory integration - informed intervention WITH Octo-Sense Technology (Addendum S) to use, she would watch the specific video and mark the desired block with an "X" on the hard copy. The observers could pause the video if they needed more time to tick the correct box. The observers could rewind the video and watch it again. The observers could also return to previous videos and electronic data sheets to see how they scored a specific action.
Excel sheet created on One-drive	The researcher created a master Excel sheet on Google Drive. The researcher developed a folder for Observer A and Observer B. For instance, Observer A would open her folder on her laptop and use the master Excel sheet. After typing the preterm infants' numbers on the Excel sheet, the observer would use "save as" to create a new file. She then completes the Excel sheet accordingly.
The researcher verified both observers' Excel sheets	The researcher collected hard copies of the *Observational checklist during Sensory integration-informed intervention WITHOUT Octo-Sense Technology and the Observational checklist during Sensory integration-informed intervention WITH Octo-Sense Technology*

	(Addendum S) from observers. The researcher verified both observers' data on Google Drive using the hard copies that the observers completed.

The researcher will discuss the data analysis and the implementation of the findings in the following section.

3.11 DATA ANALYSIS

3.11.1 Statistical Significance and Clinical Relevance

Statistical significance refers to the probability that an observed result is not due to random chance. In other words, it indicates the likelihood that an observed effect, such as a clinical outcome from a specific treatment, is real rather than coincidental. The researcher considered a result statistically significant when the p-value is less than 0.05, signifying there is less than a 5% probability that the observed effect occurred by chance. On the other hand, clinical relevance pertains to the practical significance of an impact on a patient's quality of life, such as reduced pain, increased survival rates, or improved overall well-being. As noted by Dahlberg et al. (2020), they deemed a result clinically relevant when it has a meaningful and beneficial impact on patient outcomes.

Although these concepts are related, they are not synonymous. A result can be statistically significant without being clinically relevant, and vice versa. For instance, a treatment may show a statistically significant outcome but lacks practical importance in improving patient care. Conversely, a treatment with a substantial clinical effect may fail to achieve statistical significance due to a small sample size, high data variability, or significant data dispersion.

Statistical significance and clinical relevance are fundamental concepts in clinical research. Statistical significance provides objective, unbiased evidence of a relationship or effect, while clinical relevance reflects the practical implications of these findings in improving patient care and guiding clinical decision-making. The optimal outcome in research is to achieve

statistically significant and clinically relevant results, ensuring that findings are scientifically robust and meaningful in real-world applications.

One practical approach to achieving this balance in clinical trials is to derive research data from a large, homogenous group of participants, carefully selected through well-defined inclusion and exclusion criteria. This methodology reduces variability and enhances the reliability of the findings. However, real-world clinical settings often present challenges which influence the outcomes of factors such as disease severity, age, sex, and the presence of comorbidities. These variables introduce heterogeneity that can affect the generalizability and practical application of research findings, highlighting the need to consider statistical and clinical perspectives when interpreting results.

Data of interest to this study where the number of times specified responses were observed for each infant from the ten-minute video recordings. The researcher recorded between one and five videos for each infant, and the two independent observers scrutinised them. These encounters were analysed using a three-level mixed-effects Poisson regression with fixed effects study group (control/experimental) controlled for sex (male/female) and age with random intercepts at both the infant and observer within infant levels. The researcher used predicted means by group to report individual responses and 95% confidence intervals (CI). The incidence rate ratio (IRR), the ratio of the means for experimental and control groups, was also reported with a 95% CI. The latter facilitated interpretation for effect. The researcher interpreted the p-value ≤ 0.05 as statistically significant, $0.05 < \text{p-value} \leq 0.01$ as marginally significant, and p-value > 0.1 as insignificant. Occasionally, although not statistically significant, a result was considered clinically relevant. Descriptive statistics reported frequencies and percentages, and Fisher's exact test was employed to compare groups in two-way tables.

3.12 IMPLEMENTATION OF FINDINGS

The researcher expects to reveal whether the Octo-Sense as assistive technology can improve infants' self-regulation in the NICU during sensory integration-informed intervention sessions. The researcher indicated that should the findings of this study be positive; she could utilise Octo-Sense in practice to benefit the preterm infant. The ideal would be for the researcher

to send the Octo-Sense home with the infant. The Octo-Sense could enable parents to continue the self-regulation behaviour acquired in the NICU/PICU even when they return home. With positive outcomes, the researcher would also train the multi-disciplinary team members to use this assistive technology to benefit the infants further. The researcher could make this assistive technology available to all the NICU/PICUs in South Africa, whether in the private or public sector. Furthermore, the researcher will publish the study results in accredited scientific journals.

3.13 MEASUREMENT AND METHODOLOGY ERRORS

3.13.1 Reliability

The researcher used current literature as a theoretical base while compiling the *Checklist for possible inclusion (*Addendum P) and the *Sensory integration - informed intervention WITHOUT the Octo-Sense technology* and the *Sensory integration - informed intervention WITH the Octo-Sense technology* (Addendum S). After completing the Observational checklist during Sensory integration-informed intervention WITHOUT Octo-Sense Technology and the Observational checklist during Sensory integration-informed intervention WITH Octo-Sense Technology (Addendum S), the researcher discussed it with the two observers and her supervisors. After the pilot study, the researcher changed the methodology of the two Observational checklists during Sensory integration - informed intervention WITHOUT Octo-Sense Technology and the Observational checklist during Sensory integration - informed intervention WITH Octo-Sense Technology (Addendum S). During this process, the researcher analysed items to eliminate unclear wording and determine if items discriminated against one of the two groups (Maree et al., 2020).

3.13.2 Validity

After the pilot study, the methodology changes enabled a higher content validity (Maree et al. 2020). Inter-observer errors, which is the difference between individuals answering the same question, were minimised by the following:

- Observers were suitably qualified as occupational therapists in neonatal developmental care like the General Movement Assessment, which is one of the most important tools for early diagnosis of neurodevelopmental disorders,
- Both observers had experience working with preterm infants in a NICU,
- Both observers were trained in Ayres Sensory Integration® and had experience in and out of the hospital where the study population was concerned,
- The researcher trained the observers to use the two checklists correctly.

3.13.3 Environmental factors

Environmental factors, such as medical interventions, noise, bright lights, and cleaning and disinfection of the units, may influence the results. Still, the researcher counteracted these factors as much as possible using the Developmental Supportive Care Policy 1.3 (Addendum A) guidelines regarding developmental care in the NICU and PICU.

3.13.4 Drop-out and withdrawals

There were no dropouts in this study. Unfortunately, due to unforeseen circumstances, the researcher could not record five videos of all the preterm infants. However, none of the parents/legal guardians withdrew their infants from the study, so the final data collection process included all the videos.

Lastly, the researcher will pay attention to the ethical considerations she had in mind during the research process.

3.14 ETHICAL CONSIDERATIONS

All relevant ethical guidelines were adhered to as prescribed by the Health Science Research Ethics Committee (HSREC) of the University of the Free State. The researcher awaited ethical approval from the HSREC of the University of the Free State before implementing the study. The number allocated to the study is UFS-HSD2021/0148/2707-0005 (Addendum C). The researcher obtained consent from the Head Office of the private hospital in Bloemfontein (Addendum D). At the same time, paediatricians (Addendum E) who admitted infants to the NICU provided full cooperation during the study. The researcher informed the unit manager

of the NICU, the private hospital in Bloemfontein, that the study was taking place in the specific unit.

- Unethical: The researcher deemed it unethical to serve as an observer due to potential bias in completing observational checklists.

- Data protection: During the data collection phase, the researcher selected Google Drive as the sharing platform, which is cost-effective and user-friendly. It allows data to be shared responsibly. The researcher created a secure folder on Google Drive. The researcher set up 2-factor authentication, an added security layer to obtain access to the Google platform. The researcher's Google profile is protected, but it requires the researcher to log in to the drive using her username and custom password. The researcher did not share this username and custom password. If a person unlawfully attempts to access this Google profile, the owner/researcher of the drive will be alerted immediately. Google Drive will automatically deny access to this drive if the owner responds that the action/attempt to gain access to the drive was unlawful.

  Recorded videos formed part of the metadata collected. As soon as the infants became part of the study, they were de-identified by allocating a randomised number provided by the biostatition. The researcher used a self-compiled observational list to compile information from the videos.

  The researcher created multiple secure folders within the safe drive. The folders for the pilot study contained four preterm infants, with one video for each. The researcher noted that the original checklist was inadequate. Therefore, the observers did not translate the observations into Excel data sheets.

  Per this finding, the researcher created 26 folders, one for each preterm infant in the study. The researcher transferred videos taken from a specific preterm infant to its folder, according to the randomised/unique number at the start of the data collection process. The researcher uploaded the relevant video to the preterm infant's folder and named it after its unique number. If it were preterm infant 2.3.1, the last digit would indicate that the preterm infant was part of the control group, and 2.3.2, the

previous digit, would suggest that the infant was part of the experimental group. The name of the first video would be 2.3.1 Video 1 – 2021-09-11 (date on which the researcher recorded the video), the second video would be 2.3.1 Video 2 – 2021-09-12, etc.

The researcher created a folder for Observer A containing each preterm infant's Observational checklist during Sensory integration - informed intervention WITHOUT Octo-Sense Technology and the Observational checklist during Sensory integration - informed intervention WITH Octo-Sense Technology (Addendum S) and the same for Observer B. The researcher also ensured that the Observers did not have access to each other's folders by choosing the restricted option on the Google Drive Folder.

The Observers viewed all the videos and recorded the data on a hard copy of the Observational checklist during Sensory integration - informed intervention WITHOUT Octo-Sense Technology and the Observational checklist during Sensory integration - informed intervention WITH Octo-Sense Technology (Addendum S). They transferred data from the hard copy to the Excel sheet, named with the unique number corresponding to the unique number on the video and hard copy. Once the observers had completed reporting, the researcher deleted their access to Google Drive. The researcher collected all the hard copies from the Observers. After that, the hard copies were shredded and recycled.

The researcher combined all the Excel sheets completed by the two Observers into one sheet, cleaned the data, and sent the sheet to the University of the Free State biostatistician.

Raw data documented on Excel sheets formed the primary data sets. Data cleaning took place. The researcher transferred the processed data sets and relevant documentation from Google Drive to Figshare, a public repository and a web-based interface for academic research data management and dissemination. Thereafter, the researcher permanently deleted the Google Drive folder. Please refer to the Data Management Plan (Addendum G) for a detailed explanation.

- Informed consent and confidentiality: The parents/legal guardian/s of the preterm infants received an information document explaining the purpose and value of the study. Consent forms were completed and signed. The documentation was available in English, Afrikaans, and Sesotho. The researcher provided a copy of this document to the parents/legal guardian/s (Addendum Q). During the study, each preterm infant received a unique number. Using the number rather than the name of the infant contributed to confidentiality. The researcher had access to the identity of the preterm infants. The researcher informed the Parents/caregivers that the research results might be published.
- Voluntary participation: The researcher informed the parents/legal guardians that they were entering the participation agreement voluntarily and could withdraw their infant from the study without fear of discrimination (Addendum Q).
- Compensation: The researcher did not provide monetary remuneration to preterm infants, parents, or legal guardians. The two observers received an honorarium of R13 000,00, which the researcher paid.
- Beneficence: The researcher treated the preterm infants and their parents/legal guardians respectfully and professionally. The researcher monitored the infants throughout the study to ensure their medical stability and minimal physical discomfort. The preterm infants were not in harmful situations, and the researcher anticipated no risks during the intervention.
- Competence of the researcher: The researcher worked in this NICU for 15 years, thus acquiring hands-on experience, enforced by regular courses and relevant qualifications (see 2.11.1). Working as part of the multi-disciplinary team, the researcher views herself as competent and skilled to undertake the study and to have implemented the intervention that was part of the study.
- Declaration of competing interest: The researcher declares the following financial interests/personal relationships with Mr Brandon Halasz. Mr Brandon Halasz paid for the development of the Octo-Sense and owns the Intellectual Property (IP).

- Post-study provisions: During the study, the researcher noted that infants with difficulty with self-regulation required post-intervention follow-up care. Therefore, these infants qualified for these services.
- Dissemination of findings: The researcher would email the findings to the private hospital's head office, all paediatricians involved, unit managers of the NICU/PICU, and the parents/legal guardians of all infants involved.
- COVID-19: The researcher used video recordings to execute the study, making it much safer for the observers, as they could not access the private hospital's premises. It also rendered it safer for the vulnerable population of the NICU/PICU, as the researcher eliminated additional stimulation or exposure in their environment. The researcher followed the Operational management of COVID-19 within Hospitals Policy C.1.1 (Addendum U) while working in the NICU and PICU. Stringent regulations were put in place regarding visiting hours due to COVID-19. Only the mothers of these infants were allowed to enter the NICU/PICU to see their infants between 15:00 and 16:00. Therefore, the mothers were absent during the recording of the interventions. The researcher will communicate the study's results to the parents/legal guardians.

3.15 CONCLUSION

In this chapter, the researcher focused on the research approach and methodology. The researcher presented a comprehensive study description addressing the chosen paradigm and study design. Furthermore, the researcher annotated the population, sampling and selection criteria by paying attention to the screening tool that included or excluded an infant from the study. Additionally, the researcher discussed the self-developed measurement instrument, namely the Observational checklist during Sensory integration - informed intervention WITHOUT Octo-Sense Technology and the Observational checklist during Sensory integration - informed intervention WITH Octo-Sense Technology (Addendum S) with or without the Octo-Sense technology. The researcher then addressed the data gathering via a discussion about the instruments employed to collect the quantitative data. The researcher described the pilot study and the subsequent adaptations made to the Observational checklist during Sensory integration-informed intervention WITHOUT Octo-Sense Technology and the Observational checklist during Sensory integration-informed intervention WITH Octo-Sense

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Technology (Addendum S). The researcher explained the measurement procedure adapted for the Observational checklist during Sensory integration-informed intervention WITHOUT Octo-Sense Technology and the Observational checklist during Sensory integration-informed intervention WITH Octo-Sense Technology (ADDENDUM S). The researcher reported the methodology errors, the implementation of the findings and ethical considerations.

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CHAPTER 4: RESULTS

4.1 INTRODUCTION

The previous chapter discussed the research methodology used in this study. Chapter 4 presents the anthropometric data of the study of preterm infants and the results obtained through the *Observational checklist during Sensory integration - informed intervention WITHOUT Octo-Sense Technology and the Observational checklist during Sensory integration - informed intervention WITH Octo-Sense Technology (Addendum S) during Sensory integration - informed intervention WITHOUT Octo-Sense Technology* and the *Observational checklist during Sensory integration - informed intervention WITHOUT Octo-Sense Technology and the Observational checklist during Sensory integration - informed intervention WITH Octo-Sense Technology during Sensory integration - informed intervention WITH Octo-Sense Technology* (Addendum S). Given the descriptive nature of the study, the results will be presented in tables, followed by discussions of focus areas in the results. This chapter presents the results related to sensory integration difficulties, namely infants' self-regulation in the Neonatal Intensive Care Unit (NICU) of the private hospital in Bloemfontein.

In this chapter, the researcher will first present the study's anthropometric findings, followed by presenting the results according to the study's objectives.

4.2 OBJECTIVES

Firstly, the researcher would like to take an attentive approach by referencing the four objectives mentioned in Chapter 1.

1. To describe the self-regulatory responses of infants in the Neonatal Intensive Care Unit regarding self-regulatory behaviour and autonomic responses while receiving sensory integration-informed sessions.

2. To describe the self-regulation responses of infants in the Neonatal Intensive Care Unit regarding self-regulatory behaviour and autonomic responses while receiving sensory-informed-intervention sessions supported by Octo-Sense technology.

3. To compare the self-regulation responses of the infants in the Neonatal Intensive Care Unit whilst receiving the sensory integration-informed intervention with those of the infants receiving the sensory integration-informed intervention, supported by the Octo-Sense assistive technology.

4. To describe the affordances of Octo-Sense assistive technology the infants engaged with during sensory-integration-informed intervention sessions.

In this chapter, the researcher presents information gathered as follows: First, demographic information will be discussed, including anthropometric data (4.3), video recordings (4.4), and whether the infants received tube feeding (4.5). Next, the researcher introduces Objectives 1, 2, and 3, comparing each group's behavioural and autonomic responses (4.6) during Sensory integration-informed interventions with or without the Octo-Sense. Finally, Objective 4 focuses on the affordances of the Octo-Sense technology (4.7).

4.3 ANTHROPOMETRIC DATA

The researcher will discuss the anthropometric data of the study population regarding the infants' corrected and gestational ages and gender. The researcher reflects on observations regarding the skin complexions of preterm infants during SI-intervention therapy. The researcher reflects on the total number of videos taken by both the Control- and Experimental groups. Lastly, the researcher considered the different feeding tubes used during the recordings.

4.3.1. The study population

The study population consisted of 26 premature infants admitted to the NICU of the private hospital in Bloemfontein after birth. Figure 4.1 reports on the 26 preterm infants' corrected age. The researcher gathered the infant's information from the *Checklist for possible Inclusion* (Addendum P). The researcher noted the infant's chronological age and corrected age on this checklist. The infants were included in the study when medically stable and between 32 weeks and six days to 36 weeks and six days corrected age. The researcher used the randomised list (Addendum R) to assign a specific preterm infant to either the Control or Experimental group, and the corrected age and gender were the final determinators. For

example, in preterm infant number 23.5.1, the number 23 indicated the specific group, which included the corrected age and gender. Five stated that it was the fifth preterm infant within that group, and the last digit, one, indicated the Control group. If the preterm infant number for the Experimental group was 23.6.2, 23 showed the specific group, including the corrected age and gender. Six stated that it was the sixth preterm infant, and an equal number of two indicated the Experimental group.

4.3.2 Total preterm infants per corrected age

Ball et al. 2023, mention that gestational age is the common term used during pregnancy to describe how far along the pregnancy is. Traditionally, gynaecologists would measure the gestational age of an unborn infant in weeks from the first day of the woman's last menstrual cycle to the current date. A normal pregnancy can range from 38 to 42 weeks (Ball et al., 2023). If an infant is born at 33 weeks, it indicates the gestational age. The nursing staff would note on the daily chart the number of days the infant spent in the NICU, for example, 21 days, indicating three weeks. The gestational age of 33 weeks is added to the three weeks, giving the corrected age of 36 weeks. The researcher used the corrected age of the preterm infant, resulting in the five age groups used.

- Group 1 = 32 weeks and six days
- Group 2 = 33 weeks and six days
- Group 3 = 34 weeks and six days
- Group 4 = 35 weeks and six days
- Group 5 = 36 weeks and six days

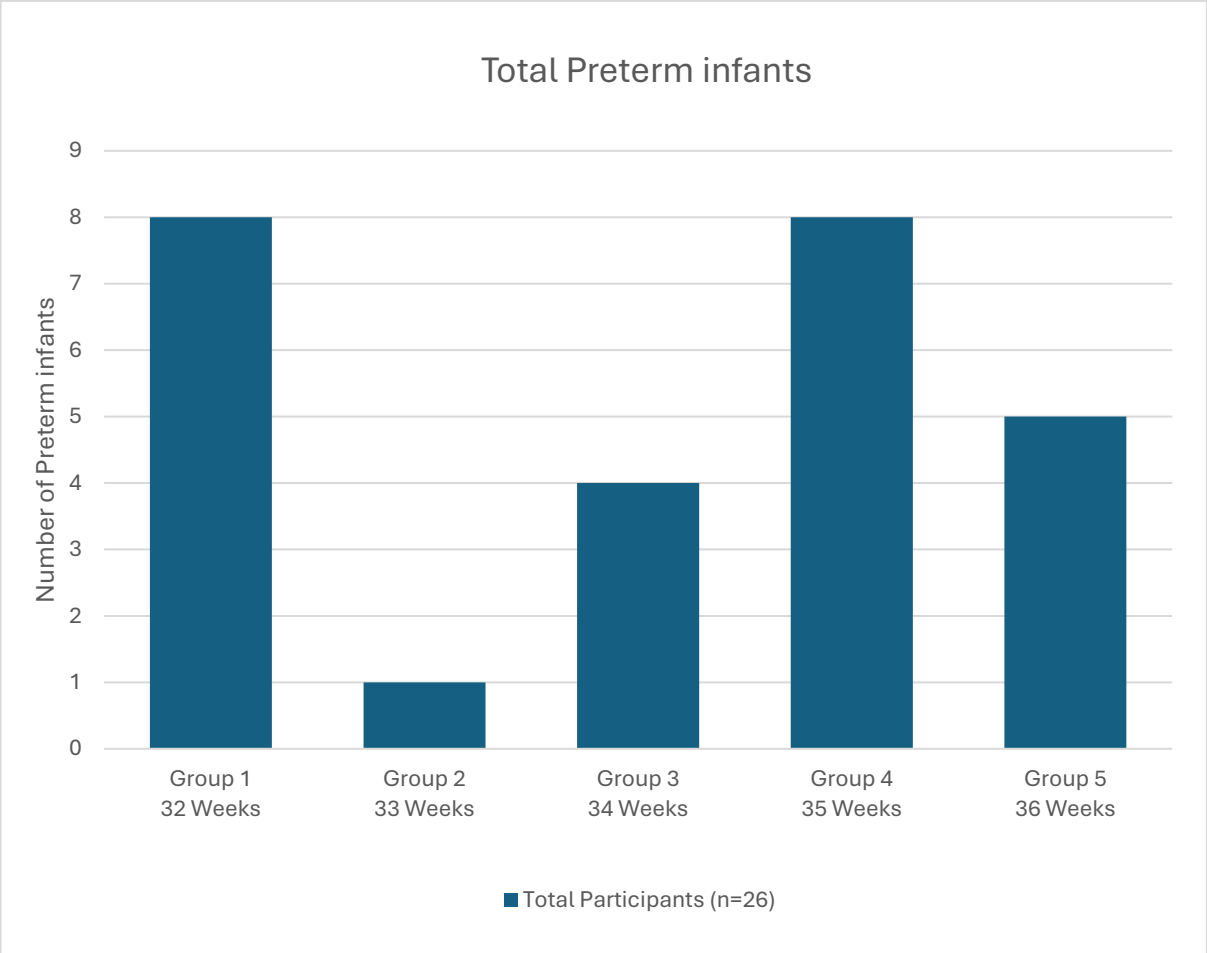

Figure 4.1 Total preterm infants per corrected age

The researcher used Figure 4.1 to visually represent the total number of preterm infants in their respective corrected age groups.

The researcher named the different groups according to the corrected age they represented. Figure 4.1 illustrates the total number of preterm infants in their respective groups. The corrected age of the 26 preterm infants ranged from 32 to 36 weeks. Groups 1 and 4 each had eight preterm infants. Group 5 included five preterm infants. Group 3 had four preterm infants, and Group 2 had one preterm infant of 33 weeks of corrected age.

Complementary to Figure 4.1, the researcher shows the number of preterm infants per age group within the Control- and Experimental groups, as seen in Figure 4.2.

4.3.3 Comparison between the Control- and Experimental Group regarding the corrected age

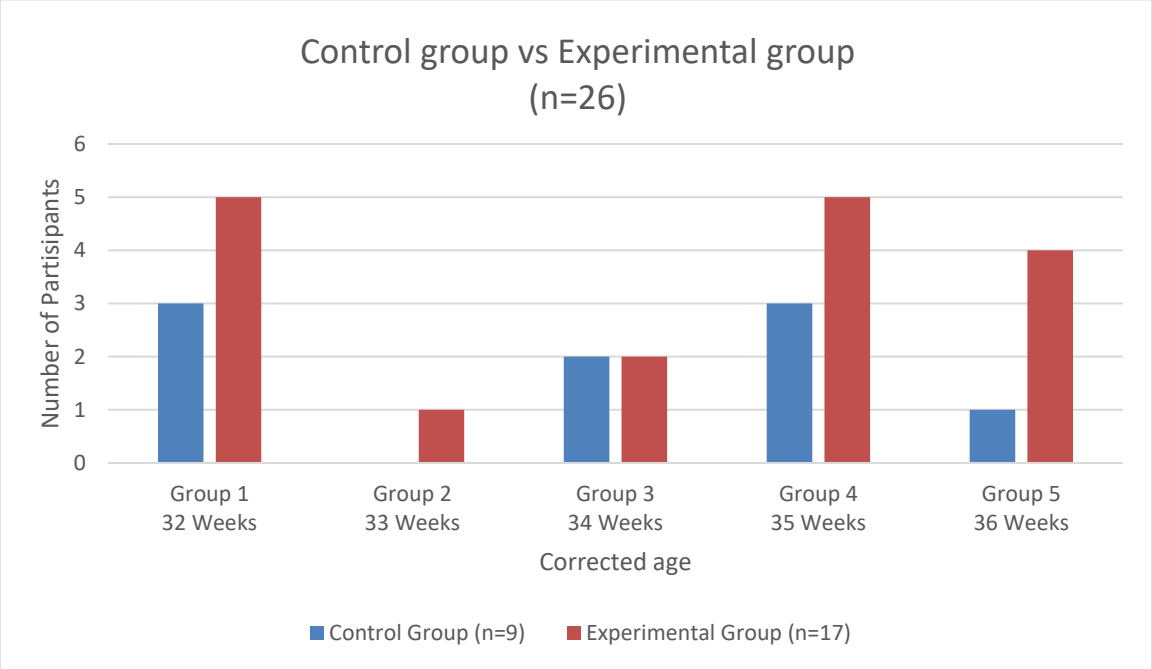

Figure 4.2 Comparison between the Control group and the Experimental group by referring to the preterm infants' corrected age

As mentioned, Figure 4.1 visually represents all preterm infants included in the study, grouped by corrected age. In contrast, in Figure 4.2, the preterm infants were grouped into either the Control- or Experimental group and their corrected age**.**

In the Control group (see Figure 4.2), there were three preterm infants in Groups 1 and 4, respectively. Conversely, the Experimental group recorded the highest number of preterm infants, with five in Groups 1 and 4. In Group 2, the Control group had no preterm infants, while the Experimental group had only one. Group 3 showed equal inclusion across the Control and Experimental groups, with two preterm infants each. The most significant variation occurred in Group 5, 36 weeks, where the Experimental group had four preterm infants compared to only one in the Control group. The key differences between the two groups are apparent in Groups 1, 4, and 5, where the Experimental group had more preterm infants than the Control group. Group 2 had no preterm infants in the Control group, while

Group 3 had an equal number in both groups. The researcher used a randomised list provided by the biostation to allocate infants to specific groups. Therefore, there is an imbalance between the number of preterm infants in the Control and Experimental groups. The randomised list further influenced the imbalance between males and females and the differences in the count of preterm infants per age group.

4.3.4 Comparison between genders within the Control- and Experimental groups, as well as according to the corrected age

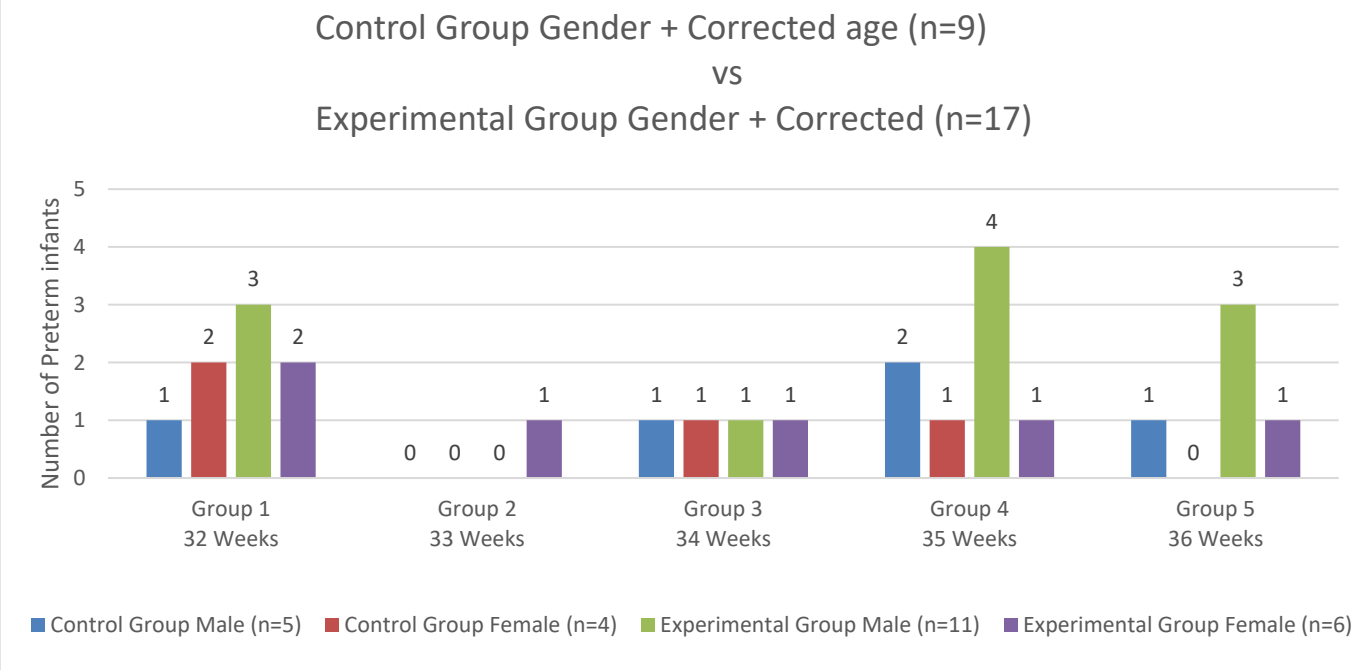

Figure 4.3 Comparison between gender within the Control- and Experimental groups, according to the corrected age

The researcher compared the two groups according to the total number of males and females included in the Control- and Experimental groups. Furthermore, the researcher compared the five groups' corrected age within the Control- and Experimental groups Figure 4.2.

The researcher refined the information in Figure 4.3 for more clarity. The researcher presents the corresponding results in Table 4.1.

Table 4.1 Comparison between genders within the Control- and Experimental groups,

Control group	**Experimental group**
Group 1 One male and two females	Group1 Three males and two females
Group 2 No Males and no females	Group 2 No male and one female
Group 3 One male and one female	Group 3 One male and one female
Group 4 Two males and one female	Group 4 Four males and one female
Group 5 One male and no females	Group 5 Three males and one female

The following discussion aims to integrate the information given in Figure 4.3 and Table 4.1:

Group 3 included two preterm infants in the Control and Experimental groups, which indicates an equal number of preterm infants regarding gender and corrected age for both groups. In Group 4, the Experimental group had the most male preterm infants. Groups 1 and 5 for the Experimental group had three male preterm infants.

The biostatistician calculated the randomisation list, and the researcher used this list to allocate each preterm infant to a specific group. The categories included in the randomisation list were gender, gestational age, and whether delayed oral feeding due to prolonged NPO was applicable. The list also included whether the preterm infant underwent prolonged invasive ventilation and whether the patient was diagnosed with a PDA. As maintained by the list, the Control group had fewer preterm infants than the Experimental group. Further, according to the randomisation list, the researcher included more males than females in the study. Thus, there is an imbalance in gender distribution. There is a noticeable difference in

the number of male and female preterm infants across the control and experimental groups (Figure 4.3 and Table 4.1).

Randomisation Impact: Randomisation influenced the allocation of preterm infants, resulting in an unequal number of preterm infants in the Control and Experimental groups (Figure 4.3 and Table 4.1).

Group Comparisons: Group 3 (Table 4.1) is the only group that shows equality between gender and corrected age within the Control and Experimental groups, while other groups have varied distributions.

4.3.5 A comparison of the age distribution between males and females for the total number of preterm infants

As gender and age form part of the anthropometric data, the researcher compared the two groups according to the total number of males and females included in the Control- and Experimental groups regarding their age, as presented in Table 4.2.

Table 4.2 A comparison of the age distribution between males and females

Age (In weeks)	Gender		n=26
	Male n=15	Female n=11	
32	4 (26.67%)	4 (36.36%)	8 (30.77%)
33	0	1 (9.09%)	1 (3.85%)
34	2 (13.33%)	2 (18.18%)	4 (15.38%)
35	6 (40.00%)	2 (18.18%)	8 (30.77%)
36	3 (20.00%)	2 (18.18%)	5 (19.23%)
Total	15 (100.00%)	11 (100.00%)	26 (100.00%)

The study's analysis of the age distribution between males and females indicates patterns despite the need for more statistical significance due to the small sample size. A comparison of the age distribution (Table 4.2) between males and females shows that the age group of 35 weeks is the most common for males, with 40%, while the age group of 32 weeks corrected age is the most common for females, with 36.36%. Table 4.2 also shows that the corrected age of 33 weeks is unique to females in this dataset with 9.09%. Males are more concentrated in the older age groups, with 40% for the 35 weeks corrected age and 20% for the 36 weeks corrected age group. Lastly, as seen in Table 4.2, the patterns indicate a more even distribution for females in the corrected age groups of 34 weeks, 35 weeks and 36 weeks, with a percentage of 18.18% each.

4.3.6 Observations made by observers regarding the skin complexions of the preterm infants during SI-intervention therapy for the total number of videos taken in both the control- and experimental group

Skin complexion is a barometer of a preterm infant's health condition. Therefore, the researcher thought it necessary to include skin complexion in the two Observational checklists during Sensory integration - informed intervention WITHOUT Octo-Sense Technology and the Observational checklist during Sensory integration - informed intervention WITH Octo-Sense Technology (Addendum S). Figure 4. 4 shows the results obtained during the study.

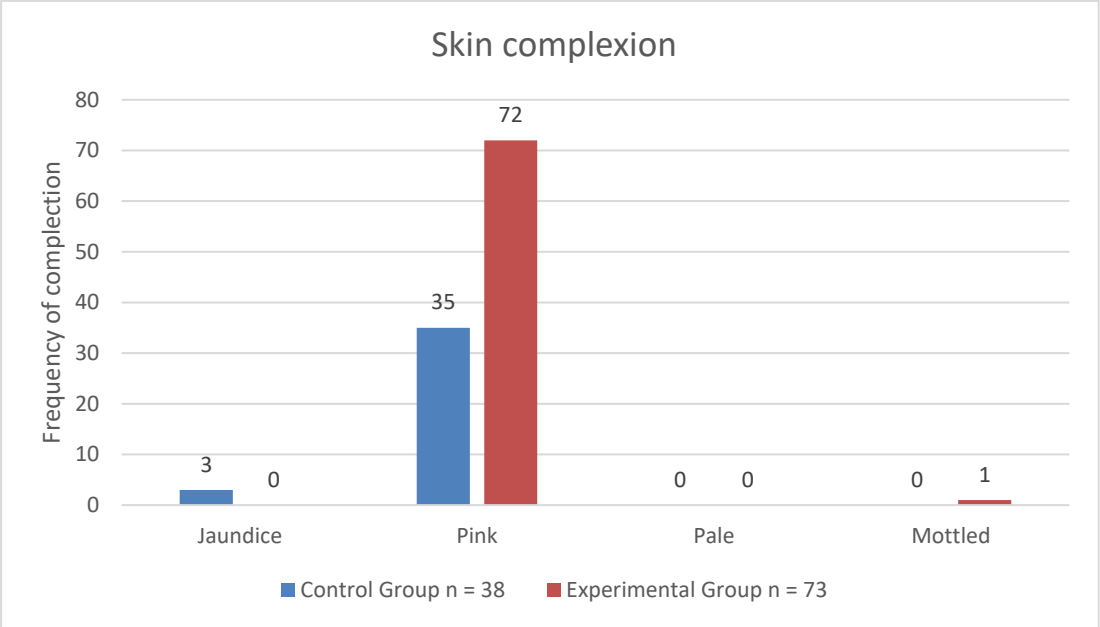

Figure 4.4 Observations of different skin complexions within the Control- and Experimental groups

The skin complexion does not implicate race in preterm infants. Figure 4.4 shows three videos where the observers noted infants with jaundice in the control group and none in the experimental group. Out of 111 videos taken during the study, 35 videos showed the infants in the control group to be pink, and 72 videos showed the infants in the experimental group to be pink. None of the videos, as indicated by the observers, showed infants to be pale. The observers noticed one video in the experimental group with a mottled infant.

4.4 THE NUMBER OF VIDEOS TAKEN

The researcher concluded that taking videos from each intervention would be beneficial. It would allow the observers to pause the video to give adequate time to ensure that the specific observation seen is marked. If the observers needed clarification on what they observed, they could rewind the video and watch it again. The data collection partially took place during the COVID-19 pandemic. If the researcher had not decided to use videos, the observers would not have had access to the NICU to observe the interventions. Also, it would have been challenging for the observers to commit to the researcher's schedule if the observers needed to be present during the intervention sessions. As seen in Table 4.3 and Table 4.4, not all preterm infants had five videos. If an infant was declared medically stable, it also indicated

that discharge would follow soon. The researcher discusses Table 4.3 to indicate the total number of videos taken for the Control group.

Table 4.3 Number of videos taken of the Control group

Preterm infant	Video 1 (n = 9)	Video 2 (n = 8)	Video 3 (n = 7)	Video 4 (n = 7)	Video 5 (n = 7)	n = 38
1	x	x	x	x	x	5
2	x					1
3	x	x	x	x	x	5
4	x	x	x	x	x	5
5	x	x	x	x	x	5
6	x	x	x	x	x	5
7	x	x	x	x	x	5
8	x	x	x	x	x	5
9	x	x				2

Table 4.3 presents data on the number of videos taken for each preterm infant in the Control group. The data reflect the number of video recordings completed per preterm infant in the Control group, totalling 38 across all preterm infants and sessions. Video 1 included all nine Control group preterm infants. Unfortunately, the researcher could take only one video of Preterm Infant 1 and two videos of Preterm Infant 9. Due to discharge, the researcher did not take five videos of Preterm Infant 1 and Preterm Infant 9.

The researcher will now discuss Table 4.4, which indicates the total number of videos taken for the experimental group.

Table 4.4 Number of videos taken by the Experimental group

Preterm infant	Video 1 (n = 17)	Video 2 (n = 5)	Video 3 (n = 5)	Video 4 (n = 14)	Video 5 (n = 12)	n = 73
1	x	x	x	x	x	5
2	x	x	x	x	x	5
3	x					1
4	x	x	x	x	x	5
5	x	x	x	x	x	5
6	x	x	x			3
7	x	x	x	x	x	5
8	x	x	x	x		4
9	x	x	x	x	x	5
10	x	x	x	x	x	5
11	x	x	x	x	x	5
12	x	x	x	x	x	5
13	x	x	x	x		4
14	x	x	x	x	x	5
15	x					1
16	x	x	x	x	x	5
17	x	x	x	x	x	5

The total number of video recordings for the Experimental group is 73 across all preterm infants and sessions. Table 44 shows that the researcher could record five videos for most preterm infants in the Experimental group. As seen in Tables 4.3 and 4.4, the researcher could record 38 videos for the control group and 73 videos for the Experimental group, which added to 111 videos for all the preterm infants. Video 1 is the only video recorded for all the Control and Experimental group preterm infants.

During the Data collection period, South Africa experienced a shortage of electricity. A power supply schedule showed when parts of Bloemfontein would lose electricity. Unfortunately,

power shortages occurred during periods when electricity was supposed to be available. The researcher had to download videos daily for the observers to watch. The downloading process was time-consuming due to the size of the videos. Due to unforeseen power outages, the researcher could not capture some videos, leading to preterm infants not having five videos.

4.5 TUBE FEEDING

The researcher took a total of 111 videos. In 79 videos, the preterm infants had either a nasogastric tube or an orogastric tube in sito. Intragastric tube feeding is the primary method of milk feeding for sick and premature infants until they can establish oral suck feeds. The RN inserts an intragastric tube into the preterm infant's stomach via the nose, NGT or mouth, OGT. The RN gives EBM or formula, fed through the tube and directly into the stomach. The following provides a comprehensive overview of the tube feeding observations in the Control group with the standard pacifier, without the Octo-Sense Technology.

4.5.1 Control group, using the standard pacifier

The researcher took 38 videos of the Control group:

- Video 1 - six of the nine preterm infants had feeding tubes.
- Video 2 - four of the eight preterm infants had feeding tubes.
- Video 3 – five of the seven preterm infants had feeding tubes.
- Video 4 - five of the seven preterm infants had feeding tubes.
- Video 5 - five of the seven preterm infants had feeding tubes.

The researcher compiled the previous information into Table 4.5, which shows the number of NGT and OGT observed during the 38 video recordings.

Table 4.5 Tube feeding: The Control group with the standard pacifier

Video	Nr of videos (n = 38)	Total with feeding tubes (n = 25)	Percentage of infants with feeding tubes (n = 25)	NGT (n = 19)	OGT (n = 6)
1	9	6	66.66%	4	2
2	8	4	50%	3	1
3	7	5	71.43%	4	1
4	7	5	71.43%	4	1
5	7	5	71.43%	4	1

The presence of feeding tubes (Table 4.5) remained consistent across Videos 3, 4, and 5, with five preterm infants having feeding tubes in each of these videos. The number of preterm infants with feeding tubes decreased from Video 1, six preterm infants, to Video 2, four preterm infants, showing a slight reduction. NGT (Table 4.5) was the most common type of feeding tube, present in 19 out of 25 instances. OGT (Table 4.5) was less common, with six cases. The researcher observed that out of the 38 videos, 19 preterm infants had an NGT, and 6 had an OGT. The NGT was the predominant feeding tube type, with a clear majority of preterm infants using it compared to the OGT. The number of feeding tubes in use five (Table 4.5) was stable in Videos 3, 4, and 5, indicating consistency in tube usage over these recordings. There was a slight decrease in the number of feeding tubes from Video 1 to Video 2, but overall, the data remained relatively stable across the videos. This information (Table 4.5) provides insight into the tube-feeding practices observed in the control group and reflects the consistency of feeding tube usage over the recorded videos.

Information regarding tube feeding for the Experimental group will follow.

4.5.2 Experimental group with the Octo-sense

As in the previous table, the following provides a comprehensive overview of the tube feeding observations in the experimental group with Octo-Sense Technology.

The researcher took 73 videos of the experimental group:

- Video 1 - 13 of the 17 preterm infants had feeding tubes.

- Video 2 - 13 of the 15 preterm infants had feeding tubes.
- Video 3 – 11 of the 15 preterm infants had feeding tubes.
- Video 4 – nine of the 14 preterm infants had feeding tubes.
- Video 5 - eight of the 12 preterm infants had feeding tubes.

As mentioned, the researcher compiled information into Table 4.6 to show the number of NGTs and OGTs observed during the 73 video recordings.

Table 4.6 Tube feeding: The Experimental group with the Octo-sense

Video	Preterm infants (n = 73)	Total with feeding tubes (n = 54)	Percentage of infants with feeding tubes (n = 54)	NGT (n = 37)	OGT (n = 17)
1	17	13	76.47%	9	4
2	15	13	86.66%	10	3
3	15	11	73.33%	7	4
4	14	9	64.29%	6	3
5	12	8	66.67%	5	3

The number of preterm infants with feeding tubes (Table 4.6) decreases from Video 1 to Video 5, with the highest number of feeding tubes in Video 1 with 13 preterm infants and the lowest in Video 5 with eight preterm infants. NGT (Table 4.6) was the most used feeding tube type in 37 out of 54 instances noted. On the other hand, OGT (Table 4.6) was less common, with 17 cases reported. Out of the 73 videos, the observers noted that 54 preterm infants had feeding tubes, highlighting a substantial use of feeding tubes among the experimental group with Octo-Sense Technology. The observers stated a high frequency of feeding tubes, as a significant proportion of preterm infants in the experimental group had feeding tubes, with a notable presence of NGT. However (Table 4.6), there was a gradual decrease in the number of feeding tubes observed from Video 1 to Video 5, indicating a possible change in feeding tube usage or preterm infant condition over time. The NGT was consistently the most frequently used feeding tube type compared to the OGT.

The researcher will present the data results supporting the study's first, second, and third objectives regarding the Control and Experimental groups in the following section.

Subsequently, the researcher will report on the findings of these three objectives in the same order as they appear on the two Observational checklists during Sensory integration - informed intervention WITHOUT Octo-Sense Technology and the Observational checklist during Sensory integration - informed intervention WITH Octo-Sense Technology (Addendum S).

4.6 THE SELF-REGULATORY BEHAVIOUR AND AUTONOMIC RESPONSES OF THE INFANTS WHILE RECEIVING SENSORY INTERVENTION-INFORMED SESSIONS, WITH AND WITHOUT THE OCTO-SENSE TECHNOLOGY

In this section, the researcher will present the data that enabled her to describe and compare the behavioural and autonomic responses noted in the control and experimental groups. Firstly, the researcher aimed to collect data that would allow for her to answer the first and second objectives. Firstly, to describe the self-regulatory responses of infants in the Neonatal Intensive Care Unit regarding self-regulatory behaviour and autonomic responses while receiving sensory integration-informed sessions. Secondly, the data presented will be on the self-regulation responses of infants in the Neonatal Intensive Care Unit regarding self-regulatory behaviour and autonomic responses while receiving sensory-informed-intervention sessions supported by Octo-Sense technology. The third objective required comparing the data obtained of the self-regulation responses of the infants in the Neonatal Intensive Care Unit whilst receiving the sensory integration-informed intervention with those of the infants receiving the sensory integration-informed intervention, supported by the Octo-Sense assistive technology.

Subsequent sections and tables compared the two groups using the Incidence Rate Ratio (IRR) and p-values. The IRR assessed the relative frequency of specific behaviours and responses between the Control and Experimental groups. At the same time, the p-values determined the statistical significance of the differences observed between the groups.

IRR is a measure used in epidemiology studies to compare the incidence rates of an event, for instance, the sucking of a pacifier for the Control group in comparison to the Octo-Sense for the Experimental group. An IRR of one (IRR = 1) indicates no difference between the groups; thus, the behaviour or response happens at the same rate. In the same way, Sedgwick (2010)

mentions that an IRR greater than one (IRR >1) suggests a higher incidence in the Experimental group than in the Control group, thus happening more often in the Experimental group than in the Control group. An IRR of less than one (IRR<1) indicates a lower incidence in the Experimental group, thus less often than in the Control group.

Furthermore, the researcher used the p-value as a statistical measure to determine the significance of results in hypothesis testing. It indicates the probability of observing the data if the null hypothesis is true (Beers, 2024). A low p-value, < 0.05 or less, suggests that the difference is statistically significant, which is unlikely to have occurred by chance. A high p-value suggests that any observed differences may be due to random variation. The third objective refers to the Incidence Rate Ratio (IRR) and p-values, which indicate the differences between the two groups.

For this study, the researcher must distinguish between clinical and statistical significance. Kazdin (2004) observed that even minor treatment effects can appear statistically significant in studies with large sample sizes (Kazdin, 2004). This study also showed that clinical significance involves a set of measures to determine whether treatment's impact leads to meaningful changes for patients(Kazdin, 2004). In the study by Temple et al., 2018, ten trials (11%) reported on the clinical significance of their findings, each using a different operational definition, making it difficult to assess the absolute efficacy of treatments across various studies. Therefore, the distinction between statistical and clinical significance can often be unclear. Statistical significance refers to the likelihood that observed results are genuine differences rather than occurring by chance (Stevens & Gibbins, 2002). On the contrary, Stevens and Gibbins (2002), who did their study on pain management in vulnerable infants, also found that clinical significance reflects the practical importance of these findings to the patient population. Like clinical utility in measurement, there is no universally accepted definition of clinical significance. It is, therefore, generally understood as the relevance of an outcome to an individual. The most accurate way to gauge clinical significance is often through the individual's verbal report of their experience with the intervention (Stevens & Gibbins, 2002). Therefore, the researcher incorporates clinical significance in the discussions,

as the observations revealed the outcomes of individual responses from preterm infants in both groups.

4.6.1 Behavioural States of the Control- and Experimental Group

The researcher presents a statistical analysis comparing the predicted means between the Control Group (n=9) and the Experimental Group (n=17) of the six behavioural states measured during the study in Table 4.7. The researcher predicted the means as minutes observed in that state per ten-minute window. The first column lists the six states: Crying, Active awake, Quiet awake, Drowsy, Active sleep, and Quiet deep sleep. The second column, Control Group, presents the predicted means for each state in the control group, along with their 95% confidence intervals (CI). The third column, Experimental Group, presents the predicted means for each state in the Experimental group, along with their 95% CI and confidence intervals (CI). The fourth column, IRR, in the listed tables, displays the Incident Rate Ratio, which measures the rate ratio between the two groups. The fifth column, the p-value, reports the p-value for each comparison, which indicates the probability of observing the difference between the two groups by chance.

The researcher will first discuss the behavioural states of the Control group and the

Table 4.7 The behavioural responses of the Control group and Experimental group

Response	Control Group Predicted Mean (95% CI) (n=9)	Experimental Group Predicted Mean (95% CI) (n=17)	IRR	p-Value
Crying	0.295 (0.339 ; 0.99)	0.043 (0.045 ; 0.132)	0.148	0.090
Active awake	0.213 (0.063 ; 0.490)	0.212 (0.000 ; 0.425)	0.995	0.994
Quiet awake	1.705 (0.653 ; 2.756)	1.903 (1.022 ; 2.783)	1.115	0.764
Drowsy	0.923 (0.268 ; 1.577)	1.937 (0.863 ; 3.012)	2.098	0.087
Active Sleep	5.950 (1.769 ; 10.132)	5.159 (2.301 ; 8.017)	0.867	0.725
Quiet deep sleep	0.845 (0.062 ; 1.627)	0.734 (0.185 ; 1.282)	0.868	0.790

The control group's behavioural responses were predominantly characterised by active sleep (Table 4.7), with a predicted mean of 5.950 (CI: 1.769; 10.132). The quiet awake state followed, with a predicted mean of 1.705 (CI: 0.653; 2.756). The active, awake state was the least observed in this group, with a predicted mean of 0.213 (CI: 0.063; 0.490), followed by crying, with a predicted mean of 0.295 (CI: 0; 0.99).

The behavioural responses of the experimental group, as captured during the 10-minute videos, were also distinguished mainly by active sleep, with a slightly lower predicted mean of 5.159 (CI: 2.301; 8.017). The least frequent response in this group was crying, with a predicted mean of 0.043 (CI: (0.045; 0.132). The quiet awake and drowsy states had similar frequencies, with predicted means of 1.903 (CI: 1.022; 2.783) and 1.937 (CI: 0.863; 3.012), respectively.

Regarding the comparison between the groups, the incidence rate ratio (IRR) for the drowsy state was 2.098, indicating that infants in the experimental group were approximately twice as likely to exhibit drowsiness as those in the control group. However, the p-value for this comparison was 0.087, exceeding the conventional significance threshold of 0.05, suggesting that the observed difference in drowsiness between the experimental and control groups is not statistically significant, though it approaches significance. While several IRRs indicated a higher incidence of certain behaviours in the experimental group, the p-values for most behavioural states imply that these differences were not statistically significant.

In addition, the researcher will discuss the visceral responses of both the Control- and Experimental groups.

4.6.2 Visceral or autonomic responses for the control- and experimental group

The lungs, heart, and organs of the digestive, excretory, reproductive and circulatory systems are all visceral organs, also called the visceral nervous system. The responses recorded in Table 4.8 indicate the visceral/autonomic responses for the Control- and Experimental groups.

Table 4.8 The autonomic responses of the control- and experimental group

Response	Control Group Predicted Mean (95% CI) (n=9)	Experimental Group Predicted Mean (95% CI) (n=17)	IRR	p-Value
Spit-up	-	-	-	-
Gag	0.036 (0 ; 0.095)	0.056 (0 ; 0.121)	1.562	0.649
Burp	0.232 (-0.010 ; 0.057)	0.017 (-0.002 ; 0.037)	0.739	0.752
Sigh	-	-	-	-
Hiccup	2.109 (-3.842 ; 8.060)	3.153 (-5.355 ; 11.696)	1.495	0.689

Notably, the spit-up and sigh autonomic responses (Table 4.8) were neither observed nor recorded in the Control group. The gag response in this group was the least common, with a predicted mean of 0.036 (CI: 0; 0.095). Followed by the burp response, with a predicted mean of 0.232 (CI: -0.010; 0.057). The highest predicted mean in the Control group was the hiccup response, at 2.109 (CI: -3.842; 8.060).

Similarly, the spit-up and sigh autonomic responses (Table 4.8) were also absent in the Experimental group. The hiccup response was the most frequent in this group, with a predicted mean of 3.153 (CI: -5.355; 11.696). The burp response was the least observed, with a predicted mean of 0.017 (CI: -0.002; 0.037). Although still infrequent, the gag response showed a slightly higher incidence with a predicted mean of 0.056 (CI: 0; 0.121).

An IRR of 1.562 for the gag response (Table 4.8) indicates that the Experimental group experienced a 56.2% higher incidence of gag events and a 26.1% lower rate of burp events (IRR=0.739) than the Control group. An IRR of 1.495 for hiccups indicates that the Experimental group had a 49.5% higher rate of hiccup events than the Control group. The p-values for gag (Table 4.8), 0.649, burp 0.752, and hiccup 0.689 are all greater than 0.05, indicating the differences in the rates of these events between the Control and Experimental groups are not statistically significant. In summary, the data (Table 4.8) suggests that the

Experimental group exhibited a higher rate of gag and hiccup events than the Control group. In comparison, the rate of burp events was lower in the Experimental group. Despite these observed differences, none of the comparisons reached statistical significance.

4.6.3 Responses noticed under the sub-heading: Face and mouth

The researcher now reports on the responses relating to the face and mouth for the Control- and Experimental groups, as seen in Table 4.9.

Table 4.9 Responses relating to the face and mouth

Response	Control Group Predicted Mean (95% CI) (n=9)	Experimental Group Predicted Mean (95% CI) (n=17)	IRR	p-Value
Tongue extension	0.468 (0 ; 1.221)	0.800 (0 ; 1.896)	1.707	0.506
Hands to face	6.471 (4.460 ; 8.482)	6.502 (5.017 ; 7.987)	1.004	0.980
Mouthing	0.242 (0.012 ; 0.4720	0.500 (0.120 ; 0.880)	2.066	0.217
Suck search	0.269 (0.055 ; 0.483)	0.390 (0.166 ; 0.613)	1.447	0.438

In the Control group, the hands-to-face response (Table 4.9) was the most frequent, with a predicted mean of 6.471 (CI: 4.460; 8.482). This response was significantly more common than the other responses. The tongue extension response had a predicted mean of 0.468 (CI: 0; 1.221). Furthermore, the mouthing and suck search responses were almost similar in frequency, with predicted means of 0.242 (CI: 0.012; 0.4720) and 0.269 (CI: 0.055; 0.483), respectively.

In the Experimental group (Table 4.9), hands-to-face is the most frequent response, with a predicted mean of 6.471 (CI:4.460; 8.482). The reaction of tongue extension was 0.800 (CI: 0; 1,896), and the mouthing response was 0.500 (CI: 0.012; 0.4720), almost like the Control group. The reaction for the suck search was the lowest, with a predicted mean of 0.390 (CI: 0.66; 0.613).

Regarding tongue extension (Table 4.9), the IRR of 1.707 indicates that the Experimental group had a higher tongue extension rate than the Control group. The p-value of 0.506 suggests that the difference was not statistically significant. Secondly, the hands-to-face observation (Table 4.9) had an IRR of 1.004, which indicates almost no difference in the rate of hands-to-face behaviour between the groups. The p-value of 0.980 also suggests no statistically significant difference between the two groups. The Experimental group had a higher IRR, 2.066, for the observation of mouthing (Table 4.9), and the p-value of 0.217 indicates that the difference was not statistically significant. Lastly, for suck search, the IRR of 1.447 showed a higher rate of suck search behaviour for the experimental group, and the p-value of 0.438 again showed that the difference in behaviour was not statistically significant. In conclusion, the researcher (Table 4.9) saw that while the IRR values suggest that the Experimental group generally has a higher incidence of face and mouth behaviours than the Control group, none of the p-values indicate statistically significant differences.

4.6.4 Responses noticed under the sub-heading: Sucking of hands and fingers

In Table 4.10, the researcher presents the findings regarding hand sucking and finger sucking for both the Control and Experimental groups.

Table 4.10 Responses relating to the sucking of hands and fingers

Response	Control Group Predicted Mean (95% CI) (n=9)	Experimental Group Predicted Mean (95% CI) (n=17)	IRR	p-Value
Hand/s	-	-	-	-
Finger/s	0.044 (0.000 ; 0.087)	0.035 (0.006 ; 0.063)	0.799	0.731

The observers reported no responses for the control group's sucking of hand. Subsequently, the sucking of finger/s had a predicted mean of 0.044 (CI: 0; 0.087).

In the same way, as was mentioned above, no sucking of hand or hands were noted for the experimental group, but the sucking of finger/s had a predicted mean of 0.035 (CI: 0; 0.087).

When considering the IRR of 0.799 (Table 4.10), the Experimental group's occurrence of finger/s is approximately 80% of the rate seen in the Control group, indicating that the Experimental group engaged in this behaviour less frequently than the Control group. A p-value of 0.731 (Table 4.10) is much more significant than the expected threshold of 0.05, indicating that the difference in finger/s behaviour between the two groups is not statistically significant. The IRR demonstrates that the Experimental group had a lower incidence of finger/s behaviour than the Control group. The high p-value shows that this difference is not statistically significant.

4.6.5 Responses noticed under the sub-heading: Attention

The researcher presents a statistical analysis (Table 4.11), comparing the predicted means of nine different responses: Fuss, yawn, sneeze, frown, eyes closed, face/eyes open and lastly, made eye contact within the Control Group (n=9), as well as within the Experimental Group (n=17).

Table 4.11 Responses noticed under the sub-heading attention

Response	Control Group Predicted Mean (95% CI) (n=9)	Experimental Group Predicted Mean (95% CI) (n=17)	IRR	p-Value
Fuss	1.195 (0.559 ; 1.832)	0.648 (0.382 ; 0.914)	0.542	0.063
Yawn	0.554 (0.273 ; 0.834)	1.184 (0.771 ; 1.598)	2.137	0.013*
Sneeze	0.085 (0.013 ; 0.156)	0.139 (0.064 ; 0.214)	1.636	0.334
Frown	0.774 (0.129 ; 1.419)	1.667 (0.550 ; 2.783)	2.153	0.127
Eyes closed	7.101 (1.779 ; 12.423)	6.211 (2.516 ; 9.906)	0.874	0.755
Face/eyes open	2.11 (0.659 ; 3.561)	2.036 (0.974 ; 3.097)	0.964	0.928
Made eye contact	-	-	-	-
Looked at camera	1.439 (0 ; 3.301)	1.392 (0.020 ; 2.764)	0.967	0.958
Avert	0.030 (0 ; 0.734)	0.0312 (0 ; 0.064)	114	0.987

**p-value <0.05 = statistically significant*

The second column (Table 4.11), the Control group, presents the predicted means for each state in the control group, along with their 95% confidence intervals (CI). As reported by the observers, the response for eyes closed was the highest within this group, with a predicted mean of 7.101(CI: 1.779 ; 12.423). The observers reported the averted response the least, with a predicted mean of 0.030 for this group. The observers did not note any eye contact response from the Control group.

The third column (Table 4.11), Experimental group, presents the predicted means for each state in the experimental group, along with their 95% CI. As reported by the observers, the response for eyes closed was the highest response within this group, with a predicted mean of 6.211 (CI: 2.516 ; 9.906), and the observers reported avert response the least with a predicted mean of 0.0312 (CI: 0 ; 0.064) for the Experimental group. The observers did not note any eye contact response from this group.

For the observation of fuss (Table 4.11) as one of the behaviours mentioned under the heading attention (Table 4.11), the IRR 0f 0.542 indicates that the Experimental group shows about 54,2% higher fussing rate than the Control group. Meanwhile, the p-value of 0.063, marginally above the typical significance threshold, 0.05, suggests that while there is a trend towards significance, the results are inconclusive.

In the case of yawning (Table 4.11), the IRR of 2.137 indicates that the Experimental group had a significantly higher yawning rate than the Control group, more than double. The p-value of 0.013, below 0.05, indicates a statistically significant difference, suggesting that yawing was more prevalent in the Experimental group.

With an IRR of 1.636 for sneezing (Table 4.11), the Experimental group had a higher incidence of sneezing than the Control group, and the p-value of 0.334 indicates that this difference is not statistically significant. Looking at the frown behaviour, the IRR of 2.153 shows that the Experimental group frowned more than the Control group and that the p-value of 0.127 indicates that the difference is not statistically significant, though it is close. Once again, when considering the IRR of 0.874 (Table 4.11), the Experimental group had a slightly lower incidence of eyes closed compared to the Control group, which again suggests no statistically significant difference, as it has a p-value of 0.755. Another behaviour mentioned under attention is the face/eyes being open. Here, one can see that the IRR of 0.928 (Table 4.11) suggests no significant difference and that the p-value of 0.928 is also insignificant. Penultimately, the researcher discussed the incidence of looking at the camera and noted that the IRR of 0.928 indicates similarities between the groups, with the Experimental group having a slightly lower incidence, and again, the p-value of 0.958 suggests no significant difference. Lastly, the avert behaviour (Table 4.11) shows an IRR of 144, which indicates a very high rate of averting behaviour in the Experimental group compared to the Control group. The p-value of 0.987 is not statistically significant.

In conclusion, yawn is the only response that shows a statistically significant difference. The results indicated that the Experimental group showed a significantly increased yawning behaviour (Table 4.11). The fuss and frown responses are close to significance. For the reactions, such as sneezing, eyes closed, face/eyes open, looking at the camera and averting,

there is no evidence of a significant difference between the two groups. Therefore, this analysis shows varying effects of the experimental condition on different responses. The considerable increase in yawning suggests a potential impact of the intervention, whereas other behaviours did not show statistically significant differences. The researcher will provide a detailed discussion of the behaviour of yawing in Chapter 5.

4.6.6 Responses noticed under the sub-heading: Regulated motor movements

The responses noted in Table 4.12 relate to flexed arm/s, flexed leg/s, and grasping, which comprise regulated motor movements.

Table 4.12 Responses noticed under the sub-heading regulated motor movements

Response	Control Group Predicted Mean (95% CI) (n=9)	Experimental Group Predicted Mean (95% CI) (n=17)	IRR	p-Value
Flexed arm/s	7.652 (5.498 ; 9.806)	8.044 (6.389 ; 9.698)	1.051	0.775
Flexed leg/s	7.847 (95.622 ; 0.072)	8.126 (6.442 ; 9.809)	1.035	0.842
Grasping	1.139 (0.507 ; 1.772)	1.490 (0.875 ; 2.106)	1.307	0.421

The responses within the Control group show that the reaction for flexed leg/s was the highest, with a predicted mean of 7.847 (CI: 95.622 ; 0.072). The second-highest response was flexed arm/s, with a predicted mean of 7.652(CI: 5.498 ; 9.806). The grasping response was noted to be the least, with an expected mean of 1.139 (CI: 0.507 ; 1.772).

The responses within the Experimental group (Table 4.12) show that the reaction for flexed leg/s was the highest, with a predicted mean of 8.126 (CI: 6.442 ; 9.809). The second-highest response was flexed arm/s, with a predicted mean of 8.044 (CI: 6.389 ; 9.698). The observers noted that the grasping response was the least, with a predicted mean of 1.490 (CI: 0.875 ; 2.106).

Firstly, the IRR of flexed arms of 1.051 (Table 4.12) indicates that the Experimental group had a slightly higher incidence of flexed arms than the Control group. Specifically, the Experimental group exhibited about 5.1% more instances of flexed arm behaviour than the Control group. The p-value of 0.775 suggests that this difference is not statistically significant. Secondly, the experimental group (Table 4.12) had a slightly higher incidence of flexed legs than the control group, according to the IRR of 1.035. Like flexed arm movements, the p-value of 0.842 indicates that the difference between the two groups is not statistically significant. Thirdly, the grasping response (Table 4.12) has an IRR of 1.307, indicating that the Experimental group had a higher incidence of grasping behaviour than the Control group. Specifically, the experimental group's grasping behaviour is approximately 30.7% higher than the control group's.

In conclusion, no responses show statistically significant differences (Table 4.12). A p-value greater than 0.05 indicates that the study results are not statistically significant.

4.6.7 Responses noticed under the sub-heading: Unregulated motor movements

Table 4.13 displays the responses concerning flaccid arms, flaccid legs, extended arms, extended legs, neck arching, and back arching. Additionally, the researcher notes observations related to finger splaying, toe splaying, and unregulated motor movements of the hand, including the stop sign gesture and fisting.

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Table 4.13 Responses noticed under the sub-heading unregulated motor movements

Response	Control Group Predicted Mean (95% CI) (n=9)	Experimental Group Predicted Mean (95% CI) (n=17)	IRR	p-Value
Flaccid arm/s	-	-	-	-
Flaccid leg/s	0.085 (0 ; 0.183)	0.538 (0.004 ; 0.102)	0.628	0.511
Extended arm/s	1.181 (0.750 ; 1.612)	1.234 (0.907 ; 1.561)	1.044	0.847
Extended leg/s	1.847 (1.030 ;2.665)	1.635 (1.097 ; 2.174)	0.885	0.656
Arching neck	0.628 (0 ; 1.613)	0.156 (0 ; 0.337)	0.248	0.078
Arching back	0.096 (0 ; 0.216)	0.062 (0 ; 0.128)	0.642	0.574
Finger splaying	1.888 (1.078 ; 2.698)	2.485 (1.700 ; 3.269)	1.315	0.291
Toe splaying	1.876 (1.069 ; 2.150)	1.632 (1.114 ; 2.150)	0.870	0.599
Stop sign	0.298 (0.104 ; 0.493)	0.384 (0.201 ; 0.568)	1.288	0.524
Fisting	0.196 (0 ; 0.397)	0.311 (0.064 ; 0.557)	1.582	0.442

When attending to the Control group's data, the observers did not note Flaccid arms within these infants. Finger splaying (Table 4.13) was the most frequently observed behaviour in the Control group, with a predicted mean of 1.888 (CI: 1.078 ; 2.698). Toe splaying (Table 4.13) had a predicted mean of 1.876 (CI: 1.069 ; 2.150), which is very close to the mean for finger splaying of 1.888 (CI: 1.078 ; 2.698), indicating that toe splaying occurred at nearly the same rate as finger splaying. The unregulated response of flaccid legs had the lowest predicted mean at 0.085 (CI: 0 ; 0.183), suggesting it was observed least frequently among the unregulated motor movement responses. Extended arm/s (Table 4.13) had a predicted mean of 1.181 (CI: 0.750 ; 1.612), while extended legs had a predicted mean of 1.847.

In the Experimental group, finger splaying showed the most frequent with a mean of 2.485 (CI: 1.700 ; 3.269), followed by extended legs with a mean of 1.635 (CI: 1.097 ; 2.174) , and

closely followed by toe splaying with a mean of 1.632 (CI: 1.114 ; 2.150) (Table 4.13), while the observers noted flaccid legs as the least with a mean of 0.538 (CI: 0.004 ; 0.102). Fisting showed a minor incidence, while the difference between the stop sign and fisting, which the researcher regarded as not significant. Flaccid arms (Table 4.13) were not observed in the Experimental group, indicating no instances of this response by the observers. The highest mean was for finger splaying (Table 4.13), with a mean of 2.485 (CI: 1.700 ; 3.269), indicating the highest observed level of this response. The unregulated response, arching of the back, had the lowest predicted mean of 0.062 (CI: 0 ; 0.128), indicating the lowest observed level of this response. Extended arms showed a predicted mean of 1.234 (CI: 0.907 ; 1.561). The arching neck's predicted mean for the unregulated behaviour (Table 4.13) was 0.156 (CI: 0 ; 0.337). The predicted mean for toe splaying was 1.632. The unregulated response, the stop sign, showed a predicted mean of 0.384 (CI: 0.201 ; 0.568). Lastly, the unregulated response, fisting, shows a predicted mean of 0.311 (CI: 0.064 ; 0.557).

The highest mean was finger splaying (Table 4.13), with a mean of 2.485 (CI: 1.700 ; 3.269). The lowest mean was for arching of the back, with a mean of 0.062 (CI: 0 ; 0.128). Low to moderate responses for arching neck and fisting were noted by the observers, with fisting slightly more frequent than arching neck. Some responses (Table 4.13), such as flaccid leg/s and arching neck, had relatively wide confidence intervals, suggesting more significant variability or less precision in these estimates. Responses like finger splaying and toe splaying have narrower confidence intervals, indicating more precision in the mean estimates for these responses.

When comparing the two groups (Table 4.13), an IRR of 0.628 for flaccid leg/s indicates that the incidence rate in the Experimental group is 62.8% of the incidence rate in the Control group, meaning the Experimental group had a lower incidence rate for this outcome. An IRR of 1.315 for finger splaying indicates that the incidence rate in the Experimental group is 131.5% of the incidence rate in the Control group, meaning the Experimental group had a higher incidence rate for this outcome. The arching neck's p-value (Table 4.13) is 0.078, thus not a statistically significant difference. Arching of the neck was more common than arching of the back, but the difference between these two behaviours was slight and not considered

significant according to the p-values. Furthermore, the p-values in Table 4.13 are at least 0.05, suggesting that the observed differences in incidence rates between the Experimental and Control groups are not statistically significant.

In summary, the comparison between the two groups shows that the Experimental group had a lower incidence rate of flaccid leg/s and a higher rate of finger splaying. Although arching of the neck was more frequent than arching of the back, the difference was not statistically significant. The p-values suggest that none of the observed differences between the Experimental and Control groups reached statistical significance.

4.6.8 Response to pacifier noticed for Sensory integration - informed interventions WITH and WITHOUT Octo-Sense Technology

The researcher used the standard pacifier for the Control group and the Octo-Sense pacifier for the experimental group. Table 4.14 represents the observations recorded for the specific responses.

Table 4.14 Response to pacifier noted for Sensory integration - informed interventions WITH and WITHOUT Octo-Sense Technology

Response	Control Group Predicted Mean (95% CI) (n=9)	Experimental Group Predicted Mean (95% CI) (n=17)	IRR	p-Value
Holding pacifier in mouth	1.173 (0.384 ; 1.962)	1.067 (0.517 ; 1.616)	0.909	0.811
Actively sucking pacifier	3.955 (1.504 ; 6.405)	3.588 (1.881 ; 5.295)	0.91	0.784

In the Control group (Table 4.14), actively sucking on the standard pacifier had a mean of 3.955 (CA: 1.504 ; 6.405) and occurred more frequently than holding the pacifier in the mouth. Similarly, in the Experimental group, actively sucking on the pacifier of the Octo-Sense had a mean of 3.588 (CA: 1.881 ; 5.295)and also occurred more frequently than holding the pacifier in the mouth.

The IRR of 0.909 (Table 4.12) for holding a pacifier in the mouth indicates that the incidence rate in the Experimental group is 90.9% of that in the Control group. Similarly, an IRR of 0.91 for actively sucking pacifiers suggests that the incidence rate in the Experimental group is 91% of the rate observed in the Control group. Holding the pacifier in the mouth and actively sucking the pacifier is slightly lower in the Experimental group compared to the Control group. A p-value of 0.811 (Table 4.14) for holding the pacifier in mouth and 0.784 for actively sucking the pacifier indicates that the differences between the Control and Experimental groups are not statistically significant.

4.6.9 General comments for the Control group

According to page three of the Observational checklist during Sensory integration - informed intervention WITHOUT Octo-Sense Technology and the Observational checklist during Sensory integration - informed intervention WITH Octo-Sense Technology (Addendum S) (Addendum S), there is a section where the observers were to write specific comments not mentioned earlier on the checklists. Allowing observers to provide open-ended feedback enables the researcher to gain deeper insights into the observations. The researcher categorised these comments into themes and quantified them to provide numerical values. The first section will present the general comments for the control group.

Table 4.15 Comments for the Control Group

Number	Description	Total Observer A	Total Observer B
1	No comment	12	15
2	Noise within the NICU	11	1
3	Sharp lights in the NICU	0	1
4	Regulated extended limbs	6	14
5	Regulated arm extension	5	4
6	Regulated extension of legs	12	3
7	Grasping in air/tubes	1	0
8	Mouthing NGT/OGT	0	1
9	Hands in the midline – grasping each other	1	1
10	Regulated asymmetrical flexion of legs	0	1
11	Jerky movements	0	1

As seen in Table 4.15, Observer A frequently observed regulated leg extension 12 times and regulated extended limbs (6 times). On the other hand, Observer B reported more instances of regulated extended limbs (14 times). At the same time, both observers recorded only one example of behaviours like grasping in the midline, mouthing NGT/OGT, and jerky movements. Observer A (11 instances) noted noise within the NICU more frequently than Observer B (Once).

4.6.10 General comments for the Experimental group

The researcher acknowledges the value of open-ended questions, which allow the observers to provide open-ended feedback, enabling the researcher to gain deeper insights into the observations; therefore, this section is for general comments for the experimental group.

Table 4.16 General Comments for the Experimental group

Number	Description	Observer A	Observer B
1	Noise	26	0
2	Regulated extended limbs	23	18
3	Regulated arm extension	4	4
4	Regulated extension of legs	17	6
5	Grasping in air/tubes	0	1
6	Mouth movements/Mouthing	0	1
7	Drowsy eyes	1	0
8	Regulated finger splaying	0	1
9	Mouthing NGT/OGT	0	2
10	Hands in the midline – grasping each other	1	0

Observer A reported a significant occurrence of noise, documenting it 26 times. The regulated movements, especially extended limbs, were frequently observed. Observer A (Table 4.16) reported this movement 23 times, and Observer B noted this movement 18 times. This movement is a typical behaviour in the experimental group. These observations highlight that noise and regulated limb movements were notable factors observed during the interventions with the Octo-Sense technology.

4.6.11 Comments regarding the standard pacifier for the Control group

The researcher used the standard pacifier for infants in the control group. The two observers commented on the pacifier use, as presented in Table 4.17.

Table 4.17 Comments regarding the standard pacifier use with the Control group

No.	Description	Observer A	Observer B
1	Pacifier not used	10	10
2	Holding pacifier in mouth	1	4
3	Took pacifier from the mouth, stopped using	0	1
4	Baby swaddled with a blanket	1	0
5	Holding on/resting hands on the pacifier	0	1

Both observers said the researcher did not use the standard pacifier in 10 out of the 38 videos. Holding the pacifier in the infant's mouth (Table 4.17) occurred four times, according to Observer B, and once, according to Observer A. Observer B noted that using the pacifier was stopped during one of the videos. In contrast, Observer A did not note that the researcher stopped using the pacifier. Observer A mentioned that an infant was swaddled once out of the 38 videos, and lastly, Observer B saw an infant that rested his hands or held onto the standard pacifier.

4.6.12 Comments regarding the Octo-sense for the Experimental group

The researcher used the pacifiers on the Octo-Sense in the Sensory integration-informed interventions where the experimental group was concerned. The observers noted the following comments:

Table 4.18 Comments regarding the Octo-Sense for the Experimental Group

No.	Comment	Total Observer A	Total Observer B
1	Octo-Sense's pacifier was not used during the session	20	20
2	Deep pressure over the body with Octo-Sense	29	17
3	Touch system	2	4
4	Grasping	3	2
5	Holding onto pacifier	5	5
6	Sucking	0	1
7	One hand holding onto Octo-Sense	3	3
8	Octo-Sense head supports positioning	13	0
9	Tentacles positioned over the body to obtain deep pressure	16	3
10	Tentacles over lower limbs to obtain deep pressure	1	3
11	Octo-Sense used from the first minute	0	1
12	Octo-Sense's head supports the pacifier	2	0
13	Holding onto the head of the Octo-Sense	1	0
14	Resting a hand on the tentacles and the pacifier	2	9
16	Swaddled baby with Octo-Sense to maintain deep pressure	2	12
17	Both hands are holding onto the Octo-Sense	4	2
18	Both hands holding onto the pacifier of Octo-Sense	5	9
19	Head of the Octo-Sense holding pacifier in place	5	0

According to both observers (Table 4.18), the researcher did not use the Octo-Sense's pacifier in 20 of the 73 videos. Observer A (Table 4.18) noted 29 times out of 73 videos that the researcher used her hands or the Octo-Sense to apply deep pressure. Observer A stated that the researcher applied deep pressure on the infants using the Octo-Sense tentacles in 16 out of 73 videos. Observer B (Table 4.18) mentioned that the researcher applied deep pressure on the infants using the Octo-Sense's tentacles 17 times out of 73 videos. In contrast, 12 out of 73 videos showed that the researcher swaddled the infant with a blanket to keep the Octo-Sense in place.

The researcher will now discuss the fourth objective, which is to name the affordances of the Octo-Sense.

4.7 THE AFFORDANCES OF THE OCTO-SENSE ASSISTIVE TECHNOLOGY SEEN WHILE THE INFANT ENGAGES WITH THE OCTO-SENSE DURING THE SENSORY-INTEGRATION-INFORMED INTERVENTION SESSIONS

In the following section, the researcher will review the different affordances of the Octo-Sense, as noted by the observers. Table 4.19 reflects whether the observers gave a yes or no answer to three different affordances. Table 4.20 indicates whether the infants were holding onto the tentacles of the Octo-Sense with one or both hands. Lastly, Table 4.21 is a condensed version of the observers' comments regarding specific affordances not mentioned in the checklist. The summary would conclude Chapter 4.

4.7.1 Specific affordances of the Octo-sense

On the Observational checklist during Sensory integration - informed intervention WITHOUT Octo-Sense Technology and the Observational checklist during Sensory integration - informed intervention WITH Octo-Sense Technology (Addendum S), the two observers had to indicate whether the Octo-Sense had the affordances of touch-able, hold-able, and grab-able. The researcher recorded and discussed these observations in Table 4.19.

Table 4.19 Specific affordances of the Octo-Sense

Affordance	Observer A (n = 73 videos)	Observer B (n = 73 videos)	Total
Touch-able	53	53	106
Hold-able	38	39	77
Grab-able	30	31	61
TOTAL	121	123	244

The observations from Table 4.19 reveal the specific affordances of the Octo-Sense, as noted by the two observers across 73 videos. Observer A noted 121 specific affordances out of 73 videos, while Observer B noted 123 specific affordances out of 73 videos. Furthermore, the affordance mainly demonstrated in the videos was "touch-able."

4.7.2 Holding on to the tentacle/s of the Octo-Sense

The observers reported that preterm infants in the Experimental group held the Octo-Sense's tentacle(s) with one or both hands. Table 4.20 presents the total observations for each activity related to having the Octo-Sense tentacles with one or both hands.

Table 4.20 Tentacles/s of Octo-Sense held by infants

Total Observations	
Holding onto tentacle/s with one hand	29
Holding onto tentacle/s with both hands	4

As mentioned above, these observations showed that instead of grabbing different tubes, these infants could grab and hold onto the Octo-Sense's tentacles with one or both hands.

4.7.3 Specific comments regarding the Octo-Sense

The *Observational checklist during Sensory integration-informed intervention WITHOUT Octo-Sense Technology and the Observational checklist during Sensory integration-informed intervention WITH Octo-Sense Technology* (Addendum S) required the observers to write comments at the end of the questionnaire. The observers commented on the Octo-Sense when they saw added affordances of the Octo-Sense not mentioned in the checklist. The researcher allocated a specific number of similar comments. The researcher grouped this information in Table 4.21. The information in this table is in descending order.

Table 4.21 The combination of comments regarding the Octo-Sense for the experimental group

No.	Comments by Observers	Number of Observations	TOTAL
1	Deep pressure over the body with Octo-Sense	46	83
2	Tentacles positioned over the body to obtain deep pressure	19	
3	Swaddled baby with Octo-Sense to maintain deep pressure	14	
4	Tentacles over lower limbs to obtain deep pressure	4	
5	Both hands holding onto the pacifier of Octo-Sense	14	47
6	Resting a hand on the tentacles and the pacifier	11	
7	Holding onto pacifier	10	
8	One hand holding onto the Octo-Sense	6	
9	Both hands are holding onto the Octo-Sense	6	
10	Octo-Sense head supports positioning	13	20
11	Head of the Octo-Sense holding pacifier in place	5	
12	Octo-Sense's head supports the pacifier	2	
13	Touch system – Skin	6	6
14	Grasping	5	5
15	Octo-Sense used from the first minute	1	1
16	Infant holding onto the head of the Octo-Sense	1	1
17	Sucking on another part of the Octo-Sense	1	1

As mentioned, Table 4.21 contains more specific information regarding both observers' comments on the Octo-Sense used with the experimental group. The comments in bright green, 1, 2, 3 and 4, relate to different ways of applying deep pressure during SI intervention with the Octo-Sense. Then, as seen in comments 5, 6, 7, 8 and 9, one or both hands went into midline. The infants held onto the pacifier in the mouth or the Octo-Sense tentacles, indicating that the infants' hand/s went into the midline. Comments 10, 11 and 12 explain how the researcher used the head of the Octo-Sense during the Sensory integration-informed intervention. The observers mentioned the touch system six times in comment 13. In the same way, the observers noted that grasping occurred six times.

Furthermore (Table 4.21), as seen in Comment 15, the researcher used the Octo-Sense from the first minute of the 10-minute recording. Then again, as seen in Comment 16, the infant grabbed or got hold of the head of the Octo-Sense. Lastly, an Observer noticed that the infant started to suck on the Octo-Sense, but did not specify which part.

As shown in Table 4.21, the researcher concluded that deep pressure showed the highest incidence rate. Although grasping, holding and sucking were observed earlier on in the *Observational checklist during Sensory integration - informed intervention WITHOUT Octo-Sense Technology and the Observational checklist during Sensory integration - informed intervention WITH Octo-Sense Technology during Sensory integration - informed intervention WITH Octo-Sense Technology* (Addendum S) the observers mentioned it again. The observers noted only one instance where the researcher used the Octo-sense technology from the start of the SI intervention session.

4.8 SUMMARY

The study aimed to describe and compare the self-regulation responses of infants in the Neonatal Intensive Care Unit during a sensory integration-informed intervention, with or without the support of assistive technology. This chapter presented the results of this study according to the information derived from the two Observational checklists during Sensory integration - informed intervention WITHOUT Octo-Sense Technology and the Observational checklist during Sensory integration - informed intervention WITH Octo-Sense Technology (Addendum S).

The researcher collected data to describe the self-regulatory responses of infants in the NICU regarding self-regulatory behaviour and autonomic responses while receiving sensory integration-informed sessions, thus the control group. The researcher established that self-regulatory responses occurred during the sensory integration-informed session, where the control group was concerned. As a result, the researcher answered the first objective.

To answer the second objective, the researcher collected data to describe the self-regulatory responses of infants in the NICU regarding self-regulatory behaviour and autonomic responses while receiving sensory integration-informed sessions supported by Octo-Sense technology, thus the experimental group. The researcher found that the experimental group also showed self-regulatory responses during the sensory integrated-informed sessions.

The third objective of the study was to compare the self-regulation responses of the infants in the control group while receiving the standard form of care supported by the standard

pacifier with the self-regulation responses of the infants in the experimental group, assisted by the Octo-Sense technology. The researcher found similarities and differences between the two groups after comparing the self-regulation responses of the infants. Most of the differences in incidence rates between the Control and Experimental groups are not statistically significant at the typical p-value of 0.05. The differences observed in the incidence rates could have occurred by chance and are not statistically significant.

Hence, the observers mentioned different affordances that answered the fourth objective, which was to describe the affordances of the Octo-Sense as assistive technology during sensory-integration-informed intervention sessions. The researcher concluded that the Octo-Sense technology had affordances that could aid preterm infants in the NICU.

In conclusion, despite the limited statistically significant differences between the two groups, using the Octo-Sense demonstrated potential benefits that may support the therapeutic value of Sensory integration-informed interventions in the NICU. The researcher envisions the probability of the Octo-Sense introduced to preterm infants as a pacifier and assistive technology with additional functionality. In Chapter 5, the researcher will interpret the results obtained. Thereafter, the researcher will analyse, discuss, and triangulate the results with the literature.

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CHAPTER 5: DISCUSSION OF RESULTS

5.1 INTRODUCTION

In Chapter 4, the researcher presented the study results through graphs, tables and descriptions. In Chapter 5, the researcher presented results that were interpreted, discussed, and triangulated with relevant literature for scientific purposes.

5.2 INTERPRETATION OF RESULTS

The researcher will discuss the study in alignment with the study objectives. Firstly, the researcher will interpret the study results according to the anthropometric data of the study population, aiming to identify the similarities and differences between the Experimental and Control groups concerning gestational age, corrected age, gender, video recordings, behavioural responses, and autonomic responses. Following that, the researcher will discuss the results obtained from the Observational checklist during Sensory integration-informed intervention WITHOUT Octo-Sense Technology and the Observational checklist during Sensory integration - informed intervention WITH Octo-Sense Technology (Addendum S) regarding the affordances of the Octo-Sense as an assistive device.

5.2.1 Anthropometric profile

Casadei and Kriel (2022) stipulate that anthropometric analysis is essential for understanding potential biases or imbalances affecting a study's outcome. Accordingly, a researcher working in paediatrics uses an anthropometric analysis. It also highlights the importance of randomisation in preterm infant allocation to minimise systematic differences between groups (Casadei & Kriel, 2022). The anthropometric profile of the study population included the infant's gestational age. It corrected age, gender, birth weight and weight when included in the study, whether the infant was on prolonged NPO, whether the specific infant had a PDA, and whether the infant was on prolonged mechanical ventilation/prolonged non-invasive positive pressure ventilation or room air. The researcher used the *Checklist for possible inclusion* (Addendum P) to acquire this information. The preterm infants included in

the study had birth weights' ranging between 683 g and 3 044 g, length varied between 42 cm and 46 cm, and head circumference ranged between 29.5 cm and 32 cm. The Mayo Clinic Staff (2024) compiled tables that showed the median birth weight, length and head circumference of premature infants at different gestational ages for males and females, similar to what the researcher noted. Subsequently, the body structure of the infants in the study correlates with infants reported in other studies. The features include the fact that preterm infants might be small, with a head more prominent than the body. Preterm infants' features are sharper and less rounded than full-term infants' due to lacking cells that store fat (Bergman 2010). As Lubbe (2020) mentioned, although fine hair covers much of the body, they struggle to regulate body temperature, which relates to low body temperature, causing weight loss. Bergman (2010) further mentions that apart from looking distinctly different from a 40-week or full-term infant, which weighs approximately 3 400 g, has a length of 51 cm and a head circumference of 35 cm (Mayo Clinic Staff 2024), preterm infants' brain, lungs and other internal organs are underdeveloped. De Almeida et al. (2020) mention that preterm birth disrupts the typical topological network organisation of the brain. Furthermore, Shandley et al. (2021) explain that the full-term neonate is born with the ability to suck successfully because the brain's neural network is already formed and functional. In contrast, the preterm infant's neural network might have been damaged before, during, or after birth. Bogdan et al. (2022) found that premature infants are prone to long-term respiratory consequences due to the development of the lung outside of the uterus, leading to dysmaturation of the structures, pulmonary pathology due to immaturity, infectious agents or mechanical ventilation and deficient control of breathing. In the same way, the preterm infant's muscle tone is affected, usually leading to low muscle tone, which adds to the difficulty in breathing (Metha et al., 2022). The Working Group of the National Institute of Child Health and Human Development (2024) indicated that Necrotizing Enterocolitis (NEC) is a common, severe gastrointestinal illness mainly affecting preterm infants in which the tissue lining of the intestine becomes inflamed and dies. More than 90 % of NEC occurs in very low birth weight preterm infants (VLBW), which is less than 1 500 g. It is one of the leading causes of illness and death among preterm infants, and 15 - 40 % of infants with NEC die from the disease. In the same way, Qian et al. (2024) reflected in their study of the ordinary condition

among preterm infants, namely Patent ductus arteriosus (PDA). They mentioned the following: the left-to-right shunting of a PDA in premature infants leads to high pulmonary blood flow and systemic hypoperfusion. It is associated with mortality and morbidities such as NEC, intraventricular haemorrhage and bronchopulmonary dysplasia (Qian et al. 2024).

Subsequently, the researcher needed an anthropometric analysis profile of the study population. The researcher's literature review showed that not only does preterm birth disrupt the typical topological network organisation of the brain, but it also influences all bodily systems and the development of internal organs and external features. As a result of this knowledge, the researcher compiled the *Checklist for possible inclusion* (Addendum P) to assist the researcher in not including a preterm infant who was not fit for the study. Therefore, the researcher noted medical conditions that might have occurred before, during, or after birth while in the NICU. As mentioned above, the researcher held high esteem for the anthropometric analysis profile during the study.

5.2.1.1 Gender

The two groups in this study differed in the total number of males and females: The Control group had five males, and the Experimental group had 11 males. The Control group had four females, and the Experimental group had six females. The total number of infants included in the Control group (9) and Experimental group (17) were not equal, as seen in Table 4.1. A p-value of 0.700 did not indicate a significant statistical difference between the genders of the two groups due to the small sample size. Unfortunately, the small sample size often resulted in lower statistical power, making it harder to detect an actual effect or difference when one exists. Smaller samples are more susceptible to random variation, thus leading to results that are not representative of the population and potentially skewing findings (Van de Schoot & Miočević 2020).

Boatella-Costa et al. (2007) highlight notable gender differences in neonatal behaviour. Their review of the literature cites Korner's (1973) findings that boys respond more intensely to visual reinforcement, whereas girls exhibit a more remarkable aptitude for learning from auditory stimuli. Korner (1973) also observed that boys showed more interest in geometric shapes, while girls preferred human faces. Additionally, boys cried more frequently than girls,

while girls were more sensitive to tactile stimulation and taste and could maintain alertness for extended periods.

Building on these findings, Lundqvist and Sabel (2000) conducted a study in Sweden comparing the behaviour of 38 healthy full-term newborns (20 boys and 18 girls) using the NBAS-3rd Edition. Their results indicated that girls outperformed boys on four of the seven items in the social interaction cluster and exhibited more excellent proficiency in self-quieting tasks. These findings suggest that girls demonstrated higher overall functioning levels than boys, leading to significant gender-based differences in neonatal behaviour.

In a subsequent study, Lundqvist (2001) assessed the self-regulation capacities of 38 newborns (18 boys and 20 girls). The findings revealed that girls possessed more potent self-regulation abilities than boys. Lundqvist further concluded that these early differences in self-regulation could have long-term implications for developmental trajectories, emphasizing the influence of neonatal gender differences on later development.

In general, people assume that there are differences between preterm male infants and preterm female infants. The researcher was hopeful in showing whether this assumption was true or false. Literature mentions different studies that were able to prove that there were differences as far as gender was concerned. Unfortunately, due to the small sample size and no statistically significant differences between the genders of the two groups, the researcher had no proof to indicate if this generalisation was true or false.

5.2.1.2 Gestational ages

After establishing an infant's primary diagnosis and gender, the researcher calculated the corrected age by adding the number of days spent in the NICU to the gestational age. Therefore, if an infant was born at 30 weeks and has spent 21 days in the NICU, the infant's corrected age would be 33 weeks. The study included infants with the corrected age of 32 weeks, six days up to 36 weeks and six days. The infant could potentially be part of the study with a corrected age of 33 weeks and if medically stable.

5.2.1.3 Corrected ages

Since the researcher used the premature infant's corrected age in assessing developmental status (Figure 4.3), it was essential to include the preterm infants' gestational ages in the inclusion criteria for this study. Figure 4.2 shows that the mean corrected age of the infants in the Control group was not like that of the infants in the Experimental group; therefore, the two groups were not comparable regarding their Corrected age.

5.2.1.4 Corrected age versus gestational age

The researcher included infants in the study (3.5.1) using the screening tool (3.5.1). Figure 4.1 shows all the preterm infants' corrected ages on the day they were included. The researcher included most infants in the study at 32 weeks corrected age and 35 weeks corrected age. Figure 4.1 illustrates that the researcher included only one infant at 33 weeks corrected age. On the other hand, Figure 4.2 indicates that the researcher included more infants in the Experimental group (n =17) than in the Control group (n =9), according to their corrected age, using the randomised list (Addendum R).

According to the literature, the main factor that increases multiple pregnancies is the use of infertility treatment. The Mayo Clinic Staff (2023) reports that approximately 30% of pregnancies resulting from fertility drugs are multiples. While most of these pregnancies are twins, up to 5% are triplets or more remarkable due to the release of more eggs than expected. As shown by Pokulniewicz et al. (2015), females who are reverting to infertility treatment are older and have multiple pregnancies. The age of the mother increases the risk of preterm birth. Preeclampsia, also known as toxaemia, leads to preterm labour and poses the most significant risk to multiple pregnancies (Begum, 2023). Sixty percent of multiples are born prematurely (<37 weeks) compared to about 10% of singleton pregnancies (Mayo Clinic Staff, 2023). Caesarean section is often needed for twin pregnancies and is inevitable in delivering triplets. Adding to the complications, as mentioned in the study by Luke et al. (2006), twins' development differs from that of triplets. Triplets had significantly shorter lengths, smaller head circumferences, and lighter weights at birth. Generally, they remained smaller in each growth parameter through 18 months. Typically, triplets scored lower on the developmental tests, with significant differences, particularly in mental development at 18 months (Luke et al. 2006).

The researcher counted two sets of twins: Twin I and Twin 2 were male, and one set of twins was female. Then, there were two sets of twins, one twin male and the other female. Interestingly, in the Experimental group, triplets were born at 31 weeks and six days gestational age. These triplets consisted of two males and one female. In the pilot study, the researcher included Triplet 3, female, at the corrected age of 32 weeks, two days. In the same way, the researcher could include Triplet 1 and 2, males, at the corrected age of 35 weeks and six days after the completion of the pilot study. In the scenario mentioned, Triplet 3's progress was not the same as that of her male siblings. The female twin, Twin 3, could have been discharged home earlier, but their mother still was hospitalised. The triplets were all discharged at the corrected age of 42 weeks and 6 days. Likewise, another three infants (singletons) were born at the gestational age of 29 weeks. The researcher included the first of these three infants in the Experimental group, a male at the corrected age of 32 weeks and six days. The second infant, a male, born at the gestational age of 29 weeks, was included at the corrected age of 35 weeks and six days. The third infant, a male, born at the gestational age of 29 weeks, was included at the corrected age of 36 weeks and six days. It was compelling for the researcher to see that the first preterm infant included in the study was 35 weeks and six days, as his infant was in the NICU for 11 weeks before being declared medically stable to be included in the study. What was also intriguing to the researcher was the twins born at the gestational age of 26 weeks. Using the randomised list, the researcher included Twin One in the Experimental group and Twin Two in the Control group at the corrected age of 32 weeks and four days. The researcher observed that the twins' development was almost identical during the study period. In the same way, Neurodevelopmental outcomes in preterm twins may relate more strongly to environmental factors than genetics. Discordant twins were born earlier and had more perinatal morbidities. Despite the initial discordance, these twin pairs have similar outcomes over time, which may reflect the positive impact of the home environment or early intervention programs.

Figure 4.2, based on the researcher's findings, the corrected age of the Control group and the corrected age of the preterm infants in the Experimental group at the time of inclusion in the study were compared (3.5.1). In the same way, as seen in Figure 4.3, the researcher compared the corrected age and gender of the preterm infants when included in the study.

Unfortunately, this study includes only one set of triplets and five sets of twins. Therefore, as mentioned earlier, the researcher could not confirm or contradict the literature regarding the development of triplets and twins. The researcher concluded that every infant in the NICU develops independently. When assessing developmental milestones, multi-disciplinary team members should consider the gestational and corrected ages. Knowing these two age categories makes comparing a preterm infant to a full-term infant feasible.

5.2.2 The number of videos taken for the Control- and Experimental group

Table 4.3 indicates that the researcher took 38 videos for the Control group (n = 9), and Table 4.4 suggests that the researcher took 73 videos for the Experimental group (n =17). The total number of videos taken by the researcher was 111. Tables 4.3 and 4.4 show that the researcher could only record Video 1 for all the preterm infants. Due to the discharge of the preterm infants, the researcher could not take five videos for all preterm infants. The researcher did not compare different videos with each other, as that was not one of the study's objectives (1.3.2).

It would have been ideal if the Control group had the same number of preterm infants as the Experimental group and if the researcher could have recorded five videos for each preterm infant. If the study had more preterm infants, it would have allowed for more comprehensive comparisons and potentially revealed statistically significant differences between the two groups.

The researcher structured the following discussion according to the Observational checklist during Sensory integration - informed intervention WITHOUT Octo-Sense Technology and the Observational checklist during Sensory integration - informed intervention WITH Octo-Sense Technology (Addendum S), ensuring a systematic approach to addressing the research objectives.

5.2.3 Behavioural states

The following discussion explains the development of behavioural states, which were the first part of the Observational checklist during Sensory integration - informed intervention WITHOUT Octo-Sense Technology and the Observational checklist during Sensory integration - informed intervention WITH Octo-Sense Technology (Addendum S). As identified in studies by Als (1982,1986), state development involves increasing quiet sleep, decreasing active sleep, and smooth and fewer transitions. Edery (2020) described circadian rhythms as endogenous biological rhythms within organisms that oscillate in the absence of environmental time cues entrain to environmental signals and remain stable in environments with fluctuating temperatures. The circadian rhythms of the preterm infant influence behavioural states. As the infants in the study were born preterm, the possibility exists that their circadian rhythm is not fully functional. Mirmiran et al. 1992, concluded that although human circadian rhythms are present as early as 29 weeks of gestation, maternal circadian rhythms generated by the mother's suprachiasmatic nucleus are essential for the optimal functioning of the endogenous foetal biological clock. Complementary to this, as was explained by Wong et al. 2021, the significance of environmental cues for entrainment is also vital as a longer duration of exposure to the cyclic environment, including light-dark cycle and periodic maternal care, leads to earlier entrainment in foetuses as young as 35 weeks gestational age. Preterm infants included in this study were born before the gestational age of 35 weeks. Furthermore, Wong et al. 2021, described that while in utero, the foetus relies on time-of-day signals from maternal circadian cues (e.g., melatonin, cortisol, temperature), which serve as entertainers to the foetal circadian system and peripheral clocks. This study showed that the circadian rhythm is present in premature infants soon after birth, although with low amplitude and reversed phase. As seen in the paragraphs mentioned above, the circadian system of the infant needs the assistance of the maternal circadian cues to develop fully. Hence, preterm infants in the NICU circadian rhythm develops without the maternal circadian cues. According to Takatsuru and Miyagawa's study (2023), ELS causes poor brain development and, more specifically, greater exposure to neonatal stress correlated with dampening the autonomic nervous systems' reactivity (Takatsuru & Miyagawa, 2023).

Adding to the previous discussions is cluster care, which, according to Avazeh and Babaei (2023), means clustering or grouping several nursing care procedures performed together instead of spacing them out over time. The main goal of clustering care is to allow premature infants to rest longer and avoid handling and disturbing their sleep patterns. Ideally, infants would sleep for two hours and 45 minutes until the subsequent cluster care procedures (Lubbe 2019). Tasks such as checking vital signs, nappy changes, medication administration, and changing the infant's position are all completed simultaneously rather than individually and at different times. Visiting parents are encouraged to speak to and touch the infant, but the sleep would be interrupted if the infant is in a quiet, deep sleep.

Achieving stable sleep-wake patterns and transitions between states is a primary developmental task in preterm infants in the NICU. Unfortunately, environmental elements such as ELS, parents visiting, and cluster care influence these behavioural patterns. During data collection, the environmental factors were the same for infants in the Control and Experimental groups. The researcher attempted to take the videos at the end of the cluster care period. At the end of cluster care, the infant could be in any of the five behavioural states, and the recording of the intervention session could start in any of the following behavioural states: crying, active, awake, quiet awake, drowsy active sleep, and quiet deep sleep.

The researcher will first discuss the behavioural states and the autonomic responses in the following paragraphs.

5.2.3.1 Crying as Behavioural State

Crying in preterm infants can signal an extreme behavioural state that may adversely affect their functioning. Lubbe (2020) mentions that the infant's reaction to overstimulation could be crying. While in the crying behavioural state, the infant's body secretes the hormone cortisol, which leads to a fight or flight reaction (Heckman et al. 1999). As the infant cannot escape from this situation, the infant would either start crying or go into a flaccid posture. Both actions would accelerate the heartbeat and oxygenation, resulting in weight loss (Cho et al.,2020). The blood oxygenation level in preterm infants is affected by stress caused by

the effort required during crying (Orlandi et al., 2012). According to the studies of Orlandi et al. (2012), preterm infants and infants with neurological conditions have different cry characteristics compared with healthy full-term infants. In Table 4.7, crying showed a predicted mean of 0.95 for the Control group, and the Experimental group had a predicted mean of 0.437, with a p-value of 0.090, suggesting that the Experimental group exhibited a higher frequency of crying during the 10-minute video sessions than the Control group. This observation may imply that the Experimental group experienced more significant stress levels during the intervention than the Control group.

5.2.3.2 Active awake behavioural state

According to The Royal Children's Hospital, Melbourne (2024), a preterm infant would appear more active and may fuss while in the active, awake behavioural state. The infant will also show more movements, irregular breathing, eyes that may be open but not focused, and sensitivity to surroundings. The researcher noticed that the active, awake behavioural state in the Control- and Experimental groups proved to be almost identical, with a p-value of 0.090, a predicted mean of 0.213 for the Control group and a predicted mean of 0.212 for the Experimental group. The researcher used the standard pacifier for infants in the Control group and the pacifier attached to the Octo-Sense for the Experimental group, as the pacifier might assist in moving into the quiet awake or drowsy behavioural state.

5.2.3.3 Quiet awake behavioural state

The quiet awake state, also known as the "open face" stage, is where the infant shows little body movement, eyes wide open, regular and steady breathing, is very responsive, and might start interacting. This stage is ideal for the infant to start breast/bottle feeding due to alertness. However, according to Lubbe (2019), this stage requires energy and, therefore, might be exhausting for the preterm infant. In the same way, this behavioural state of a specific preterm infant might not be in the cluster-care period and would disrupt the circadian rhythm. The researcher introduced the different pacifiers to both groups to encourage NNS, as NNS improves and prepares preterm infants for nutritive sucking. Pindea et al. (2019) state that NNS uses less energy since preterms only need to suck and breathe, not requiring

the suck-swallow-breath synchronicity described in the MORE model by Oeter, Richter, and Fick (1993). NNS would then have the advantage of calming the infant down, which might lead to a drowsy behavioural state (Pindea et al. 2019). If the infant has an NGT or OGT in sito, the Experimental group could quickly suck the pacifier of the Octo-Sense due to the necessary indent at the top of the pacifier's shield. It was more difficult for the Control group to suck on the standard pacifier if an NGT of OGT or non-invasive oxygen apparatus was in use. The Control group showed a predicted mean of 1.705, and the Experimental group showed a predicted mean of 1.903, with a p-value of 0.764, indicating the Experimental group was more responsive and interactive during this period than the Control group.

Therefore, the researcher concluded that the Experimental group was more able to perform NNS with an OGT or NGT inserted due to the Octo-Sense's indent. With NNS, the infant could self-regulate and, therefore, be more alert and able to interact.

5.2.3.4 Drowsy behavioural state

The researcher presented the standard pacifier used in the NICU to infants in the Control group during Sensory integration-informed intervention. If infants in the Control showed the grasping reflex, the researcher would put one of her fingers into the infant's hand. After the SI intervention, the researcher removed her finger from the infant's closed hand. If the infant was in a quiet, deep sleep state, the probability of staying in that behavioural state was high. However, if the infant is still drowsy, the infant might move into an active, awake, or crying behavioural state. The researcher could not keep her finger in the infant's hand indefinitely. On the other hand, if the researcher saw the grasping reflex within the Experimental group, the researcher could place a tentacle of the Octo-sense in one or both hands, as it has eight tentacles. In the same way, if the infant in the Experimental group showed signs of wanting to suck, she would give one of the pacifiers attached to the Octo-Sense. The infant's weight would indicate which size pacifier to give.

When infants perform the hand-to-face action, the hands would be around the mouth. Indicating the midline position, as suggested by Miyagishima et al. 2016, the infant managed to defy gravity and is more able to self-soothe while sucking the pacifier. Furthermore,

Shandley et al. 202 encourage using a pacifier to achieve NNS. Finn and Barlow (1996) described how NNS would activate the central pattern generator (Figure 2.6) for the limbic system to come into play, leading to self-regulation. Therefore, if an infant is in a drowsy behavioural state and receives SI intervention with the assistance of a pacifier, the possibility of moving from a drowsy behaviour state to active sleep and then quiet, deep sleep is more attainable.

The researcher viewed the drowsy behavioural state as an opportunity for intervention. The researcher will respond to the signals listed in Table 4.9, which include tongue extension, hand-to-face gestures, mouthing, and suck searching. These signals are an indication that the infant might have the urge to suck while being in a drowsy state. Therefore, the researcher will present the pacifier indicated for the specific infant. While performing NNS, the infant can self-regulate and move from the drowsy behavioural state to active sleep and quiet deep sleep. Then, Table 4.10 mentions the hands/fingers' responses to the mouth. After that, Table 4.12 shows flexed arms/legs and grasping as cues for establishing self-regulation. More importantly, these responses indicate positive signals to introduce the pacifier to infants in both groups when in a drowsy state, leading to self-regulation and a quiet, deep sleep state. The researcher also reacted the same way as previously mentioned when signs of discomfort, such as autonomic responses in Table 4.8, stress signs in Table 4.11, and unregulated motor movements recorded in Table 4.13, were observed.

Table 4.7 showed a predicted mean of 0.923 for the Control group, and the Experimental group had a predicted mean of 1.937 and a p-value of 0.087, indicating that the drowsy behavioural state had a marginal difference between the two groups. In Table 4.9, the Experimental group showed a higher hand-to-face incidence, with a predicted mean of 6.502, than the Control group, with a predicted mean of 6.471. During the SI intervention, the Experimental group seemed drowsier than the Control group. The higher incidence of hand-to-face interaction within the Experimental group might have led to the Experimental group being drowsier.

5.2.3.5 Active sleep

Infants typically spend more time in active than deep sleep in the first few months of life (The Royal Children's Hospital, Melbourne 2024). Active sleep, or rapid eye movement (REM) sleep, is the sleep state where one can see rapid eye movements under the eyelid, the infant's breathing is more irregular and faster, and the body shows more activity and facial movements. Premature infants' early sleep organization influences their subsequent developmental outcomes. A study by Arditi-Babchuk (2008) investigated the association between rapid eye movement (REM) activity in premature neonates and developmental outcomes at six months of corrected age. These researchers used the Mental Development Index (MDI) from the Bayley Scales of Infant Development II to determine developmental improvement.

The study found that infants with low REM activity during the neonatal period spent more time in less growth-promoting states, such as crying and unfocused alertness. At six months of corrected age, these infants demonstrated lower MDI scores than those with higher REM activity. Notably, the researchers observed that differences between high-REM and low-REM groups were independent of neonatal medical risk factors.

The findings suggest that low REM activity in premature neonates may serve as a potential early marker for developmental risk, highlighting the importance of monitoring sleep organization in this vulnerable population.

According to The Royal Children's Hospital, Melbourne (2024), the infant is easily startled and awakened. This article mentions not waking the infant in active sleep unless necessary, as neuronal connections and memories form during this phase. Furthermore, according to the study by Foreman et al. (2008), the predominance of active sleep during the preterm period reflects brain maturation. The results emphasise individual variations in state organisation influenced by endogenous and environmental factors. Gender differences are potential sources of individual variation (Foreman et al. 2008).

Table 4.7 shows the Control group's behavioural responses during the 10-minute videos predominantly characterised by active sleep, with a predicted mean of 5.950, while the

Experimental group showed a predicted mean of 5.159. Therefore, the study shows that most infants were in the active sleep behavioural state during the Sensory integration-informed interventions, which correlates with The Royal Children's Hospital, Melbourne (2024) observations.

5.2.3.6 Quiet deep sleep as a behavioural State

Quiet, deep or non-REM sleep as a behavioural state is of great value to the preterm infant in the NICU. During this stage, the infant is less aware of the surroundings, which might be overstimulating (Lubbe 2020). While in the deep sleep behavioural state, the infant usually uses less energy; as Orlandi et al. (2012) mentioned, the heart rate would be slower, and the use of oxygen would be less. With a slower heart- and breathing rate, the infant does not need that much energy, which results in losing no weight or, in the long term, assists in gaining weight. A study conducted by Semanew et al. 2024, indicated that to be discharged from NICU, preterm infants must gain an average of 15–20 g/kg of their body weight after the physiological weight loss period. The sustained weight gain within this range for three consecutive days is one of the criteria for determining if a preterm neonate is ready for discharge. If preterm infants gain weight steadily, it suggests improved general health and a potential for a shorter stay in the NICU.

The observers recorded the behavioural state of each preterm infant for every minute during the ten-minute video. All the videos did not start, for example, in the crying phase that might occur at the end of cluster care. All 111 videos showed different behavioural patterns during the recordings of the videos. The researcher started the intervention in the behavioural state where the preterm infant was at that specific moment, meeting the infant's immediate need. During the interventions with the Control group, the researcher did not have a tool to substitute the tube when the infant grabbed the tube. The researcher would still remove the tube from the infant's hand while positioning the hands close to the face. As seen in Table 4.6, most infants had either an ONT or NGT, so the infant would keep pulling on the tubes as they were inserted in the nose or mouth, irritating the infant. This action changed the behavioural state of the infant, such as moving from active sleep to active crying. Due to the interruption of sleep, the infant took longer to return to the drowsy state. Meanwhile, with

the Experimental group, the researcher gently replaces the tube with the Octo-Sense tentacle and then places the hands close to the face. This movement did not interrupt the behavioural state of the infant or interfere with the intervention.

Table 4.7 shows the Control group had a predicted mean of 0.845, and the Experimental group displayed a predicted mean of 0.734 and a p-value of 0.790. Therefore, Sensory integration-informed intervention positively affected both groups' sleep by assisting them in moving from the active sleep state to the quiet, deep sleep behavioural state.

5.2.4 Different complexions of preterm infants

Bilirubin deposition in the skin is called jaundice. According to the study of Arditi-Babchuk et al. (2024), about 80% of preterm infants develop jaundice, which usually appears 2 to 4 days after birth and resolves spontaneously after one to two weeks. The skin colour of the preterm infant changes with maturity. Therefore, hyperbilirubinemia or jaundice is a medical condition that would have stayed the same in the framework of the ten-minute videos. Preterm infants could have had jaundice in one video. As indicated in Table 4.8, the jaundice cleared up within a day or two. Therefore, the same preterm infant would be marked pink in the following video on a consecutive day. A mottled complexion could be typical for a preterm infant (Verklan et al., 2021:148). According to the results of the data analysis in Table 4.8, most of the infants' complexion was pink. Notably, no infant changed from pink to mottled or pale, as it could indicate stress caused by overstimulation, discomfort or pain. All preterm infants stayed in the same complexion state from the start to the end of the ten-minute video. The researcher interpreted this fact as positive, as no preterm infant experienced that much stress during SI-informed therapy to cause a change in the infant's complexion, irrespective of the use of the Octo-Sense.

5.2.5 Visceral

The Assessment of Preterm Infants' Behaviour (APIB) developed by Als (1988) is appropriate if the examiner deeply respects and accepts each infant's individuality and if all behaviour is acceptable and essential. The length and expense of training involved, as well as the depth of immersion required to understand infant development, are prerequisites for using the APIB

and, as such, are critical factors in considering the choice of this instrument for a particular purpose. The APIB assessment requires a total investment in training and use. The ability to use this test successfully needs extensive practice and experience. The researcher used the APIB as a guideline to develop the Observational checklist during Sensory integration-informed intervention WITHOUT Octo-Sense Technology and the Observational checklist during Sensory integration-informed intervention WITH Octo-Sense Technology (Addendum S). In the studies performed by Als et al., 2005, 1988, the researchers concluded that these preterm infants, in the face of the demands of the examination, show significantly more difficulties with respiration, colour, and visceral reactivity as well as tone fluctuation and imbalance of extensor and flexor movements and postures. The preterm infants from these studies typically show low-keyed, strained, lidded alertness or hyper-alertness and cry strainedly. These preterm infants showed irregular respirations, paling, duskiness and visceral straining, gas passing, spitting up, gaging, and hiccoughing. The group showed low tone and poor postural modulation, with much extensor tone overflow, disorganised and uncontrolled movements and extensor postures. The group require a significantly more careful approach, with quiet holding into flexion and frequent time-outs for recovery. They generally have difficulty moving from a crying state to an animated alert state. Although they try to self-regulate and restabilise, they are not quickly successful. Both these study results were positive, but again, the limitation was that this is a costly and time-consuming measuring instrument (Als et al., 2005, 1988). Mary Vanesko, MOT, OTR/L, mentioned at the Summit for Professional Education that visceral responses included hiccups, gagging, and spitting up. Visceral signs are stress caused by discomfort or pain (Sarkaria& Gruszfeld, 2022). In Table 4.9, the researcher duly acknowledged that the observers noted signs of spitting up and sighing. If the observers stated the response, it often indicates that the number of occurrences was too low to be meaningful or statistically analysed, thus insignificant. The absence of data impacts the overall comparison. It may constrain conclusions about these responses while emphasizing those with enough data. The gag- and hiccup response between the two groups did not show significant differences. On the other hand, as was seen in Table 4.9, the p-value of 0.752 for the stress response burp showed that the Experimental group showed less of this response than the Control group.

5.2.6 Face

More specifically, in Table 4.10, the face refers to the mouth, which includes tongue extension, hands-to-face, mouthing, and suck search responses. The fact that the infants in both the experimental and the control groups did show tongue extension, hands-to-face, mouthing, and suck search responses are of value. These positive responses indicate the need to self-soothe (LaRossa, 2024), which leads to self-regulation. It also shows the infant's readiness to suck on a pacifier, which, according to Oetter and Richter (2020), could lead to self-regulation. The response in Table 4.9 showed insignificant differences between the two groups. Both groups reacted similarly, indicating that the SI-informed occupational therapy intervention could facilitate a self-soothing response in preterm infants.

5.2.7 Sucking

The observers did not note the sucking of hands, but it does not mean that sucking of hands did not occur. The occurrence was too low to be significant. According to Lubbe's Best practice guidelines: Neurodevelopmental supportive care of the preterm infant (2019), preterm infants suck their fingers to obtain self-soothing, leading to self-regulation. The observers noted the sucking of fingers for both the groups. The sucking of fingers is noteworthy, as it indicates the infant's attempt to self-regulate during therapy. It is also an indication to the researcher that the infant might suck on the pacifier. There were no significant differences between the two groups.

5.2.8 Attention

The researcher mentions clinical significance in the following discussion. The researcher described her reasoning for clinical significance and statistical significance Chapter 4, page 15.

The responses, fuss, yawn, sneeze, frown, eyes closed, face/eyes open, made eye contact, looking at the camera, and averting, as shown in Table 4.11, could be signs of stress (Lubbe, 2019; Als, 1999). The fussiness response was clinically significant, with a p-value of 0.063, as the control group showed more fussiness than the experimental group. Other responses did not show clinically significant differences between the groups. Overall, the Experimental

group appeared more prone to yawning, while the Control group tended to fuss. This table provides insights into how different conditions might affect attention-related responses, particularly in encouraging yawning in the experimental group. As Table 4.17 shows, infants in the NICU are more likely than not to have a feeding tube either in the nose or mouth, which might lead to excessive sneezing and frowning due to overstimulating these areas of the face (Lubbe, 2019). The observers might have noted the sneeze and frown reactions with the infants with NGT or OGT in sito. Infants in the NICU close their eyes (LaRossa, 2024) to avoid overstimulation. Therefore, the researcher and observers must distinguish between closed eyes due to stress and the behavioural state of moving from drowsy to active sleep to deep sleep. Apart from the fuss and yawn responses that were clinically significant, as demonstrated in Table 4.12, the other responses for both groups did not show any significant differences. Both groups exhibited stress responses, including fussing, yawning, sneezing, frowning, and avoiding eye contact with the researcher.

Notably, the reaction of yawning with a p-value of 0.013 was noted more in the Experimental group than in the Control group. Giganti et al. 2001, studied spontaneous yawing in low-risk, premature infants between 30 to 35 weeks of corrected age in the NICU in an enclosed incubator. This study also used video recordings of five hours. The behavioural states of quiet sleep, active sleep, wake and drowsy in 3-minute periods. The researcher recorded the contextual behaviours before and after yawn events using a 1-minute window. Yawning periods have predicted higher levels of motoric activation than non-yawn periods. The researcher conducted a sequence analysis of preceding and following states with or without yawns to examine stability or change. All states with or without yawn events had state stability for the preceding and following epochs, with two exceptions: firstly, the drowsy state with yawning was associated with state change in the preceding 3-min period, most often wake, and secondly, the drowsy state without yawning was related to state change in the following period, wake or active sleep. Yawns were not present in quiet sleep. The results suggest that yawning is associated with increased behavioural arousal that is not state-specific. However, yawning in the drowse state predicts state transitions in the preceding period but not the following. It was proposed by Giganti et al. 2001, that the drowse state may be an unstable state that becomes more stable when yawning is present.

The researcher could conclude that the yawning response in the Experimental group was an effort to move into a behavioural state that was more desirable at a specific moment. Despite the different stress signs, these infants tried to self-regulate and restabilise but were unsuccessful (Als et al. 1988). As Als et al. 2005 mentioned, they require a significantly more careful approach, which is possible with quiet holding into flexion and frequent time-outs for recovery. Due to overstimulation and fatigue, the infant would most likely reach the active sleep behavioural state at the end of the intervention (Lubbe 2019).

5.2.9 Regulated motor movements

Responses noticed for regulated motor movements included flexed arm/s, flexed leg/s and grasping. As explained by Dubowitz et al. 1999, muscle tone, or the resistance of a muscle to stretch, is generally much lower actively and passively in the preterm infant compared with the full-term infant. During their stay in the NICU, the preterm infant demonstrates more extension and difficulty moving against gravity than the predominantly flexed full-term infant. Compared to the full-term infant, the preterm infant's muscle tone never achieves the full degree of flexor tonus (Dubowitz et al. 1999). In the same way, as presented by Miyagishima et al. 2016, a predominance of extensor tonus is demonstrated by preterm infants by showing a tendency for neck hyperextension, decreased antigravity movement, and reduced midline movements. Primitive reflexes, including the Moro/startle reflex and palmar grasp, may either be absent or persist longer than the full-term infant (Dubowitz et al. 1999).

During the SI intervention administered to both groups, the infants would stretch out all four limbs, a regulated extension of the limbs as gravity is the pull force. Flexed arms and -legs indicate that the infant was, with the assistance of the researcher, able to move its limbs back into flexion against gravity. This position resembles the foetus's position. This position indicates that the infant is flexed and positioned in the midline, which could be side-lying or prone, which is suitable after the intervention. The infant's hands would then be close to the face, enhancing self-soothing and self-regulation, with or without the pacifier.

According to Sherer (1993), the palmar grasp reflex is a primitive, prehensile, involuntary response to a mechanical stimulus present in a newborn. Equally important, as Petrikovsky

and Kaplan (1993) found, this reflex appears around 16 weeks of gestation and is elicited in preterm infants as young as 25 weeks of postconceptional age. Historically, Pollack (1960) found in his study that the pressure applied to the palm produces traction on the fingers' tendons, leading to the clinging action. The thumb is not affected by this reflex. The response when the hand/fingers are touched comprises two phases: finger closure and clinging. The infant's fingers flexibly enclose the researcher's finger (Pollack 1960). The higher brain centres regulate the palmar grasp, though it is a spinal reflex, as recorded by Schott and Rossor (2003). In the same way, according to the study of Shani et al. (1970), the afferent nerve fibres include the ulnar and median sensory nerves that supply the palmar surface. When the infant showed signs of grasping, the researcher would put her finger in the infant's hand. The experimental group exhibited grasping as a regulated motor movement more frequently than the control group, and using the Octo-Sense's tentacles became intentional. The researcher could not keep her finger in the infants of the Control group's hand indefinitely. On the other hand, the Octo-Sense stayed with the infants in the Experimental group until discharge.

5.2.10 Unregulated motor movements

As each infant functions according to their circadian rhythm (Van Gilst et al. 2023), the researcher found it challenging to begin every intervention at the "just right" moment. However, it would be understandable if the intervention on specific infants started after a stressful intervention, as Sarkaria and Gruszfeld (2022) mentioned, such as drawing blood, as seen in Figure 2.10, or changing an NGT or OGT. The paediatricians and nursing staff in the NICU must disinfect their hands regularly with alcohol while attending to the preterm infant's needs. Medical staff use alcohol wipes to clean a specific part of the infant's skin before each painful procedure. Lubbe (2021) mentions that the preterm infant's olfactory senses are fully functional at the gestational age of 28 weeks; therefore, preterm infants smell and inhale the vape of surgical alcohol before a painful procedure. The earlier-than-typical exposure to painful procedures results in injury to the cerebellar hemisphere, according to Cook et al. (2023), which leads to secondary underdevelopment of the cerebral cortical projection regions. Every infant in the NICU reacts differently to the harmful environment (Nicholson et

al. 2017). According to Sakamoto et al. (2010), the anterior cingulate cortex is associated with pain processing and visceral sensation. As noted by the observers and confirmed by Metha et al. (2022), the preterm infants had difficulty moving against gravity due to low muscle tone, as most preterm infants have low muscle tone. Therefore, the unregulated motor movements seen in Table 4.13, namely the flaccid legs, extended arms and -legs, and arching of the neck and back. Whereas finger splaying, toe splaying, and stop sign and fisting (LaRossa 2024; Lubbe 2021) are signs of stress and overstimulation, which leads to avoidance responses. Painful medical interventions have a preference over therapy by an occupational therapist. When all the above actions coincide, the infant will show unregulated motor movements. In summary, the comparison between the two groups shows that the Experimental group had a lower incidence rate of flaccid leg/s and a higher rate of finger splaying.

Although neck arching had a predicted mean of 0.628 for the Control group and a predicted mean of 0.156 for the Experimental group, it was not statistically significant. The p-values suggest that none of the observed differences between the Experimental and Control groups reached statistical significance.

5.2.11 Tube feeding

Table 4.16 and Table 4.17 showed that most preterm infants in both groups had either an NGT or OGT in sito. These tubes can lead to overstimulation of the mouth and tongue, leading to visceral signs such as gagging caused by discomfort or pain (Sarkaria& Gruszfeld, 2022), which leads to an underdeveloped pain modulatory response (Cook et al., 2023). Therefore, the observers would mention this movement as an unregulated response. Equally crucial, as Horn and Joolay explained in their book Neonatal Guidelines and Drug Doses (2020), these tubes are removed and replaced every third day to prevent infection. As mentioned earlier, discomfort is the most common complication of nasogastric/orogastric tube placement. Then, more severe complications are associated with placement-related issues, as shown by Eau Claire (2023), such as accidental placement in the trachea that can lead to pleural injury, pneumothorax, tracheobronchial aspiration, pneumonia, and death. A study by Akkaya-Gül and Özyazicioğlu (2024) claimed that using a pacifier with 25% dextrose (Syrup simplex)

effectively reduces pain and improves physiological and behavioural stability during orogastric tube insertion. Despite the negative response these tubes have on the preterm infant, it is vitally important, as these infants need food. The brain's complex neuronal network, as described by Shandley et al. (2021), as well as the Central Pattern Generator (CPG), Figure 2.6, is underdeveloped in a preterm infant, therefore the inability to suck after birth. The MORE model stands for the relationships among Motor action, Oral skill, Respiration, and Eyes (or vision), developed by Oetter, Richter and Frick (1993). The MORE model, also known as the suck-swallow-breath synchronicity model (Figure 2.15), describes the development of the feeding system, which is also related to self-regulation. NNS is an automatic, predictable, rhythmical, and involuntary response elicited when given tactile input in or around the mouth (Sohn et al., 2011). Furthermore, Foster et al. (2016) mention that using a pacifier affords NNS, providing calmness and psychological stability. A preterm infant can perform NNS while having an NGT or OGT, especially if it has an indent like the pacifiers of the Octo-Sense. The infant associates the fullness of his tummy with sucking, although it is NNS, with tube feeding. According to Pineda et al. (2019), NNS is an essential infancy skill for oral feeding and self-regulation. Infants introduced to NNS can handle increased milk volume and daily feeds better if previously introduced to NNS (Foster et al., 2017). NNS makes the conversion from tube feeding to bottle feeding more successful. More importantly, as Lubbe (2021) mentioned, secondary outcomes include reduced hospital stays due to increased maturation and weight gain.

5.2.12 Holding and sucking of different pacifiers

During the sensory-informed-intervention sessions, the Control group used the standard pacifier and one of the pacifiers attached to the Octo-Sense for the Experimental group. Table 4.14 indicates that infants in both groups held on to the pacifier, and both groups showed active sucking during the intervention. The researcher viewed these observations positively, as both groups responded well to the Sensory integration-informed intervention when utilising a pacifier.

5.2.13 Holding on to tentacle/s versus researcher's finger

In Table 4.13, both groups showed a grasping response. When grasping was observed, the researcher placed a finger in the infant's hand for the Control group. If the researcher had to do the containment hold or deep pressure, she needed both hands and had to take her finger out of the infant's fisted hand. This scenario would be the same if an infant has unintentionally grabbed onto one of the tubes or cables. The researcher had to loosen the grip and remove the infant's hand. This action by the researcher caused the infant, who might have been in a drowsy state, to transition to the active, awake behavioural state. When the infant was in the experimental group, the researcher placed one of the Octo-Sense's tentacles into the infant's hand. Therefore, it was easier for the infants in the experimental group to stay in the same behavioural state or move from the drowsy state to the quiet, deep state.

5.2.14 General comments for the Control and Experimental group

The general comments section is a valuable tool in research. The researcher can gain deeper insights into the observations by allowing observers to provide open-ended feedback. This section can capture nuances, unexpected findings, and personal reflections that structured questions might miss. It helps paint a more comprehensive picture of the research subject and highlight areas for further investigation or improvement.

In summary, the researcher will highlight the most important findings and conclusions to review what was discussed previously concerning the different behavioural responses.

Firstly, the discussion of the outcome of the five behavioural states:

- Crying suggests that the Experimental group exhibited a higher frequency of crying during the 10-minute video sessions than the Control group.
- Active awake behavioural states in the Control- and Experimental groups proved to be almost identical. If the researcher used the pacifiers of the Octo-Sense during the crying stage, it could assist infants in moving from the crying stage to the active, awake behavioural stage using the pacifier and tentacles of the Octo-Sense. If the infant in

the Control group did not want to take the standard pacifier, it could lead to the infant moving back to the crying state.

- Quiet awake indicated that the Experimental group was more responsive and interactive during this period than the Control group. In this behavioural state, the preterm infant is approachable for interaction and learning a new skill, such as NNS, which the Octo-Sense could have assisted.
- The drowsy behavioural state showed that the Experimental group seemed drowsier than the Control group. The higher incidence of hand-to-face interaction within the Experimental group might have led to the Experimental group being drowsier. Again, if the researcher had used the Octo-Sense's pacifiers and tentacles, it might have assisted the infants in moving into this drowsy state.
- Active sleep shows that most infants from both groups were in the active sleep behavioural state during the Sensory integration-informed interventions, which correlates with The Royal Children's Hospital, Melbourne's (2024) observations.
- Quiet deep sleep shows that the Sensory integration-informed intervention positively affected both groups' sleep by assisting them to move from the active sleep state to the quiet, deep sleep behavioural state. There could be a possibility that both groups used the given pacifiers for NNS, which could have led to self-regulation and quiet deep sleep.

Secondly, the observation of complexion showed no change during the SI intervention for both groups, which is a positive outcome for the study. Thirdly, the visceral responses noted agree with the literature, namely that infants might show signs of distress by having visceral responses while in the NICU. Then the responses named under "face", namely tongue extension, hands-to-face, mouthing and suck search, were all observed as favourable responses to the SI intervention for both groups. After that, the observations for the sucking of fingers supported the same observations. The following were the responses noted as unregulated motor movements, such as the fuss and frown responses, which are close to significance. For the reactions, such as sneezing, eyes closed, face/eyes open, looking at the camera and averting, there is no evidence of a significant difference between the two groups. Therefore, this analysis shows varying effects of the experimental condition on different

responses. Lastly, as seen in Table 4.11, yawn is the only response that shows a statistically significant difference, indicating that the Experimental group showed a significantly increased yawning behaviour. The considerable increase in yawning suggests a potential impact of the intervention, whereas other behaviours did not show statistically significant differences.

5.2.15 Specific affordances of the Octo-sense

In the succeeding paragraphs, the researcher will discuss the specific affordances of the Octo-Sense technology used with the Experimental group.

5.2.15.1 Touch-able

In Table 4.19, both observers mentioned that the preterm infants did touch the Octo-Sense. Receptors and neural pathways associated with tactile perception are known to be the first to develop in utero (Gottlieb, 1971). As early as 1952, Hooker was able to identify that in the seventh week of gestation, the different types of skin sensory receptors gradually grow to be finally present on the whole skin by the 20th week (Humphrey 1978). At the same time, the connections between the spinal cord and the brain are functional only by the 20th week to the 24th week (Lowery et al., 2007). The mother can perceive passive tactile stimuli when the fetus kicks against the maternal abdomen. Quickening is the kick felt by the mother between the 16th and 22nd week of pregnancy (Hueker et al., 2023). Plasticity in the nervous system during the early stages of development indicates the human's learning ability before birth. Moreover, Valiani and HadiAlijanvand (2021) reported that from the 27th week of pregnancy, the touch receptors at the sensory neuron terminals can convert mechanical pressure into electrical waves, and the fetus begins to understand the sense of touch. Therefore, according to Marx and Nagy (2017), fetuses showed differential responses to touch, particularly in reaching out to touch the uterus wall and self-touch, dependent on the fetus's gestational age. At the same time, fetuses in the third trimester touched the uterus wall significantly longer than fetuses in the second trimester did when the mother touched her belly, compared to the control group, where the mother did not touch her belly. In this way, the preterm infant experienced touch when he touched/kicked the amniotic sack and uterus wall of his mother (Marx & Nagy 2017). The untimely evacuation deprived the preterm infant of

touching the amniotic sack and uterus wall of his mother, as well as the touch of the mother. With the Octo-Sense in the infant's nest, the Octo-Sense simulates the mother's uterus wall. The preterm infant could then have the same reaction the fetus had while in utero.

According to André et al. (2020), how a preterm is touched is crucial for preterm infants exposed to an atypical early developmental environment. Tactile stimulation, as part of sensory stimulation, occurs after preterm birth while in the NICU. This stimulation occurs during the precise time of cortical reorganisation, particularly in the sensory areas (André et al., 2020). Equally important, as André et al. (2020) mentioned, preterm infants responded to light, 0.008 gram, mechanical stimuli. In contrast, the preterm infants in the control group did not respond to this stimulus. Parents also reported that their prematurely born children exhibit atypical sensitivity to "benign" tactile stimuli (André et al., 2020). Taking the above-mentioned into account, the researcher made sure that she used deep pressure when touching the preterm infants.

In the absence of the mother's uterus, but with the Octo-Sense in reach, it provides an imitated wall that the infant can touch. Adding the researcher's containment touch/hold could assist the infant in managing self-regulation without having to use valuable energy. Based on the information above, the researcher concluded that the Octo-Sense might have therapeutic value due to its touch-ability.

5.2.15.2 Grab-able

The preterm infants included in the study were of the corrected ages between 32 weeks, six days and 36 weeks, six days. In Table 4.19, both observers mentioned that the preterm infants did grab at the Octo-Sense. In the study of Habek et al. (2003), the researchers used ultrasonography (US) to assess the perinatal outcomes of fetal grasping of the umbilical cord. In this retrospective clinical study, routine antenatal US examination revealed fetal grasping of the umbilical cord from 32 to 41 weeks of gestation in seven normal single pregnancies. Therefore, as demonstrated by Habek et al. (2003), it could be possible that the preterm infants had the normal reflex to grab the Octo-Sense's tentacles, as that would have been the fetus's action while in utero. The preterm infants display the Moro/startle reflex for an

extended period in the NICU (Sohn et al. 2011). If the preterm infant could grab onto a tentacle or a multi-disciplinary team member could place a tentacle in both hands, it would assist in containment if both hands could be positioned into midline while holding onto the tentacles. Containment could lead to self-regulation (Parry et al., 2023).

More than one study indicates that fetuses grab onto the umbilical cord while in utero. This action continues after birth and is called the Moro/startle reflex. Due to preterm birth, these infants tend to display this reflex for extended periods. The preterm infant in the NICU could grab any one of the eight tentacles. Therefore, the therapeutic value of the Octo-Sense's grabability could benefit these infants.

5.2.15.3 Hold-able

As the researcher described in the previous paragraph, the preterm infants in the study did grab at the Octo-Sense. The action after to grab would be to hold. In Table 4.19, both observers mentioned that the preterm infants did hold onto the Octo-Sense. This part of the checklist only required a yes or no answer. Therefore, the observers did not mention specifically where the preterm infant held the Octo-Sense. The study by Habek et al. (2003) assessed perinatal outcomes in pregnancies accidentally diagnosed with fetal grasping of the umbilical cord on ultrasonography in late gestation as a possible cause of fetal hypoxia due to mechanical occlusion of umbilical circulation. In the study done by Gillam-Krakauer et al. (2024), perinatal asphyxia occurs due to the disruption of blood flow or gas exchange to or from the fetus. As Mandala et al. (2023) pointed out, this condition can lead to severe systemic and neurological complications due to reduced oxygen and blood supply to vital organs. While in utero, the fetus might let go of the umbilical cord instinctively, as holding on too long might cause fetal hypoxia and death (Habek et al., 2003). As Dr Bruce Fagel mentioned on his webpage, many infants will hold and squeeze their umbilical cord inside the uterus, and then they will let go of it. These factors may explain why the infants grabbed and held onto the Octo-Sense, whether the head or tentacles and then let go of it.

While in utero, fetuses display the action of grabbing onto the umbilical cord and then instinctively letting go of it, as holding on too long might cause fetal hypoxia and even the

death of the fetus. In the NICU, the preterm infant can grab onto any part of the Octo-Sense or its tentacles, but there is no need to let go, as it imposes no hazard on the preterm infant. For these reasons, the researcher sees the hold-ability of the Octo-Sense and its tentacles as having therapeutic value.

5.2.15.4 Holding on to the tentacle/s of the Octo-Sense

In Table 4.20, the observers mentioned that the preterm infants held the tentacle/s with one or both hands, which was more specific. The holding on to the tentacle/s follows grabbing and holding, as described and explained under Grab-able (5.2.15.2) and Hold-able (5.2.15.3). The Octo-Sense has eight tentacles. That means that there would be a tentacle that the researcher could place into the preterm infants' hand/s. As mentioned, it would keep the infants from pulling on the NGT and OGT, which leads to the re-insertion of the tubes, causing discomfort and pain (Cook et al., 2023). Throughout the data collection period, the researcher showed multi-disciplinary team members how to insert the tentacles into the infants' hands and position the Octo-Sense's head to support the pacifier to assist the preterm infant with NNS. The Octo-Sense was available to the infant for the duration of the study.

To encapsulate, the researcher sees the affordances, namely touch-able, grab-able, and hold-able, together with holding on to the tentacle/s of Octo-Sense and the head of the Octo-Sense in a positive light. All the factors mentioned above might have therapeutic value, which could assist the preterm infant on his arduous journey while in the NICU.

5.2.15.5 Specific comments regarding the Octo-Sense

During the SI intervention, for the Experimental group, the researcher applied deep pressure with her hands to different parts of the preterm infant's body. Instead of taking that deep pressure away, the researcher replaced her hands with different parts of the Octo-Sense to continue that deep pressure (Kaya Kara et al., 2020). Due to the weight of the Octo-Sense, it was possible to use the head and the tentacles to provide continuous deep pressure. Usually, during therapy, the researcher places one of her fingers into the hand/s of the infant when showing the grasping reflex. The researcher placed the tentacles into the infant's hand/s or guided the hand towards the mouth. It might look like the infant is holding the

pacifier by himself, but it is a grasping reflex towards the mouth/face, which follows Shahani et al. (2003), Schott and Rossor (2003) and Pollack (1960) observations. With this movement, the infant pulls out the OGT or NGT, but as soon as the hand touches and holds on to the pacifier or tentacles of the Octo-Sense, the infant might keep on holding on to the pacifier or tentacles. Correct positioning and deep pressure improve the chance of beginning to self-regulate when the infant's hands are in the midline Parry et al. (2023).

The observers noted the following comments regarding the responses seen:

- The observers' comments (Table 4.21) regarding deep pressure showed 83 responses (Kaya Kara et al., 2020).
- The observers noted 47 responses regarding holding the pacifier or tentacles with one or both hands. This response indicates that the infants are searching for "something" to hold onto (Habek et al., 2003).
- The researcher used the weighted head (André et al., 2020) of the Octo-Sense to assist positioning, which was mentioned 20 times by the observers.
- The Octo-Sense touched the skin of the infants, but it did not elicit the Moro/startle reflex (Shahani et al. (2003), Schott and Rossor (2003) and Pollack (1960).
- The observers mentioned grasping five times in Table 4.21, although they noted it under specific affordances.
- The following three actions occurred once, namely the use of the Octo-Sense from the beginning of the intervention, the infant holding on to the head of the Octo-Sense, and lastly, the observers noted that an infant was sucking on the part of the Octo-Sense that is not the pacifier. As mentioned earlier, the Octo-Sense is manufactured with a specific, non-toxic silicone, making the complete Octo-Sense suitable for the preterm infant to perform NNS and possible self-regulation without assistance.

5.3 SUMMARY

The anthropometric profile included gestational age, corrected age, gender, and the number of videos taken during the study. The researcher discussed the observations' results in the same order they appear on the two Observational checklists during Sensory integration -

informed intervention WITHOUT Octo-Sense Technology and the Observational checklist during Sensory integration - informed intervention WITH Octo-Sense Technology (Addendum S). The behavioural states were discussed in detail, followed by the observed possible complexions. Also, the observations that could have been signs of stress or discomfort, such as visceral signs and facial expressions, were considered. Next, the researcher reviewed the sucking of the different pacifiers, as well as the observations made regarding attention, which included sneeze, yawing and frowning. The regulated motor movements, as well as unregulated motor movements, were conversed about. In addition, the researcher considered tube feeding, which influences how and if the infants could suck the standard pacifier compared to the pacifier of the Octo-Sense. The researcher highlighted the holding and sucking of different pacifiers, as well as the general comments. Additionally, the researcher explained the specific affordances of the Octo-Sense.

Through the discussion and interpretation of the study results presented in Chapter 4, the researcher made valuable conclusions regarding each aspect observed through the self-developed checklist used in this study regarding using the Octo-Sense as an assistive technology during sensory-integrated interventions.

Chapter 6 will discuss the study's findings, limitations, recommendations and value.

CHAPTER 6: CONCLUSIONS AND RECOMMENDATIONS

6.1 OPENING REVIEW

This chapter will conclude the study by summarising the key research findings concerning the research aims and questions and discussing the value and contribution. It will also review the study's limitations and propose opportunities for future research.

6.2 SUMMARY OF FINDINGS

This study aimed to describe and compare the self-regulation responses of preterm infants in the Neonatal Intensive Care Unit during a sensory integration-informed intervention, with or without the support of assistive technology. The first two objectives were similar: describing the self-regulation responses of preterm infants in the Neonatal Intensive Care Unit regarding self-regulatory behaviour and autonomic responses while receiving sensory integration-informed therapy. The Control group was assisted with the standard pacifier used in the NICU, while the Experimental group used the Octo-Sense assistive technology. The third objective compared the self-regulation responses of the preterm infants in the Control group to that of the Experimental group. The fourth objective was to describe the affordances of the Octo-Sense assistive technology while engaging with the Octo-Sense during the sensory-integration-informed intervention sessions.

As mentioned, the researcher will now summarise the study's outcomes in the order of the four objectives.

6.2.1 Objectives

6.2.1.1 Objective I – Control group

Objective 1 describes the preterm infants' self-regulatory responses in the Neonatal Intensive Care Unit regarding self-regulatory behaviour and autonomic responses while receiving sensory integration-informed therapy.

- The six behavioural states are crying, active awake, quiet awake, drowsy, active sleep and quiet deep sleep. The crying behavioural state is a state which indicates overstimulation and that the infant is not able to self-regulate. The quiet, deep sleep state is the most advantageous for NICU preterm infants. Within the six behavioural states, the infant in the Control group spent the most time in the active sleep behavioural state, and they spent the least time in the crying behavioural state. The researcher should maintain the active sleep behavioural state during the sensory integration-informed therapy so that the infant can move into a quiet, deep sleep state.
- The observers did not note the autonomic responses of spit-up and sighing during the study, but the observers pointed out that hiccups occurred. This autonomic response is related to stress. The researcher is now more vigilant in adapting the sensory integration-informed therapy intervention at the first sign of these stress cues.
- The responses related to the face and mouth showed a high incidence regarding the ability to move their hands to their face. The observers also recorded tongue extension, mouthing, and suck-search behaviour. The researcher would present the pacifier once one of these responses is present. It would assist in self-regulation while NNS takes place.
- Although the Control group did not show the behaviour of hand/s sucking, the observers noted the regulatory behaviour of sucking finger/s. The researcher will attempt to bring the hands close to the face from the beginning of the sensory integration-informed therapy. The preterm infants might then move to a behavioural state that surpasses their current behavioural state, such as being drowsy, and then move to active sleep. The researcher could present the pacifier to the infant as the observer notices the sucking behaviour.
- The observers noted that eyes closed had the highest incidence rate mentioned as one of the attention responses. The researcher aims to keep the preterm infants in this behavioural state, which might indicate active sleep so that the preterm infants could transition to the quiet, deep sleep behavioural state. The lowest behavioural response regarding attention was the response of aversion or shifting of vision as a stress cue.

The researcher noted that preterm infants did not make eye contact, so she should avoid making eye contact during the sensory integration-informed therapy.

- The response under the sub-heading regulated motor movements showed high responses for flexed arms/s and flexed legs/s, while the lowest response was for the grasping behavioural response. The researcher sees flexed arm/s and flexed leg/s in a positive light, as this flexed position resembles the position of the foetus while in utero. Therefore, the researcher will attempt to keep all four limbs in flexion, indicating that the infant's limbs are in the midline, as is the mouth. These responses indicate to the researcher that she should apply deep pressure and containment hold to assist the infant in retaining this position. Correct positioning could lead to self-regulation. The researcher could place a finger in the infant's hands to minimise the startle reflex if the researcher sees the grasping reflex.
- The observers noted the unregulated motor movements response for finger splaying as often seen. The researcher should pay attention to these stress cues during the sensory integration-informed therapy. She should act by bringing the infant in flexion and midline. She could also swaddle the infant and position the infant in side-lying, if permissible, to lessen the effect of gravity. The standard pacifier could assist in self-calming, leading to self-regulation. The observers did not note responses for flaccid arm/s. The researcher views this positively, which might indicate that sensory integration-informed therapy is not overwhelming for preterm infants in the NICU, as flaccid limbs indicate overstimulation. The researcher should note finger splaying as a stress cue. The researcher should then do a containment hold and apply deep pressure on the flexed legs and the head. By bending the elbows, the researcher assists in moving the arms into a flexed position, with the hands in midline. The flexed position enables the infant to have his hands close to the face, which in return may encourage the infant to perform the response of sucking his fingers. The researcher could introduce the pacifier to provide sensory input in the mouth.
- The response noted by the observers while using the standard pacifier showed a high incidence of actively sucking and holding the pacifier in the mouth during the Sensory

integration-informed intervention. The researcher saw this as complementary to the study. Sucking indicates NNS, which leads to self-regulation.

6.2.1.2 Objective 2 – Experimental group

This objective describes the self-regulation responses of preterm infants in the Neonatal Intensive Care Unit regarding self-regulatory behaviour and autonomic responses while receiving sensory informed-intervention therapy supported by Octo-Sense technology.

- The six behavioural states are crying, active awake, quiet awake, drowsy, active sleep and quiet deep sleep. The crying behavioural state is a state which indicates overstimulation and that the infant is not able to self-regulate. The quiet, deep sleep state is the most advantageous for NICU preterm infants. Preterm infants in the Experimental group spend the most time in the active sleep behavioural state. Preterm infants in this group did not show a high incidence of crying during the observations. The researcher should maintain the active sleep behavioural state during the sensory integration-informed therapy so that the infant can move into a quiet, deep sleep state.
- The autonomic responses noted in the Experimental group did not show responses such as spit-up and sighing. There was, however, a high incidence of hiccups within this group. Therefore, the researcher pays attention when hiccups occur as a stress cue, as sensory integration-informed therapy should not be stressful.
- The responses related to the face and mouth showed the highest incidence regarding the ability to move their hands to their face. Suck search response was noted less than tongue extension and mouthing behavioural responses. The researcher should present the pacifier of the Octo-Sense when the infant shows tongue extension and mouthing behavioural responses. These responses might indicate that the infant is receptive to sensory input in the mouth.
- The Experimental group did not show the behaviour of hand/s sucking. The observers noted the regulatory behaviour of the preterm infants sucking their finger/s. The researcher will attempt to bring the hands close to the face from the beginning of the sensory integration-informed therapy. The preterm infants might then move to a

behavioural state that surpasses their current behavioural state, such as being drowsy, and then move to active sleep.

- The observers noted that closed eyes had the highest incidence rate mentioned as one of the attention responses. The researcher aims to keep the preterm infants in this behavioural state, which might indicate active sleep so that the preterm infants could transition to the quiet, deep sleep behavioural state. The lowest behavioural response regarding attention was the response of aversion or shifting of vision as a stress cue. The researcher noted that preterm infants did not make eye contact and that she should avoid making eye contact during the sensory integration-informed therapy.
- The response under the sub-heading regulated motor movements showed high responses for flexed arms/s and flexed legs/s, while the lowest response was for the grasping behavioural response. The researcher should use containment hold and deep pressure to contain the infant in the foetal position. When showing the grasping response or Moro-reflex, the researcher should place one of the Octo-Sense's tentacles in the infant's hand/s.
- The behaviour responses noted by the observers under unregulated motor movements for the Experimental group showed no response noted for flaccid arm/s, and the highest response was for finger splaying. If the observers did not note flaccidity, it could be that the infant was not overwhelmed by the sensory integration-informed therapy. The researcher should note finger splaying as a stress cue. The researcher should then do a containment hold, apply deep pressure on the flexed legs and the head, and move the arms midline. As a result, the infant may move the hands to the face, indicating to the researcher to present the Octo-Sense pacifier and could place tentacles in the infant's hands to minimise the Moro reflex, which could lead to self-regulation.
- The response while using the Octo-Sense technology pacifier showed a high incidence of actively sucking during the Sensory integration-informed intervention, and holding the pacifier in the mouth was also noted. Therefore, the researcher should position the infant in side-lying, midline, and flexion after sensory integration-informed therapy to encourage NNS.

6.2.1.3 Objective 3

In Objective 3, the self-regulation responses of the preterm infants in the Neonatal Intensive Care Unit who received the sensory integration-informed intervention, assisted by the standard pacifier, were compared to those of the preterm infants who received the sensory integration-informed intervention, supported by the pacifier attached to the Octo-Sense as assistive technology.

- The observers noted that the behavioural state of crying was higher in the Experimental group than in the Control group. On the other hand, the Experimental group showed more signs of drowsiness than the Control group. Of all six behavioural states, the active sleep behavioural state showed the highest incidence for both groups. The previously mentioned could indicate that the sensory integration-informed therapy might have value, as the infant should be able to move from the active sleep state to the quiet, deep sleep state when able to self-regulate.
- During sensory integration-informed therapy, autonomic responses indicate discomfort. The gag response was seen more frequently in the Experimental group than in the Control group. Hiccups had the highest incidence for both groups. The researcher needs to be more attentive when preterm infants have hiccups. As hiccups could indicate overstimulation, the researcher should bring the infant back into the foetal position. The researcher should add deep pressure and apply a containment hold. If the infant is showing signs of tongue extension or sucking of hands, the researcher should introduce the pacifier indicated for that specific group to minimise unregulated autonomic responses.
- The responses noted under the sub-heading face and mouth display that hand-to-face was the highest response in both groups. The researcher sees this as complementary to sensory integration-informed therapy, as it indicates that the infant is initiating self-regulation independently. Therefore, the researcher should present the indicated pacifier to assist preterm infants in NNS, enabling them to perform this response for longer. The responses for tongue extension, mouthing as well as suck search showed

a higher incidence in the Experimental group than in the Control group but was not statistically significant.

- The sucking of hand/s was not noted in either of the groups, while the observers pointed out the sucking of finger/s in both groups. The sucking of fingers is a way to perform self-regulation. The researcher could leave the infant's fingers in his mouth or initiate NNS by providing the indicated pacifier for that group. The pacifier is more beneficial, as the infant could perform NNS with a pacifier while positioning the hands close to the mouth/face.
- In the responses noticed under the sub-heading, namely attention, the Experimental group showed the highest response for yawning. The yawning responses were the only statistically significant responses in the study. The Experimental group showed a higher response to frowning than the Control group. Frowning might indicate that the infant could be uncomfortable. Frowning is seen more when the infant has an NGT or OGT inserted, as it is a constant irritation. Proving sensory integration-informed therapy could assist in calming the infant down, and self-regulation might follow. Both groups had a high incidence of the infant's eyes being closed. Eyes closed relates to the behavioural state of active sleep. When the infant is in the active sleep behavioural state, the researcher may continue with sensory integration-informed therapy to enhance moving into quiet, deep sleep.

In conclusion, the researcher acknowledged that the Control- and Experimental groups did not differ significantly in how the preterm infants reacted to the sensory integration-informed therapy.

6.2.1.4 Objective 4

The researcher used Objective 4 to describe the affordances of Octo-Sense assistive technology the preterm infants engaged with during sensory-integration-informed intervention sessions.

The observers commented on how the Octo-Sense could be applied to provide deep pressure and proprioceptive input. The observers mentioned the following:

- The researcher positioned the Octo-Sense over the infant's body to obtain and maintain deep pressure and proprioceptive input.
- The tentacles of the Octo-Sense were positioned over the body to obtain deep pressure while the infant was sucking the pacifier.
- At the end of the sensory-integration-informed intervention, the researcher did not remove the Octo-Sense but swaddled the infant with the Octo-Sense, thereby maintaining the Octo-Sense's deep pressure. Correct swaddling implies that the pacifier of the Octo-Sense would stay in the infant's mouth to maintain NNS and self-regulation.
- The researcher positioned the Octo-Sense's tentacles over the infant's lower limbs while the infant was actively sucking on the Octo-Senses pacifier.

The observers remarked on the infant's hand positions as follows:

- Both hands were holding onto the Octo-Sense while actively sucking the pacifier.
- Both the hands were holding onto the Octo-Sense's pacifier while actively sucking.
- The hands rested/held onto the Octo-Sense's tentacles while actively sucking the pacifier.
- One hand held onto the Octo-Sense while actively sucking.

The observers discussed the head of the Octo-Sense:

- The preterm infants held onto the head of the Octo-Sense.
- The researcher used the head of the Octo-Sense for positioning the pacifier while the infant was actively sucking the pacifier.
- After completing the sensory-integration-informed intervention, the researcher used the Octo-Sense to maintain the positioning.

Lastly, the observers noted that the preterm infants sucked on different parts of the Octo-Sense and not only on the pacifier.

To review the information mentioned above, the Octo-Sense could be used to apply deep pressure, proprioceptive and tactile input, as the Octo-Sense allows for the use different parts

simultaneously. If the preterm infant shows the grasping or Moro reflex during the sensory-integration-informed intervention, preterm infants could hold onto any part of the Octo-Sense, while actively sucking the pacifier. The inventor planned purposefully for the Octo-Sense to be manufactured with non-toxic silicone; therefore, it is not harmful to the infant if sucking on the Octo-Sense. The Octo-Sense has multiple functions, which could assist the preterm infant to perform NNS to obtain self-regulation.

6.3 LIMITATIONS

- The study's main limitation was the small number of preterm infants. A more extensive study population would have increased the statistical significance of the study results. Various factors contributed to the size of the study population of 26 preterm infants, with 17 preterm infants in the experimental group and nine in the control group, respectively. The randomised list (Addendum R) was available to all age groups and medical conditions. Still, unfortunately, the randomised list did not lead to an equal distribution where gender and corrected age were concerned (4.3.4, Table 4.1 and Figure 4.3), and it did not provide for an equal distribution of preterm infants in the two groups.
- The implementation of the study was a complex process in terms of individual, infant-centred intervention planning for each preterm infant included in the study.
- The strict in- and exclusion criteria (3.5.1.1 and 3.5.1.2) posed additional challenges and were time-consuming.
- In Chapter 3, the researcher stated that the sensory integration-informed intervention video recordings should be 10 minutes and would occur at the end of cluster care. The effect was that all preterm infants were in different behavioural states at the beginning of the SI intervention, and it took longer than 10 minutes to console the preterm infants, enabling them to transfer to the quiet, deep sleep behavioural state. The ideal would have been to start each intervention when the infant was active and awake and continue until the infant was in a quiet, deep sleep.
- Due to the constraints imposed by the pandemic and the time limitations associated with the degree program, the researcher faced many restrictions in the data collection

process. The researcher contemplated extending the data collection period, but unfortunately, it was not feasible. An extended data collection period would have increased the number of preterm infants, but it would not necessarily have led to a more equal gender distribution or corrected age distribution.

- The study only included preterm infants admitted to the NICU of the private hospital in Bloemfontein. As a result, the generalisability of the study findings constrained the findings. Further research is recommended, including a broader population and the private and public sectors.
- During the data collection period, South Africa experienced an unprecedented struggle to obtain an uninterrupted power supply from Eskom. Due to unforeseen power outages, the researcher could not capture some videos, which resulted in preterm infants not having five videos.
- The collection of data took place during the COVID-19 pandemic, which brought time constraints, and made it difficult for the researcher to obtain informed consent from the parents/legal guardians.
- When the researcher looked at the data analysis, she realised four items on the Observational checklist during Sensory integration - informed intervention WITHOUT Octo-Sense Technology and the Observational checklist during Sensory integration - informed intervention WITH Octo-Sense Technology (Addendum S) were irrelevant, or the formulation of the question should have been different to obtain more information. Firstly, the head position was insignificant, as the researcher changed the head position during and after the sensory integration-informed therapy. Thus, noting the head position during the therapeutic intervention was irrelevant. Secondly, the researcher would position the infant supine, irrespective of the infant's current position. At the end of the intervention, the researcher would always position the infant into the midline, flexion, and side-lying to ensure neuro-developmental care (Parry et al., 2023; Lubbe, 2019; King & Norton, 2017; Als, 1999). Thirdly, according to the neuro-developmental care procedures followed in the NICU, all preterm infants would be in a nest. The researcher should have considered this when she created the Observational checklist during Sensory integration - informed intervention WITHOUT

Octo-Sense Technology and the Observational checklist during Sensory integration - informed intervention WITH Octo-Sense Technology (Addendum S). While the researcher watched the videos, most nests were too small or too large. The researcher should have added the question: Was the nest appropriate concerning the preterm infant's body? Lastly, in retrospect, the type of "bed" in which the infant was irrelevant. The infant would have been in an open incubator, which made the recording of videos easy, as there were no hindrances that made the observations unclear. The infant might have been in an enclosed incubator. The SI intervention was still the same, but the closed incubator manufactured of bevelled, see-through plastic distorted the video images. The researcher had to obtain permission from the Unit Manager to pull the preterm infant's "bed" out of the closed incubator for 10 minutes. By opening the closed incubator, the temperature inside the incubator drops. The closed incubator assists the preterm infant in a stage where the infant cannot regulate his temperature (Dunne et al., 2024). The healthiest preterm infants would have been in a crib. The space in the crib did not have much room for the nest and the baby, which might have restricted the preterm infants' extension movements of all four limbs. Researchers should keep these suggestions in mind for future research.

The general observations highlighted the potential environmental influences within the NICU that may affect the preterm infants' responses and behaviours during the interventions. Pineda et al. (2019) stipulate that noise levels within the NICU should not exceed 45 dB. The observers mentioned audible background noises in the videos. Alarms went off, monitors were beeping, phones were ringing, trolley wheels were squeaking, the Unit door was opened and closed, the sound of the paper towel dispensers, and the observers heard the voices of personnel and parents. As was also mentioned by Pineda et al. and Lubbe (2017), REM sleep is interrupted by bright lights. The observers noted that preterm infants were too exposed to bright lights, as the nursing staff does not closely control the amount and types of light. These observations highlight the potential environmental influences within the NICU that may affect the preterm infants' responses and behaviours during the interventions.

6.4 RECOMMENDATIONS

Although the results did not show significant differences between the Control- and Experimental groups, the researcher could draw valuable information gathered regarding the self-regulation of preterm infants in the Neonatal Intensive Care Unit while engaged with Sensory Integration-informed intervention.

6.4.1. Recommendations for clinical practice

The researcher presents the following recommendations for clinicians working in the NICU.

- Preterm infants in the NICU would benefit if the pacifiers received from the hospital had an indent at the top of the pacifier's shield. This study showed how many preterm infants had NGT and OGT. A pacifier without an indent makes performing NNS while on an oscillator, ventilator, CIPAP, or nose-canula impossible. The pacifiers parents bring to the hospital are also not suitable.
- Preterm infants, with their immature CNS, significantly benefit from the correct approach regarding their neurological thresholds. When an infant is born too soon, the brain and CNS take longer to reach maturity. Therefore, the multi-disciplinary team members should be more aware of the preterm infant's gestational age and chronological age when planning the infant's treatment.
- The unit manager of the NICU should ensure that all therapists working in the unit have taken a course on neuro-developmental care, as this is a specialised field.
- Registered nurses should ensure they have syrup simplex or EBM and a pacifier readily available before administering a painful procedure alone or with the paediatrician.
- The unit manager should inform registered nurses that neurodevelopmental care requires an infant in a drowsy behavioural state to be encouraged to use NNS, which assists in self-regulation and transposes to a quiet, deep sleep behavioural state.
- Parents should be involved in their infant's progress in the NICU as part of the early intervention programme, which indicates the importance of the first thousand days. Even though the doctor has explained the infant's condition to the parents, the occupational therapist should ask them to re-explain the discussion in their own words

to prevent misunderstandings. Due to cultural differences, parents interpret their infant's stress cues differently than the medical staff. Handouts with pictures and simple explanations could clear up this difficult situation. As much as parents want to take their preterm infant home, it co-insides with fear and anxiety. Promoting handling (changing the diaper) and caring (KMC/breastfeeding/bottle feeding) while in the NICU would increase parents' confidence as the discharge date draws closer.

- Everybody working in the NICU must be more considerate towards the preterm infant's needs, especially to be conscious of the "noise" they make. The private hospital should install an instrument visible to all in the NICU indicating decibel noise levels. Members of the multi-disciplinary team should educate parents on why loud voices are harmful to preterm infants' neurodevelopment.

6.4.2. Recommendations for future research

- The researcher recommends further research using sensory integration-informed interventions with preterm infants in the NICU regarding the effect of NNS.
- Taking videos longer than 10 minutes would benefit a follow-up study.
- Future studies could explore these responses further, possibly with a larger sample size and an improved Observational checklist during Sensory integration-informed intervention WITHOUT Octo-Sense Technology and the Observational checklist during Sensory integration-informed intervention WITH Octo-Sense Technology (Addendum S).
- For further research, the researcher proposes conducting research in private and public hospitals.
- According to the researcher, the screening tool *Checklist for possible inclusion* (Addendum P) was unexpectedly valuable. One reason is that the observers did not note any infant turned from pink to pale, which would have indicated that the infant was experiencing stress or pain. The researcher used the normative reference values of the preterm infants for possible inclusion during the SI intervention therapy sessions. The normative reference values, as mentioned by Armentrout et al., 2021, included that the heart rate should be between 120 – 160 beats per minute, the

respiratory rate should be between 35 – 65 breaths per minute, the body temperature should be between 36.5 – 37. 5 degrees Celsius; penultimately the oxygen saturation should be between 89% - 94%, and lastly, the above assessments determined the physiological stability of the infant. No SI intervention therapy session had to be interrupted or stopped due to an infant going into a state of distress (Horn & Joolay, 2020). The *Checklist for possible inclusion* (Addendum P) compiled by the researcher could be a valuable screening tool for follow-up studies.

6.4.3 Noteworthy experiences during the research

- Although the parents were excited if their infant was in the Experimental group that would use the Octo-Sense, some parents whose infant was in the Control group felt offended that their infant was not allowed to use the Octo-Sense. The researcher should have put more effort and time into explaining the study to the parents whose preterm infants were in the Control group. The explanation of how the randomised list works could also have given insight to the parents.
- Parents whose preterm infants were in the Experimental group were optimistic about the Octo-Sense and wanted to buy it for their preterm infant to take home. The researcher explained that the Octo-Sense was in the developmental stage and was not for sale. It would have pleased the researcher if the preterm infant could have taken the Octo-Sense home.

6.5 VALUE OF THE STUDY

The results of this study added value in terms of the following:

- The researcher advocates that a pacifier should always be available to a preterm infant in the NICU.
- The researcher can recommend sensory integration-informed therapy, especially using a pacifier to enhance NNS, as NNS leads to self-regulatory behaviour.
- The study results show that using deep pressure through the correct placing of hands/containment hold as part of sensory integration-informed therapy enabled the

preterm infants to move from an undesirable behavioural state to a more favourable one that could lead to deep sleep.

- The researcher can recommend preventative measures for intervention with premature infants, especially regarding over- and under-stimulation within the NICU.
- The study's findings will help raise awareness among the multi-disciplinary team working with premature infants about the importance of sensory integration-informed therapy.
- This study's results suggest a risk for premature infants regarding optimal development without sensory integration-informed intervention as part of neurodevelopmental care in the NICU.

6.6 OVERALL CONCLUSION

The literature discussion regarding the development of preterm infants has again brought attention to the possible developmental difficulties and delays those preterm infants struggle with, the long-term implications of premature birth, and the impact that the NICU environment has on these preterm infants.

Although the researcher reported limitations and mentioned that the results did not show significant differences, the study could add value to the profession of occupational therapy, especially occupational therapists working with preterm infants in the NICU.

This research study's methodological framework might serve as a pilot study with a larger preterm infant group across multiple hospitals and over an extended period. This adapted study may lead to statistically significant results.

The Octo-Sense as assistive technology could be used in the NICU to support Sensory Integration-informed intervention. NNS proves advantageous for modulating self-regulation, increasing levels of alertness, extending the duration of quiet and deep sleep, enhancing coordination, and supporting low muscle tone. After discharge, the Octo-Sense goes home with the infant, which promotes the transfer of knowledge that the parents learned while the infant was in the NICU. Based on the study's findings, the researcher discussed the study's limitations and recommendations from which future research might benefit. The chapter

concluded with the study's contribution to favouring preterm infants in the NICU of the private hospital in Bloemfontein.

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ADDENDUM A

Developmental Supportive Care, Policy 1.3

MEDICLINIC

DEVELOPMENTAL SUPPORTIVE CARE

POLICY MCSA.C.N.MC.1.3

Purpose

The purpose of this policy is to support the developmental needs of the preterm baby within the hospital environment to improve neuro-developmental outcomes

Applicability

This policy is applicable to:

- Medical practitioners
- Nurse practitioners
- Ancillary supportive personnel

Policy statement

Developmental needs of the preterm baby need to be supported during hospitalisation to improve patient outcomes.

Developmental care must be practised as far as possible in line with the condition of the preterm baby.

All arterial and intravenous lines must remain visible at all times.

Responsibilities

Person	Responsibilities
Multidisciplinary team	Adhere to developmental care principles and guidelines: • Patient advocacy • Parent education

1. Guidelines regarding the physical environment

Sound and hearing	Rationale
Minimise the noise levels to below 80 dB during the day and 60 dB at night.	American Academy of Paediatrics recommends 45 dB in the neonatal critical care unit. Promote sleep/ wake cycle. Preterm baby may demonstrate physiological instability to noise. Noise can lead to sensory nerve damage and hearing loss. Promotes growth and development.
Attend to alarms promptly and set the alarm volume as low as clinically safe.	
Do not play a radio in the unit. ◦ Music therapy is only recommended after 36 weeks and not on continuous play.	
Do not tap or bang on incubators. • Close incubator doors quietly. • Discourage the use of the top of an incubator as writing or storage area.	
Clear water from tubing regularly.	
Talk softly at the bedside but preferably away from the bedside. ◦ Educate the parents to talk softly to the preterm baby as cues allow.	
Decrease the volume of tone of the telephone.	
Maintain and ensure appropriate use of equipment.	
Light and vision	**Rationale**
Minimise overall light levels to 10-600lux. (1-60ftc)	Benefit to retinal and ocular development outcome. Beneficial to endocrine stability. Promote sleep-wake cycle. The preterm baby may demonstrate behavioural and physiological instability to light or visual stimuli. Promotes growth and development.
Use individual lighting for procedure and observation, 10-15lux.	
Protect the eyes from bright lights during procedures.	
Reduce exposure to light by using an incubator cover.	
Provide eye protection for preterm babies under phototherapy, and shield preterm babies in adjacent bed spaces.	
Dim lights at night, if safe to do so, to improve sleep-wake cycle (0-0,5lux).	
Black and white stimuli only to be used from 36 weeks.	
Offer opportunity for visual stimulation if preterm baby is displaying longer attention span.	

Smell and taste	Rationale
Parents may expose preterm baby to the smell of breast milk.	Benefit to retinal and ocular development outcome. Beneficial to endocrine stability. Promote sleep-wake cycle. Preterm baby may demonstrate behavioural and physiological instability to light or visual stimuli. Promotes growth and development.
Protect preterm baby from noxious smells and odours e.g. strong smelling hand rub and cleaning solutions.	
Open antiseptic preparations away from the preterm baby.	
Avoid the use of perfume.	
Place small amounts of milk on to the pacifier (dummy) to stimulate positive oral experience.	

2. Guidelines regarding handling and interventions

Handling and interventions	Rationale
Provide opportunities for undisturbed rest - three periods of minimum 2 hours each.	Develop an appropriate sleep-wake cycle.
Cluster care but avoid completing a number of stressful interventions at the same time.	Preterm baby may demonstrate behavioural and physiological instability to inappropriate tactile stimuli.
Stop when preterm baby shows stress signals and allow time out.	
Interventions should ideally take place during arouse state. • Observe the preterm baby stress cues.	Prevents tactile aversion. Promotes growth and development.
Gently prepare preterm baby for handling with a soft voice and gentle touch to facilitate physiological stability.	To provide positive touch and maintain body temperature.
Encourage positive touch by using slow, controlled but firm handling using a palmar touch.	
Vary the preterm baby's head and body position, mindful of the preterm baby's physiological status and response to handling.	See Mediclinic neonatal procedure, NEOBP 054
Avoid stimulating the preterm baby with stroking and patting.	
Where clinically possible, consider day and night patterns for interventions e.g. weighing and bathing of the preterm baby.	
Promote containment holding during uncomfortable procedures.	
Bedding and boundaries should be breathable, washable and made of 100% cotton material.	
Promote skin-to-skin kangaroo care.	

3. Guidelines regarding positioning

Positioning	Rationale
Use supportive positioning techniques to enhance flexion and promote comfort.	Prevent pressure sores.
Position preterm baby on a soft, breathable mattress.	Prevents breathing difficulties.
Provide boundaries that are soft and firm but not rigid. • It should be high enough to allow for kicking and muscle exercise. • It should have a see-through cover to allow visibility and security.	Optimise alignment. Support posture and movement within containment boundaries.
Allow for movement within provided boundaries.	
Always swaddle a preterm baby while transferring to and from an incubator.	Modify positioning and handling to support behavioural regulation of sleep/ wake states.
Consider swaddling of the unsettled but physiological stable preterm baby in incubators.	
Swaddle preterm baby for bath.	
Encourage hand to mouth contact and non-nutritive sucking with an appropriate size pacifier (dummy).	Provide positions that encourage controlled, individual exposure to stimuli while monitoring for signs of behavioural stress.
No nest or boundaries to cover the face.	
Promote hands to face and midline posture.	Promote appropriate muscular development.
Place a tummy roll from the head to umbilical cord to support a flexed position when lying prone. • The tummy roll must be as wide as the preterm baby's wrist and not higher than the width of the preterm baby's arm.	
Allow for flexed position with knees together when choosing the nappy size.	

4. Guidelines regarding pain management

Pain management	Rationale
Use developmental supportive care guidelines to improve neonatal pain management.	To minimise the need for pharmacological treatment of pain.
Use pharmacological measures according to prescription for ongoing pain as prescribed.	Scope of Practice: Regulation 2598, as amended. Chapter 2(d).
Promote early and continued parental involvement.	
Encourage parents to observe preterm baby's behavioural cues, including readiness for handling.	Patients' Rights: focus is on individualised care
Emphasise the preterm baby's low tolerance for stimulation.	
Encourage parents to assist with cares where they can (containment holding, cupping, foot brace).	
Offer information on preterm baby developmental care.	

Definitions

Term	Definition
Developmental supportive care	Care of a preterm baby to support positive growth and development, allowing for the stabilising of physiological and behavioural functioning. (NANN 2000)
Containment holding	Cupping of the head and other body areas with a steady hand applying positive, gentle pressure.
Stress cues	Preterm baby's ability to respond to its environment (behavioural or physiological).
Non-nutritive sucking	Sucking activity without nutrition or fluid delivered to the preterm baby.
Boundaries/nesting	Supporting the preterm baby in a foetal position.
Swaddling	Wrapping a preterm baby in a blanket with the arms and legs bent up and hands close to the mouth.

Associated documents and records

Title	Number	Location
Mediclinic neonatal procedure: Assist parents with skin-to skin kangaroo care.	NEOBP 054	Intranet
Neonatal critical care assessment, monitoring and evaluation	N3038	Intranet
Implementation Record	N1009	Intranet
Neonatal high care assessment, monitoring and evaluation	N3516	Intranet

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Author	Version	Details of update	Effective date	Approver
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Lorraine Botha	1.2	Logo and brand change, inclusion of key principles, content review	2012 11 01	Estelle Jordaan
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Prepared by

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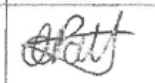
Mother and Child Specialist Committee	Aliné Hall		Clinical Quality Specialist: Mother and Child	2017 10 06

Approved by

Department/Area/ Group/Forum	Representative name	Signature	Designation	Date
Nursing	Dr Estelle Coustas	Estelle Coustas	Nursing Executive	2017 10 28

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ADDENDUM B

Disinfection Guidelines Policy C. IPC1.5

MEDICLINIC

DISINFECTION GUIDELINES

POLICY MCSA.C.IPC.1.5

Purpose

The appropriate use of disinfectants is essential to ensure and maintain safe patient care. All items and equipment used during patient care and in the environment must be cleaned and disinfected to prevent cross contamination.

Disinfection cannot be efficiently attained without initial, thorough manual cleaning of surfaces and equipment, removing organic material and dirt.

This policy includes:

- Principles of disinfectants
- Disinfection guidelines: equipment, routine method, alternative method and comments.

Applicability

This policy is applicable to:

- Medical practitioners
- Nurse practitioners
- Ancillary personnel
- External Service providers

Policy statement

Infection prevention and control practices are to be adhered to in all patient care situations, to prevent contamination of the environment and transmission of pathogenic micro-organisms to patients.

Responsibilities

Person	Responsibilities
Housekeeping personnel	• Adherence to and implementation of cleaning policies
Housekeeping supervisor	• Ensure adherence to the disinfection guidelines • Ensure that disinfectants are reconstituted correctly
Infection Prevention and Control (IPC) Manager/Practitioner & Patient Safety Manager	• Ensure that nurse practitioners adhere to decontamination protocols • Monitor compliance to the policies • Audit disinfection registers
Nursing practitioners	• Adhere to disinfection guidelines • Ensure that surfaces and equipment are always first cleaned and then disinfected • Always decontaminate equipment after patient use
Pharmacy Manager	• Ensure adequate supply of disinfectants used in that healthcare facility
Theatre Manager	• Ensure adherence to the policy • Ensure that instruments and equipment are adequately decontaminated between patient use • Ensure that registers are completed for all items placed in high level disinfectants • See Corporate Policy: **Disinfectants Daily Monitoring** and • **Disinfectant Register** (N2921)
Unit Manager	• Ensure that there is compliance to disinfection guidelines • Monitor cleaning and disinfection processes in the nursing unit

Principles of disinfection

1. The main objective is to prevent pathogens from reaching a susceptible site where it can cause an infection.
2. The method of cleaning depends on the type of material being treated, the pathogenic micro-organisms involved, time available and the risk posed to the patient and personnel and the recommendations of the manufacturer.
3. To ensure effective disinfection, all visible organic matter must be removed by first cleaning with a detergent and water **prior** to disinfection: ◦ Antiseptics and disinfectants **do not** make dirt safe • Dirt provides bacteria with a protective coat, and the disinfectant may not penetrate sufficiently to inactivate the bacteria ◦ Organic matter de-activates some disinfectants ◦ Organic matter may be more difficult to remove after exposure to chemical or heat disinfectants
4. It is essential that the disinfectant is stored in the correct container and when used, is compatible with the item to be disinfected, according to the manufacturer's guidelines.
5. Knowledge regarding the adverse side effects / exposure restrictions and the processing of products in contact with the disinfectant is essential.
6. Manufacturer Safety Data Sheets (MSDS) must be readily available and not older than five years.
7. Disinfectants should never be mixed as they may inactivate each other's active ingredients.
8. A record must be kept of all items disinfected in a high level disinfectant. See corporate policy, **Disinfectant: daily monitoring.**

Types of disinfectants

Disinfection agent	Spectrum	Uses	Advantages	Disadvantages
Alcohols (60 – 90%) including ethanol, isopropanol	Low to intermediate level disinfectant	• Semi-critical and non-critical items • Thermometers, stethoscopes • Rubber stoppers on multidose vials • Alcohol with detergent is effective for spot disinfection on surfaces, floors and countertops	• Fast acting • No residue • No staining • Low cost • Widely available	• Volatile, flammable • Irritant to mucous membranes • Inactivated by organic matter • May harden rubber • Cause glue deterioration or crack acrylic plastics
Chlorine and related compounds Sodium hypochlorite (5.25% - 6.15%) house bleach at a concentration of 100-5000 ppm free chlorine	Low to high-level disinfectant	• Tonometers • Spot disinfection of surfaces • Hydrotherapy tanks • Water systems in haemodialysis (Concentrated hypochlorite or chlorine gas is used)	• Low cost • Fast acting • Readily available • Liquid, tablets, powder	• Corrosive to metal in high concentrations (>500 ppm) • **Inactivated by organic matter** • Discolouration/ bleaching of fabrics • Releases toxic chlorine gas when mixed with ammonia • Skin and mucous membrane irritant • **Unstable** if left uncovered, exposed to light or **diluted**
Aldehydes - Glutaraldehyde: >2% aqueous solution buffered to pH 7.5 – 8.5 with sodium bicarbonate Other formulations available	High-level disinfectant/ sterilant	• Endoscopes (20 min at 20°C)	• Good material compatibility	• Allergenic, irritant to skin and respiratory tract • Direct contact causes skin injury • Relatively slow activity against *M. tuberculosis* • Require monitoring for continued efficacy levels: • 0.05 ppm (0.2 – 3 mg) • Short term exposure (15 min) • Long-term exposure (8 hours)

Continue...

Type of disinfectants, continued

Disinfection agent	Spectrum	Uses	Advantages	Disadvantages
Peracetic acid 0.2 – 0.35% and other stabilised organic acids	High-level disinfectant/ sterilant	• Automated endoscopic systems • Sterilisation of heat-sensitive items, e.g. haemodialysis machines • Suitable for manual instrument processing	• Rapid sterilisation cycle time at low temperature (30-45 min at 50-55°C) • Active in the presence of organic matter • Environmentally friendly by-products (water, oxygen, acetic acid)	• Corrosive to some metals • Unstable when activated • May irritate skin, conjunctivae and mucous membranes
Ortho-phthalaldehyde High level disinfectant (HLD) 0.55%. E.g.: CIDEX® OPA	High-level disinfectant/ sterilant	• Endoscopes • Medical devices	• Excellent stability over wide pH range • No need for activation • Superior mycobactericidal activity compared with glutaraldehyde • Ready to use	• More expensive • Stains skin and mucous membranes if not rinsed adequately • Stains items not thoroughly cleaned • Eye irritation on contact • Hypersensitivity reactions • Slow sporicidal activity • Monitoring for continuing efficacy levels: use life up to 14 days
Hydrogen peroxide 7.5%	High-level disinfectant/ sterilant	• Cold sterilisation used for heat sensitive items • 30 min at 20°C	• No activation • No odour • Eco-friendly	• Material compatibility concerns with metals such as brass, copper, zinc, etc.
Hydrogen peroxide 7.5% plus Peracetic acid 0.23%	High-level disinfectant/ sterilant	• Haemodialysis disinfection	• Fast acting (high level) disinfection in 15 min) • No odour • No activation required	• Material compatibility concerns with metals such as brass, copper, zinc, etc. • Damage to eye, skin
Glucoprotamin	High-level disinfectant	• Manual endoscope processing 15 min at 20°C	• Good mycobactericidal activity • High cleansing performance • No odour	• Lack of activity against some spores and enteroviruses

Continue.....

Type of disinfectants, continued

Disinfection agent	Spectrum	Uses	Advantages	Disadvantages
Phenolics	Low to intermediate-level disinfectant	• Environmental decontamination and non-critical items • **To be avoided**	• Not inactivated by organic matter	• Leaves a residual film on surfaces • Harmful to the environment • No antiviral activity • Reported hyperbilirubinaemia in infants (avoid in nurseries)
Iodophores (30-50 ppm free chlorine)	Low-level disinfectant	• Disinfection of non-critical items, hydrotherapy tanks • Main use is as an antiseptic (2-3 ppm chlorine)	• Relatively non-irritating and non-toxic	• Inactivated by organic matter • Adverse reaction with silicone tubing • May stain fabric • Non commonly used as a disinfectant
Quaternary ammonium compounds	Low level disinfectant	• Environmental surfaces • Skin antiseptic	• Stable • Non-irritating • Good cationic detergent	• **Not recommended unless combined with other disinfectants**

Adapted from: Understanding Infection Prevention and Control. Mehtar, S. 2010.

Decontamination guidelines for equipment

Equipment	Routine method Non-Infected patients	Alternative method Infected patient/ contaminated with blood or bodily fluids	Comments
Airways, endotracheal tubes and laryngeal mask airways	Single use	Single use	
Ambu-bags (Bag valve masks)	• See manufacturers guidelines • Wash with detergent and water after use • Rinse with clean water • Dry • Steam Sterilise (preferred) or Ethylene oxide	Single use	See Mediclinic basic nursing procedure manual
Aprons	Single use	Single use	
Bath / shower	Clean with non-abrasive detergent Rinse and dry	Clean with non-abrasive detergent Rinse and dry Wipe with hypochlorite solution (1:1000 ppm) after cleaning	

Continue.....

Decontamination guidelines for equipment, continued

Equipment	Routine method Non-infected patients	Alternative method Infected patient/ contaminated with blood or bodily fluids	Comments
Bed frames / cots	Clean with non-abrasive / detergent	Clean with non-abrasive cleaner/ detergent Disinfect with Hypochlorite Solution 1:1000 ppm	See corporate policy: Disinfection of beds and Environment
Bedpans / urinals	**Reusable:** Place in bedpan washer (Washer/ disinfector > 80°C x 1 min) **or** • Clean with non-abrasive cleaner (non-sterile gloves should be worn) • Rinse and dry • Wipe with hypochlorite solution (1:1000 ppm) • Store inverted on rack **Disposable**: Single use and dispose of in macerator • Clean outer rigid plastic support with soap and water and disinfect with hypochlorite 1:1000 ppm • Store inverted	Place in bedpan washer (Heat washer/ disinfector > 80°C x 1 min) **or** • Use a single-use item and dispose of in macerator **or** • Clean with non-abrasive cleaner (non-sterile gloves should be worn) • Rinse and dry • Wipe with hypochlorite solution (1:1000 ppm) • Store inverted on rack	**Do not soak** bedpans/ urinals in a communal container of hypochlorite solution
Blinds	As per manufacturer's instructions		Blinds should be cleaned with a detergent and water
Blood pressure monitor cuff	Vinyl cuffs: Clean with detergent and water daily and wipe down with 70% Alcohol surface disinfectant in between patients • Material cuffs: Wash weekly with detergent and water **(Not encouraged to be used)**	Dedicated equipment • Wipe bladder and tubing with detergent and water and then with 70% alcohol surface disinfectant after use	Cuffs should be on a cleaning maintenance plan to ensure that it is cleaned regularly

Continue.....

Decontamination guidelines for equipment, continued

Equipment	Routine method Non-infected patients	Alternative method Infected patient/ contaminated with blood or bodily fluids	Comments
Bottles & teats (Baby feed)	Wash bottles and teats using detergent and water • Use coarse salt to clean teats • Use a bottle brush to clean the bottle • Rinse bottles and teats well • Disinfect by submerging in a freshly made hypochlorite solution e.g. Biospot, Presept (125 ppm for 30 minutes) **or** • Steam sterilise in the microwave in a bottle steriliser as per manufacturer's instruction		**No bottles to be added during the disinfecting / sterilising period** • Cold sterilisation: only use hypochlorite solutions
Bowls / Basins (Patient washing)	Use non-abrasive detergent and water Disinfect with hypochlorite 1:1000 ppm • Clean after each use • Store dry and inverted. (discard if damaged)	Provide an individual bowl which is returned to the isolation area once cleaned and disinfected after each use • Use detergent and water to clean • After cleaning wipe with hypochlorite solution (1:1000 ppm) **or** • Heat disinfect (if indicated)	Autoclave if contamination risk is high
Buckets / bins ("kick abouts") (Stainless steel)	Detergent and water • Dry and store inverted	Wash with detergent and water and then • Disinfect with Hypochlorite solution (1:1000 ppm) • Autoclave if indicated	
Carpets (see floors)			
Clipper blades	**Single use only**		
Computer and keyboards	Damp dust daily with a detergent • Wipe keyboard carefully to remove visible dirt		Use a keyboard cover which is changed frequently

Continue.....

Decontamination guidelines for equipment, continued

Equipment	Routine method Non-infected patients	Alternative method Infected patient/ contaminated with blood or bodily fluids	Comments
Crockery & cutlery	Wash in dishwasher at 80°C **or** • Manual cleaning with hot water (55- 65 °C) and detergent • Rinse and leave to dry properly • Condemn all chipped/cracked crockery	• Wash in dishwasher at 80°C or • Manual cleaning with hot water (60°C) and detergent • Rinse and dry properly	**Disposable cutlery and crockery to be used with viral haemorrhagic fever or rabies only** • Wear disposable gloves for manual cleaning
Cuff Pressure monitor (ET tube)	**See Manufacturers Guidelines** Between patient use: • Wipe down with damp cloth and detergent. Dry • Disinfect with 70° Isopropyl Alcohol	After patient use: • Clean by wiping down with damp cloth and detergent • dry • Disinfect with 70% Isopropyl Alcohol	Tracoe smart cuff pressure monitor per patient be used.
Curtains (Interbed)	Machine washable with thermal disinfection **General Nursing Units:** • When visibly soiled • Monthly as per scheduled cleaning maintenance plan. **ICU:** • When visibly soiled • Weekly and with discharge **Emergency Centre:** • When visibly soiled Weekly	Machine washable with thermal disinfection Wash on discharge of the patient	Thermal disinfection achieved at 71°C for 3 minutes or 65°C for 10 minutes
Curtains (Window)	Machine washable with thermal disinfection or dry cleaned • When visibly soiled Planned maintenance	Machine washable with thermal disinfection on discharge of the patient	
Automated blood pressure monitor (Dinamap®)	Wipe down daily with a damp cloth and detergent and leave to dry Disinfect with 70% alcohol surface disinfection between patients	Dedicated equipment if possible • Clean with a damp cloth and detergent Wipe down after use with hypochlorite solution (1:1000ppm) or 70% alcohol surface disinfectant	

Continue.....

Decontamination guidelines for equipment, continued

Equipment	Routine method Non-infected patients	Alternative method Infected patient/ contaminated with blood or bodily fluids	Comments
Duvets	The duvet inner should be changed and machine washed **after each patient or when soiled** During use it should have a linen duvet cover in place Linen cover to be washed as other linen (See linen)	Dedicated duvet, placed in yellow bag with linen notification Dedicated wash cycle >65°C in laundry when changed and on discharge of patient	Thermal disinfection achieved at 71°C for 3 minutes or 65°C for 10 minutes
Ear Pieces (Auroscopes)	Wash with detergent and water • Rinse and dry • Wipe with 70 % alcohol surface disinfectant • Store dry	Dedicated equipment	**Do not soak**
Endoscopes • Cystoscopes • Bronchoscopes	See policy Endoscopes decontamination & Processing		**NOTE:** • **Heat tolerant: Heat sterilise** • **Heat sensitive: High level chemical disinfectant with compatible agent.**
Floors (Carpet)	Vacuum daily (high efficiency filter on exhaust) • If soiled, follow manufacturer's instruction • Allow to dry • Washed or steam cleaned according to the schedule • Open windows for drying and to disperse fumes	Not recommended in clinical patient areas with infectious patients • For contaminated spillage, clean with detergent, disinfect as per manufacturer's instruction – spot clean • If odour or staining persists, affected carpet to be replaced • Vacuum daily • Washed on discharge of the patient	Do not use nursing unit until carpet is completely dry Clean periodically as part of a cleaning maintenance programme

Continue.....

Decontamination guidelines for equipment, continued

Equipment	Routine method Non-infected patients	Alternative method Infected patient/ contaminated with blood or bodily fluids	Comments
Floors (Washable surfaces)	Clean with detergent and water • Allow to dry	In areas where infectious patients or patients with resistant organisms are accommodated, the floors should be first cleaned with detergent and the wiped with a hypochlorite solution (1:1000 ppm) • For blood spillage: (See policy: Cleaning of Blood spills)	Floors are not to be cleaned during meals, doctors' rounds and wound dressing rounds • Do not sweep with brooms as this aerosolises some pathogens e.g. staphylococci
Fridge (Medication/ blood products)	Wash inside and outside **weekly** with a detergent and water solution or more frequent when visibly soiled		Monitor temperatures between 2 to 8 °C • Defrost once a month • Place contents in another fridge while defrosting • No food or food products are stored in this fridge • If fridge is switched off and unplugged – ensure that it is plugged in and switched on again • **The cold chain should be maintained at all times**
Furniture & fittings (Beds, lockers, chairs, steps, IV stands, rails, ledges, shelves, over bed trolleys, telephones)	Clean with detergent and water • Vacuum clean fabric / upholstered furniture – (should have high efficiency filter on exhaust) • Clean with detergent solution and wipe down with hypochlorite solution (1:1000 ppm) according to manufactures guidelines upon discharge	Clean with detergent solution and wipe down with hypochlorite solution (1:1000 ppm) according to manufactures guidelines	See Mediclinic policy on cleaning of beds and surrounds
Hand wash basin/ sink outlet (drains) See below for Sinks			

Continue.....

Decontamination guidelines for equipment, continued

Equipment	Routine method Non-infected patients	Alternative method Infected patient/ contaminated with blood or bodily fluids	Comments
Humidifiers	Empty daily • Clean with warm water and detergent. • Dry. Fill only with sterile water. • Heat disinfect the chamber after each patient use (sterilise) • Gas sterilisation where available	Single use	Wash with detergent and water before sterilisation
Incubators	Wash all removable part and clean thoroughly with detergent and water • Dry properly	Wash with detergent and water • Disinfect by wiping down with a 70% Alcohol surface disinfectant or **weak** hypochlorite solution (1:125 ppm) • Aerate the incubator for about 6 hours before re-use	**Note**: Available Chlorine (hypochlorite solution) incorrectly diluted can be harmful to premature infants. • Each incubator must be disinfected between patients. • **Aerate** the incubator before re-use
Intravenous infusion or syringe pumps (IVACs)	Wipe down with a detergent and water daily and after each use (with special attention to often hand touched surface)	Wipe down hand touched surfaces often with a 1: 1000 ppm hypochlorite solution or 70% alcohol surface disinfectant (Always consult the manufacturer guidelines first)	**Spray solutions onto paper towel first and wipe down**
Instruments (Surgical)	Refer to theatre guidelines for individual instrument guidelines		
Laryngeal mask airway	Single use OR • Wash thoroughly with detergent and water solution • Rinse and dry • Autoclave		

Continue.....

Decontamination guidelines for equipment, continued

Equipment	Routine method Non-infected patients	Alternative method Infected patient/ contaminated with blood or bodily fluids	Comments
Laryngoscopes	**All new laryngoscopes are fully autoclavable** **Old laryngoscopes:** **Blade:** • Unscrew detachable bulb, if not fibre-optic • Brush the connection with a single-use brush • Wash with detergent and water solution • Rinse and dry • Autoclave (**Not** the fibre optic model) **OR** • Immerse in 70% alcohol (surface disinfectant) and soak for 10 minutes after cleaning with detergent **OR** • Immerse in Cidex OPA and soak for 10 minutes and rinse and dry Replace bulb once autoclave process complete **Handle:** Clean handle and wipe with 70% alcohol (surface disinfectant)	The same as for routine cleaning • If possible, send blades to CSSD for sterilisation (First consult manufacturers guidelines)	Store safely to prevent recontamination
Linen	Machine wash with thermal disinfection	Dedicated linen, placed in yellow bag with linen notification • Dedicated wash cycle at least >65°C for 10 min in laundry	Thermal disinfection achieved at 71°C for 3 minutes or 65°C for 10 minutes

Continue.....

Decontamination guidelines for equipment, continued

Equipment	Routine method Non-infected patients	Alternative method Infected patient/ contaminated with blood or bodily fluids	Comments
Mattress covers	Must have a plastic, impermeable cover • Wash with detergent and water and dry properly	Must have a plastic, impermeable cover • Wash with detergent and water when soiled and / or weekly. Dry. • Wipe down with hypochlorite solution (1:1000 ppm) or 70% Alcohol surface disinfectant. Allow to dry. • Covers can be washed and tumble dried after discharge of patient	• **Can be a major source of infection** • Replace torn mattress covers immediately
Medicine fridge (See fridges)			
Mops	• Detachable mop head to be washed daily by the laundry department • Tumble dried or air dried and then stored dry	• Designated mop for use in isolation area • Autoclave after terminal disinfection	• Mop heads should be exchanged daily • Ensure that mops are not soaked in the sluice room
Nail brushes (surgical scrub of personnel hands)	Use only if essential	Single use	Sterile / single use only
Ophthalmoscope	Clean by wiping down with detergent and water • Dry Disinfect with 70% alcohol surface disinfectant		When not in use keep dry and covered
Oxygen masks	Wash with detergent and water solution daily if used • Rinse and dry • Store safely to prevent contamination **Do not store covered in a glove.**		Single use item Discard after patient use
CPAP mask	Wash with detergent and water solution daily if used • Rinse and dry • Store safely to prevent contamination		There are disposable and re-usable items available (some up to 5 uses) Have to be managed according to the manufacturers guidelines

Continue.....

Decontamination guidelines for Equipment, continued

Equipment	Routine method Non-infected patients	Alternative method Infected patient/ contaminated with blood or bodily fluids	Comments
Pillows	Treat as for mattress covers		Waterproof covers should be used
Proctoscopes	Clean with detergent and water • Autoclave / pasteurise / HLD		Sterilised scope to be used for each patient
Razors	Single use only		
Sinks / Hand wash basins & taps	Remove any solid organic matter, discard into appropriate waste container • Clean daily with detergent • Rinse and dry	Clean with detergent • Rinse and dry • Wipe with hypochlorite solution (1:1000 ppm)	
Spray tops	• Wash with detergent and water. Rinse and remove all excess water and allow to dry		Use correct top for different solutions
Sputum container	Single use only	Single use only	
Stethoscopes	• Daily: Clean tubing, bell and diaphragm with detergent and water Disinfect and wipe bell, diaphragm and earpieces with 70 % alcohol between patient and personnel use	Dedicated equipment per patient Daily: Clean tubing, bell and diaphragm with detergent and water. Wipe bell, diaphragm and earpieces with 70 % alcohol surface disinfectant after each use and on discharge	Disinfect with 70 % alcohol after each patient contact
Suction bottles (Re-usable bottles without receptal liner)	Wash with detergent and water after each patient use or when emptied • Rinse and dry • Pasteurise / autoclave / HLD, **OR** • Soak in hypochlorite solution (1:1000 ppm) for **one** hour • Rinse and dry	Wash with detergent and water after each patient use or when emptied • Rinse and dry • Pasteurise/ autoclave/HLD, **OR** • Soak in hypochlorite solution (1:1000 ppm) for **one** hour Rinse and dry	

Continue.....

Decontamination guidelines for Equipment, continued

Equipment	Routine method Non-infected patients	Alternative method Infected patient/ contaminated with blood or bodily fluids	Comments
Suction container (With receptal liner)	Disposable receptal liners are discarded as healthcare risk waste when ¾ full • Wash container with detergent and water after each patient use and when visibly soiled • Rinse and dry • Line container with disposable receptor liner, single use item	Disposable receptal liners are discarded as healthcare risk waste when ¾ full • Wash container with detergent and water when visibly soiled • Rinse and dry • Line container with disposable receptor liner, single use item Wipe down daily with a hypochlorite solution(1:1000 ppm) as with terminal disinfection	Discard according to the healthcare risk waste (HCRW) guidelines/policy and that of the HCRW contractor • Double bag disposable receptor liners if not using a rigid container, because of the possibility of leakage • **Note**: Never leave fluid in reservoir if not used. Ensure regular change of receptal liner if it is a long-term patient with limited secretions
Suction tubing	PVC suction tubing: single use only • Silicone tubing: **re-use is not recommended** • If re-used, it must be cleaned properly with an enzymatic cleaner according to the CSSD procedure and autoclaved/ sterilised after cleaning • **All organic matter must be removed prior to sterilisation**	Discard into healthcare risk waste container • Discard if patient had a communicable disease or if grossly soiled	
T-tube for: **Nebulising** **Oxygen therapy** **(Single use for the same patient)**	• Wash with detergent and water solution after use • Rinse and dry		Store safely to prevent contamination
Thermometers • **Digital** • **Tympanic** • **ThermoFlashTM** • **Rectal probes**	See policy: Disinfection of Thermometers		

Continue.....

Decontamination guidelines for Equipment, continued

Equipment	Routine method Non-infected patients	Alternative method Infected patient/ contaminated with blood or bodily fluids	Comments
Toilet Seats & Flush Handles	Wash and thoroughly clean with detergent and water and dry Wipe / disinfect with hypochlorite solution (1:1000 ppm)	Wash with detergent and water and dry Wipe down with hypochlorite solution (1:1000 ppm) If soiled with body fluids - use disposable cloth to clean and discard into health care risk waste container	
Toys	Ensure that no soft toys are available • All surfaces must be fully washable	No shared toys allowed	
Trolleys (Dressing)	Wash daily with detergent and water and dry • Dressing trolley: Wipe with 70% alcohol Surface disinfectant before each use and in between patients	After use on an infectious patients or when contaminated with body fluids, wash with detergent and water dry and disinfect with hypochlorite solution (1:1000 ppm)	Do not use an alcohol hand rub which contains an emollient (e.g. Steri-Tech)
Ventilators Machine	Wash with detergent and water solution • Wipe down with hypochlorite solution (1:1000 ppm)/ 70% alcohol surface disinfectant **Always consult the manufacturers guidelines**		Wash down outside and dry See clinical guidelines for respiratory equipment

Continue.....

Decontamination guidelines for Equipment, continued

Equipment	Routine method Non-infected patients	Alternative method Infected patient/ contaminated with blood or bodily fluids	Comments
Ventilators Circuits	Single use item preferred **or** • Re-usable circuits: Wash with detergent and water, rinse and dry. • Sterilise by autoclave		• See clinical guidelines for respiratory equipment • No recommendation on period of change of disposable circuits. • Change according to manufacturer's guidelines and may differentiate between 'wet' and 'dry' circuits • HME filters to be changed daily, every 24hrs or when wet. • Take care to eliminate any condensation forming in circuit • In case of condensation, discard fluid periodically in the sluice • Apply strict hand hygiene • Prevent spillage of condensate in patient's trachea-bronchial tree
Wheelchairs	• Wipe down daily with detergent and water, dry and disinfect with hypochlorite solution (1:1000 ppm) at the end of a shift • Wipe down with 70% Alcohol surface disinfectant in between patients	Wipe with detergent and water and dry • After initial cleaning, wipe down with hypochlorite solution (1:1000 ppm)	Make sure that somebody in the nursing unit, housekeeping personnel or porters is responsible for cleaning
Ventilators Temperature Probes	Re-usable: • Wash with water and detergent after each patient use and sterilise or high level disinfect • (According to manufacturer's guideline)		See clinical guidelines for respiratory equipment
Work surfaces	Wipe with detergent and water and dry	Wipe with detergent and water and dry • Wipe down with hypochlorite solution (1:1000 ppm)	

Continue.....

Decontamination guidelines for equipment, continued

Equipment	Routine method Non-infected patients	Alternative method Infected patient/ contaminated with blood or bodily fluids	Comments
Yankhauer suction catheter	• Wash with detergent and water. • Rinse with sterile water • Wipe clean • Store dry Not preferred. **A single use** suction catheter is available		Store safely to prevent contamination

Definitions

Term, Acronym or abbreviation	Definition
Antiseptic	A chemical substance that inhibits the growth and development of micro-organisms, which is non-toxic and non-irritant. It does not necessarily destroy micro-organisms and is safe to use on living (animate) surfaces.
Detergent	A cleaning agent, which is surface acting. Detergents concentrate on all water interfaces and possess emulsifying properties. As a result detergents demonstrate cleaning properties. Detergents are effective in the removal of dirt and bacteria when used physically in conjunction with the mechanical action of friction and water, e.g. soap
Dirty	Covered with visible marks or stains.
Disinfectant	A chemical agent that is applied to non-living objects to destroy micro-organisms, excluding spores. They are used on inanimate objects (furniture and the environment) and surfaces because they have adverse effects on living tissue.
Disinfection	Antimicrobial agents that are applied to non-living objects to destroy micro-organisms. • Disinfectants cannot be used on living tissue. • Spores are not destroyed by disinfectants.
Sterilant	An agent used to sterilise equipment by eradicating all living organic matter including bacterial spores.
Sterilisation	The complete elimination or destruction of all living micro-organisms and spores by using chemical agents, heat or gas.
Decontamination	Decontamination is a general term for the destruction or removal of microbial contamination and non-microbial matter to render an item safe. This will include methods of cleaning, disinfection and sterilisation as appropriate.

Associated documents and records

Title	Number	Location
Material Safety Data Sheets (MSDS) product lists		Nursing units & Intranet (Pharmacy documents)
Mediclinic infection prevention and control policies		Intranet
Disinfection Register	N2921	Intranet

References

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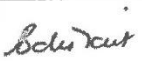
4. Hoffman, P., Bradley, C. & Ayliffe, G. 2004. Disinfection in Healthcare. 3rd Edition. Massachusetts: Blackwell Publisher
5. Mehtar, S. 2010. Understanding infection prevention and control. Claremont: Juta and Company Ltd.
6. WelchAllyn, Fiber optic Laryngoscope Blades and Handles. Available: www.welchallyn.com [2017, November 14]

History and version control

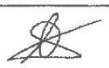
Author	Version	Details of update	Effective date	Approver
Norma Paverd	1	Initial release	1998 01 01	Unknown
Andrea Haakestad	2	Formatted and revised	2003 09 01	Estelle Jordaan
IPC Committee	3	Product update	2008 01 01	Estelle Jordaan
Clinical Governance Specialist committee	4	Minor changes	2011 03 21	Estelle Jordaan
Briëtte du Toit	5	Format changes Table with levels of disinfection added	2017 12 01	Dr Stefan Smuts

Approval and sign-off

Prepared by

Department/Area/ Group/Forum	Representative name	Signature	Designation	Date
IPC Specialist Committee and Nursing Quality Specialists	Briëtte du Toit		Infection Prevention and Control Officer	2017 11 14

Approved by

Department/Area/ Group/Forum	Representative name	Signature	Designation	Date
Clinical Department	Dr Stefan Smuts		Chief Clinical Officer	2017 11 14

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ADDENDUM C

Health Sciences Research Ethics Committee

HSREC

Approval

Ethics Number:

UFS-HSD2021/0148/2707-0005

UNIVERSITY OF THE FREE STATE
UNIVERSITEIT VAN DIE VRYSTAAT
YUNIVESITHI YA FREISTATA

UFS·UV
HEALTH SCIENCES
GESONDHEIDSWETENSKAPPE

Health Sciences Research Ethics Committee

25-May-2022

Dear **Mrs Rene De Bruin**

Ethics Number: UFS-HSD2021/0148/2707-0005

Ethics Clearance: **Self-regulation of preterm infants in the Neonatal Intensive Care Unit while engaged with Sensory Integration-informed intervention and Octo-Sense technology**

Principal Investigator: **Mrs Rene De Bruin**

Department: **Occupational Therapy Department (Bloemfontein Campus)**

Submission Page

SUBSEQUENT SUBMISSION APPROVED

With reference to your recent submission for ethical clearance from the Health Sciences Research Ethics Committee. I am pleased to inform you on behalf of the HSREC that you have been granted ethical clearance for your request as stipulated below:

- Changes in time Planning.
  - Initial time planning in protocol indicated that the data collection for the study will end on 30 April 2022.
  - Due to circumstances outside the researchers control (covid-regulations and admissions), the number of participants of the study is not yet adequate.
  - After consultation with the biostatician involved, it was recommended that the study data collection period be extended to 31 May 2022.
  - In summary, I would like to propose that the time line for data collection will be extended from 30 April 2022 to 31 May 2022.
  - After consultation with the biostatician, the data analysis time line moved from May 2022 - June 2022 to June 2022 - August 2022.
  - The student will start with write-up in June 2022.
  - Changes also indicated in section 6.
- The rest of the time planning will remain the same and the researcher will still work towards submitting November 2022.

The HSREC functions in compliance with, but not limited to, the following documents and guidelines: The SA National Health Act. No. 61 of 2003; Ethics in Health Research: Principles, Structures and Processes (2015); SA GCP(2020); Declaration of Helsinki; The Belmont Report; The US Office of Human Research Protections 45 CFR 461 (for non-exempt research with human participants conducted or supported by the US Department of Health and Human Services- (HHS), 21 CFR 50, 21 CFR 56; CIOMS; ICH-GCP-E6 Sections 1-4; International Council for Harmonisation (ICH) Harmonised Guideline, Integrated Addendum to ICH E6(R1), Guideline for Good Clinical Practice (GCP) E6(R2), 2016, SAHPRA Guidelines as well as Laws and Regulations with regard to the Control of Medicines, Constitution of the HSREC of the Faculty of Health Sciences.

For any questions or concerns, please feel free to contact HSREC Administration: 051-4017794/5 or email EthicsFHS@ufs.ac.za.

Thank you for submitting this request for ethical clearance and we wish you continued success with your research.

Yours Sincerely

Prof. A. Sherriff
Chairperson : Health Sciences Research Ethics Committee

Health Sciences Research Ethics Committee
Office of the Dean: Health Sciences
T: +27 (0)51 401 7795/7794 | E: ethicsfhs@ufs.ac.za
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YUNIVESITHI YA FREISTATA

UFS·UV
HEALTH SCIENCES
GESONDHEIDSWETENSKAPPE

Health Sciences Research Ethics Committee

13-Aug-2024

Dear **Mrs Rene De Bruin**

Ethics Number: UFS-HSD2021/0148-0002

Ethics Clearance: **Self-regulation of preterm infants in the Neonatal Intensive Care Unit while engaged with Sensory Integration-informed intervention and Octo-Sense technology**

Principal Investigator: **Mrs Rene De Bruin**

Department: **Occupational Therapy Department (UFS Main Campus)**

Submission Page

SUBSEQUENT SUBMISSION APPROVED

With reference to your recent submission for ethical clearance from the Health Sciences Research Ethics Committee. I am pleased to inform you on behalf of the HSREC that you have been granted ethical clearance for your request as stipulated below:

- Annual re-approval: The ethical clearance of this project is extended to 12 August 2025.

The HSREC functions in compliance with, but not limited to, the following documents and guidelines: The SA National Health Act. No. 61 of 2003; Ethics in Health Research: Principles, Structures and Processes (2015); SA GCP(2020); Declaration of Helsinki; The Belmont Report; The US Office of Human Research Protections 45 CFR 461 (for non-exempt research with human participants conducted or supported by the US Department of Health and Human Services- (HHS), 21 CFR 50, 21 CFR 56; CIOMS; ICH-GCP-E6 Sections 1-4; International Council for Harmonisation (ICH) Harmonised Guideline, Integrated Addendum to ICH E6(R1), Guideline for Good Clinical Practice (GCP) E6(R2), 2016, SAHPRA Guidelines as well as Laws and Regulations with regard to the Control of Medicines, Constitution of the HSREC of the Faculty of Health Sciences.

The Principal Investigator (PI) bears final responsibility for the RIMS application. In the event of any misconduct or improper activities perpetuated by a third party, the PI will be held vicariously liable. The HSREC will bear no responsibility or liability for any actions of a PI and/or third party or breach of confidentiality caused by the PI and/or third party.

For any questions or concerns, please feel free to contact HSREC Administration: 051-4012650/9860 or email EthicsFHS@ufs.ac.za.

Thank you for submitting this request for ethical clearance and we wish you continued success with your research.

Yours Sincerely

Dr. C. Armour (Barrett)
Chairperson : Health Sciences Research Ethics Committee

Health Sciences Research Ethics Committee
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ADDENDUM D

Permission to Conduct Research at the private hospital in Bloemfontein

For 2021 and Addendum for 2024

MEDICLINIC

MEDICLINIC CORPORATE OFFICE
25 OUTOIl STREET
STELLENBOSCH
7600
SOUTH AFRICA
PO BOX456
STELLENBOSCH
7599
SOUTH AFRICA

09 June 2021

Ms R de Bruin
3A Third Street
Westdene
BLOEMFONTEIN
9301

E-mail: renedebruinot@gmail.com

Dear Ms DE Bruin

PERMISSION TO CONDUCT RESEARCH AT MEDICLINIC BLOEMFONTEIN

Your research proposal entitled "Self-regulation of preterm infants in the Neonatal Intensive Care Unit while engaged with Sensory Integration-informed intervention and Octo-Sense technology", refers.

It is in order for you to conduct your research at Mediclinic Bloemfontein, and I wish you success with this project.

pp.

Yours sincerely
DR CHRIS DU PLESSIS
General Manager Clinical Services

Gmail Rene de Bruin <renedebruinot@gmail.com>

RE: CAUTION: POSSIBLE IMPERSONATION FROM EXTERNAL EMAIL ADDRESS! - Addendum to Consent Form

4 messages

Olivia Adams <Olivia.Adams@mediclinic.co.za> Thu, Jul 4, 2024 at 9:56 AM
To: Rene De Bruin <renedebruinot@gmail.com>
Cc: MCSA Research Committee <Research@mediclinic.co.za>

Dear Rene,

We acknowledge your email. I will discuss it with my coordinator, and if we need any other information, I will communicate with you.

Kind regards,

Olivia Adams

Research Administrator

Clinical Services

MEDICLINIC SOUTHERN AFRICA

Mediclinic Corporate Office

25 Du Toit Street

Stellenbosch, 7600

PO Box 456

Stellenbosch, 7599

T +27 21 809 6500

www.mediclinic.co.za

MEDICLINIC

EXPERTISE YOU CAN TRUST.

From: Rene de Bruin <renedebruinot@gmail.com>
Sent: Thursday, 04 July 2024 09:22
To: Olivia Adams <Olivia.Adams@Mediclinic.co.za>
Subject: CAUTION: POSSIBLE IMPERSONATION FROM EXTERNAL EMAIL ADDRESS! - Addendum to Consent Form

CAUTION: POSSIBLE IMPERSONATION.
CAUTION: EXTERNAL EMAIL ADDRESS USING INTERNAL PERSON NAME.

Good day Olivia

I hope you are well.

I am an Occupational Therapist. On 9 June 2021, I received permission from Mediclinic to collect data in the Neonatal Intensive Care Unit of Mediclinic, Bloemfontein. Data collection has been completed. I am currently writing my dissertation.

I am attaching the **Permission to conduct research at Mediclinic Bloemfontein** for your information.

The Ethics Committee of the University of the Free State (HSREC) requires me to adapt the consent form the parents signed before the study. The new consent form mentions that the researcher will act according to the requirements of the POPI Act, and the latest data management plan makes provision to de-identify the participants.

Data was saved in Figshere with the assistance of the Sasol Library of the University of the Free State. Data will be stored for ten years and then archived. There will be limited access to this data. Parents could apply to have access.

The researcher also mentions that the Octo-Sense, which was the focus of the study, might be commercialised. Mr Brandon Halasz holds the IP. He developed the Octo-Sense before the research started, and the University of the Free State acknowledged this fact.

Please acknowledge this information as well as your consent in written form.

Kind regards

Ren頤e Bruin

Rene de Bruin <renedebruinot@gmail.com> Thu, Jul 4, 2024 at 10:25 AM
To: Olivia Adams <Olivia.Adams@mediclinic.co.za>
Cc: MCSA Research Committee <Research@mediclinic.co.za>

Thank you for your response.

René de Bruin
Occupational Therapist
Pr.No.: 0230227
082 55 99 121 renedebruinot@gmail.com www.renedebruin.com

[Quoted text hidden]

Nomfundo Maseko <Nomfundo.Maseko@mediclinic.co.za> Mon, Jul 15, 2024 at 11:20 AM
To: Rene De Bruin <renedebruinot@gmail.com>
Cc: MCSA Research Committee <Research@mediclinic.co.za>

Dear René,

I hope you are keeping well. Thanks for the sharing the recent templates.

We will upload the document. Please share your findings after your dissertation has approved and marked.

All the best with the writing ! Hope you have a great week ahead.

Best regards,

Nomfundo Maseko

Research Coordinator

MEDICLINIC SOUTHERN AFRICA

Mediclinic Corporate Office

25 Du Toit Street

Stellenbosch, 7600

PO Box 456

Stellenbosch, 7599

T +27 21 861 6093

MEDICLINIC

EXPERTISE YOU CAN TRUST.

From: Rene de Bruin <renedebruinot@gmail.com>
Sent: Thursday, 04 July 2024 09:22
To: Olivia Adams <Olivia.Adams@Mediclinic.co.za>
Subject: CAUTION: POSSIBLE IMPERSONATION FROM EXTERNAL EMAIL ADDRESS! - Addendum to Consent Form

CAUTION: POSSIBLE IMPERSONATION.
CAUTION: EXTERNAL EMAIL ADDRESS USING INTERNAL PERSON NAME.

Good day Olivia

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Data was saved in Figshere with the assistance of the Sasol Library of the University of the Free State. Data will be stored for ten years and then archived. There will be limited access to this data. Parents could apply to have access.

The researcher also mentions that the Octo-Sense, which was the focus of the study, might be commercialised. Mr Brandon Halasz holds the IP. He developed the Octo-Sense before the research started, and the University of the Free State acknowledged this fact.

Kind regards

René de Bruin

[Quoted text hidden]

Rene de Bruin <renedebruinot@gmail.com> Mon, Jul 15, 2024 at 11:31 AM
To: Nomfundo Maseko <Nomfundo.Maseko@mediclinic.co.za>
Cc: MCSA Research Committee <Research@mediclinic.co.za>

Good day Nomfundo

Thank you for your feedback and well wishes.

I will share my dissertation with you after it has been marked.

Kind regards

René

René de Bruin
Occupational Therapist
Pr.No. - 0230227
082 55 99 121 renedebruinot@gmail.com www.renedebruin.com

[Quoted text hidden]

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ADDENDUM E

Consent Form for Paediatricians

For 2021 and Addendum for 2024

INFORMATION LETTER

Dear Doctor

Thank you for your interest and valuable time to read the information regarding the research study in obtaining a Masters' Degree.

This study has been approved by the Health Sciences Research Ethics Committee (HSREC) at the University of the Free State 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.

This study aims to describe the self-regulation of infants in the NICU while engaged with the Octo-Sense technology.

The objectives of this study are to observe and document the effect of the Octo-Sense on the infant's autonomic responses as indicator of self-regulatory behaviour whilst engaged with the Octo-Sense. As well as to observe and document the infant's self-regulatory behaviour whilst engaging with the Octo-Sense. And then to describe the affordances of the Octo-Sense as assistive technology for self-regulation.

All infants admitted to Unit I NICU, as well as Unit J PICU, will be screened to be included in the study. Infants in isolation will not take part in this study. The daily routine of the Unit will not be disrupted. The researcher and two observers, who are also occupational therapists and have been working in these units for more than 5 years, will conduct the study. The best interest of the infants would be a primary consideration.

I declare that:

- I have had the chance to ask questions and all my questions have been adequately answered.
- I understand that the infants in my care, whose parents/legal guardians, has given informed consent for their infant to be included in the study, has done it voluntary. They had not be pressurised to give consent for their infant to be part of the study.
- I may choose to withdraw any of the infants in my care from the study at any time and will not be prejudiced in any way.
- Any of the infants in my care may be withdraw from the study, before completion of study, if the researcher feels it is in the infants' best interest.

By signing below, I .....give consent for the infants under my care to be part in the research study entitled: To describe the self-regulation of infants in the NICU while engaged with the Octo-Sense technology.

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

....

Signature of Doctor **Signature of Witness**

It is only with your contribution that this study can make a valuable contribution to the field of occupational therapy in the NICU.

If you have any questions regarding this process, please do not hesitate to contact us.

Kind regards

René de Bruin – 082 559 9121 (Researcher)

Monique Strauss – 083 656 1541 (Supervisor)

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YUNIVESITHI YA FREISTATA

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GESONDHEIDSWETENSKAPPE

1 June 2024

ADDENDUM TO ORIGINAL CONSENT FORM FOR THE STUDY:

Self-regulation of preterm infants in the Neonatal Intensive Care Unit while engaged with Sensory Integration-informed intervention and Octo-Sense technology

Conducted by: René de Bruin, Occupational Therapist

The Protection of Personal Information Act of 2018 (POPIA) applies to research activities involving individuals' identifiable personal information. Research's impact on participants' right to privacy is not just a POPIA obligation but also an integral part of research ethics.

Parents/legal guardians of preterm infants signed the consent forms between 2021 and 2022. Unfortunately, these consent forms were not POPIA compliant. The researcher did not mention that she would use videos from NICU infants, Mediclinic Bloemfontein. Therefore, the new consent form.

With this new consent form, parents/legal guardians consent that the researcher may use these videos taken between 2021 and 2022 in her study. The researcher shared the videos with two observers appointed to watch the videos to complete the observational checklists used in the study. The researcher will not share the videos with anyone other than the two observers or on any public platform. The researcher transferred all data to Figshare. The researcher permanently deleted the Google Drive folder she used to save the data during the data-gathering period. Figshare, the University of the Free State's platform, has allowed data safekeeping for ten years, after which the platform would automatically archive the data. The researcher shredded all the hard copies of all the data sheets.

The Octo-Sense pacifier (silicone octopus) used in the study is a new assistive device that Mr Brandon Halasz developed before the study. Mr Brandon Halasz owns the Intellectual Property (IP). The previous consent form mentioned that infants in the control group would use the standard pacifier, and infants in the experimental group would use the Octo-Sense pacifier.

As soon as the researcher included an infant in the study, the infant was de-identified by giving a randomised number provided by the biostatition's randomised list. The researcher continued to use randomised numbers throughout the study.

The researcher may publish the study's results in academic journals. However, the researcher will not publish the videos used to gather data.

The Unit Manager of Unit I, Mediclinic, Bloemfontein, gave the researcher permission to review the daily admissions list by the Unit Manager.

I, ...

(Name and surname of the Paediatrition, working in the NICU, Mediclinic, Bloemfontein)

Acknowledge that the researcher, René de Bruin, an occupational therapist, took videos of some infants admitted to the NICU, Mediclinic, Bloemfontein. I had given her permission to review the daily admissions list of the NICU during the data collection period.

.....	.....
Signature of Paediatrician	Date

Researchers contact information:	**Supervisor's contact information:**
René de Bruin	Mrs Monique Strauss
Occupational Therapist/Researcher	Department of Occupational Therapy
082 559 9121	051-401-2829
renedebruinot@gmail.com	

To lodge a complaint against the researcher, contact HSREC at:

HSREC Administration
T: +27 51 401 2352
E: ethicsfhs@ufs.ac.za

HSREC Administration
T: +27 51 401 9860
E: ethicsfhs@ufs.ac.za

All correspondence addressed to:
The Chair: Health Sciences Research Ethics Committee
Block D, Rooms D115 and D112
Francois Retief Building
Po Box 339 (G40)
Nelson Mandela Drive
Faculty of Health Sciences
University of the Free State
Bloemfontein
9300

University of the Free State – Sasol Library

051-401-2989

Ufslibrary@ufs.ac.za

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ADDENDUM F

Consent Form for Unit Managers

For 2021 and Addendum for 2024

INFORMATION LETTER

Dear Unit Manager

Thank you for your interest and valuable time to read the information regarding the research study in obtaining a Masters' Degree.

This study has been approved by the Health Sciences Research Ethics Committee (HSREC) at the University of the Free State 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.

This study aims to describe the self-regulation of infants in the NICU while engaged with the Octo-Sense technology.

The objectives of this study are to observe and document the effect of the Octo-Sense on the infant's autonomic responses as indicator of self-regulatory behaviour whilst engaged with the Octo-Sense. As well as to observe and document the infant's self-regulatory behaviour whilst engaging with the Octo-Sense. And then to describe the affordances of the Octo-Sense as assistive technology for self-regulation.

All infants admitted to Unit I NICU, as well as Unit J PICU, will be screened to be included in the study. Infants in isolation will not take part in this study. The daily routine of the Unit will not be disrupted. The researcher and two observers, who are also occupational therapists and have been working in these units for more than 5 years, will conduct the study. The best interest of the infants would be a primary consideration.

I declare that:

- I have had the chance to ask questions and all my questions have been adequately answered.
- I understand that the infants in my care, whose parents/legal guardians, has given informed consent for their infant to be included in the study, has done it voluntary. They had not be pressurised to give consent for their infant to be part of the study.
- I may choose to withdraw any of the infants in my care from the study at any time and will not be prejudiced in any way.
- Any of the infants in my care may be withdraw from the study, before completion of study, if the researcher feels it is in the infants' best interest.

By signing below, I .....give consent for the infants under my care to be part in the research study entitled: To describe the self-regulation of infants in the NICU while engaged with the Octo-Sense technology.

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

....

Signature of Unit Manager **Signature of Witness**

It is only with your contribution that this study can make a valuable contribution to the field of occupational therapy in the NICU.

If you have any questions regarding this process, please do not hesitate to contact us.

Kind regards

René de Bruin – 082 559 9121 (Researcher)

Monique Strauss – 083 656 1541 (Supervisor)

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1 June 2024

ADDENDUM TO ORIGINAL CONSENT FORM FOR THE STUDY:

Self-regulation of preterm infants in the Neonatal Intensive Care Unit while engaged with Sensory Integration-informed intervention and Octo-Sense technology

Conducted by: René de Bruin, Occupational Therapist

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With this new consent form, parents/legal guardians consent that the researcher may use these videos taken between 2021 and 2022 in her study. The researcher shared the videos with two observers appointed to watch the videos to complete the observational checklists used in the study. The researcher will not share the videos with anyone other than the two observers or on any public platform. The researcher transferred all data to Figshare. The researcher permanently deleted the Google Drive folder she used to save the data during the data-gathering period. Figshare, the University of the Free State's platform, has allowed data safekeeping for ten years, after which the platform would automatically archive the data. The researcher shredded all the hard copies of all the data sheets.

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As soon as the researcher included an infant in the study, the infant was de-identified by giving a randomised number provided by the biostatition's randomised list. The researcher continued to use randomised numbers throughout the study.

The researcher may publish the study's results in academic journals. However, the researcher will not publish the videos used to gather data.

The Unit Manager of Unit I, Mediclinic, Bloemfontein, gave the researcher permission to review the daily admissions list by the Unit Manager.

I, ...

(Name and surname of the Neonatal Intensive Care Unit Manager, Mediclinic, Bloemfontein)

Acknowledge that the researcher, René de Bruin, an occupational therapist, took videos of some infants admitted to the NICU, Mediclinic, Bloemfontein. I had given her permission to review the daily admissions list of the NICU during the data collection period.

.....	.....
Signature of Unit Manager	Date

Researchers contact information:	**Supervisor's contact information:**
René de Bruin	Mrs Monique Strauss
Occupational Therapist/Researcher	Department of Occupational Therapy
082 559 9121	051-401-2829
renedebruinot@gmail.com	

To lodge a complaint against the researcher, contact HSREC at:

HSREC Administration
T: +27 51 401 2352
E: ethicsfhs@ufs.ac.za

HSREC Administration
T: +27 51 401 9860
E: ethicsfhs@ufs.ac.za

All correspondence addressed to:
The Chair: Health Sciences Research Ethics Committee
Block D, Rooms D115 and D112
Francois Retief Building
Po Box 339 (G40)
Nelson Mandela Drive
Faculty of Health Sciences
University of the Free State
Bloemfontein
9300

University of the Free State – Sasol Library

051-401-2989

Ufslibrary@ufs.ac.za

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ADDENDUM G

Health Sciences Research Ethics Committee

Data Management Plan

UNIVERSITY OF THE FREE STATE
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YUNIVESITHI YA FREISTATA

UFS HEALTH SCIENCES

HSREC DMP V2.0

Health Sciences Research Ethics Committee

RESEARCH DATA MANAGEMENT PLAN

Researchers are directed to the Protection of Personal Information Act 4 of 2013 for guidance regarding POPIA.
Note that this MUST be signed by the Principal Investigator, and this task cannot be delegated.
All text written in grey are provided as guidance and may not be relevant to all research.

Protocol information		
Principal Investigator		
Protocol title		
Collaborator(s)	**Name**	**Role**
Salutation, name and surname of Principal Investigator		**Signature: Principal Investigator** *My signature confirms that the information provided is true and accurate*
Date Signed:		

Version table		
Version	**Changes made**	**Date**

For more information on the Data Management Plan please visit: https://ufs.libguides.com/c.php?g=977378&p=8142054

POPIA Risk profile		
Answer all questions	**Yes**	**No**
Will the Research Participants include Children or Special Personal Information?	☑	☐
Will the research involve processing Personal Information on a large scale?	☐	☒
Will the research involve the evaluation or scoring of Personal Information to make automated decisions with legal consequences or that will that have a significant effect on Research Participants?	☐	☒
Will the Research involve Processing where researchers are getting Research Participants' Personal Information from sources other than the Research Participants themselves?	☐	☒
Will the Personal Information of Research Participants be disclosed to Third Parties?	☐	☒
Are any people or organisations that will have access to the Personal Information located in another country?	☐	☒
Will unique identifiers be used to link, combine, compare or match Personal Information from multiple sources?	☐	☒
Does the Research involve the use of new technology or technology that is, or might be, perceived by individuals as intrusive on their privacy?	☐	☒
Would the Processing of Personal Information contemplated by the researcher be outside of the reasonable expectations of the individuals?	☐	☒
Will the Research involve contacting or interacting with individuals in ways they might find intrusive?	☐	☒

Research Data Management Plan

1. Data collection

Provide a short description of the type of data you plan to collect or create.
How will the data be collected or created?
Frequency of new data - how often will you get new data, and over what period?
Will the data be collected continuously or at specific time points? Will the frequency of data collection change over time?
If using existing data, where will this data be obtained from?
Describe the existing data that will be used.
Do you have permission to use existing data, are there any restrictions on the re-use of data?
Please provide appropriate documentation to support the use of existing data.

2. Documentation and metadata

Clarify whether metadata will be collected and processed?
Provide a short description of the documentation and metadata that will accompany the data. if relevant.

3. Ethics and Legal Compliance

"Personal information" means information relating to an identifiable, living, natural person, and where it is applicable, an identifiable, existing juristic person, including, but not limited to:

1. *information relating to race, gender, sex, pregnancy, marital status, national, ethnic or social origin, colour, sexual orientation, age, physical or mental health, well-being, disability, religion, conscience, belief, culture, language and the birth of the person;*
2. *information relating to the education or the medical, financial, criminal or employment history of the person;*
3. *any identifying number, symbol, e-mail address, physical address, telephone number, location information, online identifier or another particular assignment to the person:*
4. *the biometric information of the person;*
5. *the personal opinions, views or preferences of the person;*
6. *correspondence sent by the person that is implicitly or explicitly of a private or confidential nature or further correspondence that would reveal the contents of the original correspondence;*
7. *the views or opinions of another individual about the person; and*
8. *the name of the person if it appears with other personal information relating to the person or if the disclosure of the name itself would reveal information about the person;*

"Special personal information" means

1. *the religious or philosophical beliefs, race or ethnic origin, trade union membership, political persuasion, health or sex life or biometric information of a data subject; OR*
2. *The criminal behaviour of a data subject to the extent that such information relates to –*
    a. *The alleged commission by a data subject of any offence; or*
    b. *Any proceedings in respect of any offence allegedly committed by a data subject or the disposal of such proceedings.*

3.1. ACCOUNTABILITY:

Who is responsible for ensuring that the data will be managed in accordance with POPIA principles? Note that this person will be held liable for non-compliance in certain situations.
How will this person ensure that the data is managed in a POPIA compliant manner?
Do you plan to collect information that is considered "Special personal information" or personal information of children?

3.2. PROCESSING LIMITATION:

Who is ultimately responsible for ensuring that all data that is processed is done so lawfully and in line with the documented informed consent, research ethics approvals and other role player regulations?

Will data be obtained directly from the participants? Is the participant aware that you have gathered his/her information, and has the participant consented to using the information? If the information is not collected directly from the participant, please justify this.

Is the collected data relevant to answer the aims and objectives of the research, and not excessive?

3.3. PURPOSE SPECIFICATION

Elaborate on how the researchers will ensure that data that is collected for a specific purpose will only be used for the purposes specified. If you intend to reuse personal information, is it in accordance and compatible with the purpose for which it was collected?

Is the participant aware of the continued use of their personal information?

For what time period may you retain this specific data (this is especially relevant in the case of the use of data from a third party, e.g. Department of Health)?

How will you keep track of when the personal information must be destroyed (if relevant)?

What process will be used to destroy personal information that prevents its reconstruction after you no longer require it?

What future purposes might the personal information be used for?

If the personal information will be de-identified, specify how the personal information will be de-identified.

3.4. FURTHER PROCESSING LIMITATION

Elaborate on how researchers will address further processing of existing data. Reflect on the "purpose specification" above.

What measures have been put in place to ensure that there is oversight and regulation of further processing of data?

3.5. INFORMATION QUALITY

What measures have been put in place to ensure that personal information collected is complete, accurate, not misleading and up to date?
What quality control measures will be put in place to ensure this?
What processes do you have in place to allow participants to update their information or withdraw consent (if applicable)?

3.6. OPENNESS

Which measures have been implemented to ensure that the participants and/or other role players (e.g. relevant head of department) have been informed of the data collection?
Does the participant information document have the contact details of the researcher(s) as well as the HSREC for queries regarding the research and their rights as participants/role players?
Does the participant know who is responsible for data safety in the research project?
Have you provided information to the participant as to how to lodge a complaint about the use of their personal information?
How will the personal information be collected?
Has the participant been informed of their rights to access information and right to object to the processing of information?

3.7. SECURITY SAFEGUARDS

Is this research high-risk or low-risk research based on the risk profile above?
Elaborate on data security safeguards. Which programme will you use to manage research data? Is that programme POPIA compliant?
What procedure do you have in place to identify foreseeable internal and external risks to data? Is data deidentified, anonymised or pseudonymised?
What processes do you have in place to prevent data from falling into inappropriate hands?
What procedure do you have in place to establish and maintain appropriate safeguards against identified risks?
How do you determine who has access to and who has accessed data?
How do you determine who has the right to access data?
What processes do you have in place to alert you when data is accessed or modified without consent/authorisation?
What processes do you have in place to identify the source of a data breach and the procedure to follow to neutralise the breach?
What process do you have in place that safeguards are continually updated in response to new risks or deficiencies in previously implemented safeguards?
What processes do you have in place to prevent a recurrence of a data breach?
What procedure is in place to inform the participant that their data has been compromised?
What procedure is in place to inform the HSREC of any data security breach?

3.8. DATA SUBJECT PARTICIPATION

Will participants be able to access their personal information?
What process should they follow to do so (if appropriate/applicable)?
What processes do you have in place to allow participants to correct personal information that you hold or withdraw consent to use such information?
What processes do you have in place to ensure that a request from a participant is adhered to?

4. Storage and Backup

How will the data be stored and backed up during the research?
How will you manage access to data?
If identifiable data will be collected, please mention where data will be stored and backed up.

5. Selection and preservation

Which data are of long-term value and should be retained, shared and/or preserved?
What is the long-term preservation plan for the dataset?
Where will the dataset be kept? How will you archive the data?
What data will you share with others? What licences apply?
What data/research material should be kept beyond the end of the project?
What data/research material should be destroyed? When? How?
How long will you preserve your data? Where will you preserve your data?
If identifiable data will be collected, please mention how long it will be kept, how it will be destroyed and who will destroy it. *Please refer to the HSREC research data retention plan for guidance on the duration of data retention (**https://www.ufs.ac.za/health/departments-and-divisions/health-sciences-research-ethics-committee**)*

6. Data sharing

Who else has a right to see or use this data, even before you share it?
Who needs access to your data? Members of the research team (e.g. biostatisticians)?
How will you ensure that data is shared safely between members of the research team?
How will you share the data? Are there any restrictions on data sharing (outside of your research group) required?
Do you have a material/data transfer agreement in place?
Do you need to anonymise data during research or when preparing for sharing, and how will you do this?
Does the organisation comply with EU GDPR or the ASSAf Code of Conduct?
Is there a contract in place if this is a foreign organisation?

7. Responsibilities and resources

Who is ultimately responsible for data management in this research project?
Who will be assigned the right to make changes to this plan?
What resources do you need to implement the plan (filing cabinet, software, training, SOPs?)

8. Budget

What are the relevant costs related to the management and curation of your data? This does not refer to the costs of conducting the research but the costs of data management and curation. Have such costs been budgeted for?

9. What are the relevant policies that influence data management activities?

What are the relevant policies, laws, and procedures that influence your data management activities?
Are there any restrictions imposed by the primary data owner (e.g. the Department of Health, the University of the Free State)
If your data is personal, sensitive or commercial, how will you share it safely, including plans to anonymise data?
Have you established who owns the copyright in your data?
Could the data be considered high value and/or vulnerable? For example, is your data likely to attract "hacktivists"? How could this be mitigated?
How will you destroy any personal, sensitive or commercial data identified above?

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ADDENDUM H

Directorate: Research Development (DRD)

Addressing Intellectual Property

and

Conflict of Interest

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2. STATEMENT OF CONFLICT OF INTEREST

Subject: Non-Conflict of Interest for Master's Study at the University of the Free State (UFS) Using the Octo-sense Device

Inventor: Mr. BL Halasz

Researcher: René de Bruin

Device: Octo-Sense

Background:

The Octo-sense device was invented by Mr. BL Halasz, who is also an intellectual property holder. The design of the Octo-sense device was completed in 2015, and the initial mould and prototype were developed in 2016. Mr. Halasz initiated the patent process with Stegmanns Attorneys in 2017. Mr. Halasz and the researcher had only a superficial relationship at the time of the device's development and registration. This statement addresses and clarifies any potential conflicts of interest regarding using the Octo-sense device in the researcher's master's study at UFS.

Measures to Mitigate Conflict of Interest

1. Agreement Between Inventor and Researcher:

1.1 An agreement allows the researcher to use the Octo-sense device in the master's study.

1.2 The agreement permits the researcher to publish the study results alongside UFS and receive any academic accolades resulting from the study.

1.3 The researcher is committed to sharing the study's final results with Mr. Halasz.

1.4 The researcher will not be remunerated for her efforts during or after the study.

1.5 Mr Halasz confirms that there are no current efforts to gain financially from the device, although this may change.

2. Informed Consent

The consent forms signed by all preterm infants' parents include information that Mr BL Halasz developed the Octo-sense device, which will be used in the study.

3. Transparency and Ethical Conduct

The study's protocol and videos document the transparent and ethical manner in which the researcher experimented. The ethics committee may audit these videos if necessary.

4. Independent Observers

Video analysis and recording of visual findings were conducted by two independent observers selected for their qualifications in occupational therapy (OT) and experience in neonatal intensive care units (NICU).

5. Data Processing

The UFS statistics and actuary departments processed the findings and raw data collected by the observers. The researcher received the compiled data to analyse and draw conclusions for the master's degree.

6. Compliance and Availability of Data

All guidelines were followed, and approval was received at each stage of the master's study. All information, from the observers' observation forms to the raw and processed data, is available on Figshare for transparency and verification.

CONCLUSION

In the interest of full transparency, the ethics committee is welcome to audit all data and findings to confirm the absence of any conflict of interest. The measures outlined above ensure that the study is conducted ethically and without bias, preserving the integrity of the research and the academic process.

`

ADDENDUM I

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The development of the Brain

W. Maxwell Cowan

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Expected presentation date	Oct 2024
Portions	The image on page 116 Developing brain is viewed from the side in this sequence of drawings, which show a

succession of embryonic and fetal stages

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Table 1

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Abnormal Nutritive Sucking as an Indicator of Neonatal Brain Injury

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Shandley et al., 2021

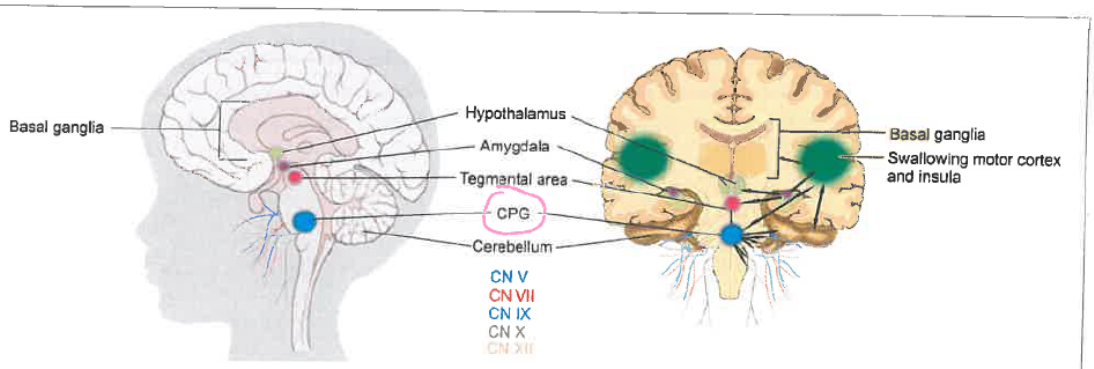

FIGURE 6 | Sucking and swallowing brain network. Sucking and swallowing is a bilateral process in the brain, each hemisphere has been shown to act both contralaterally and ipsilaterally, therefore, for simplicity, the black arrows on the right, coronal view of the brain indicate the complex integration and communication between the areas in only one hemisphere currently believed to be involved in the motor aspects of sucking. CPGs (blue), are at the core of this complex system. A second level of controls includes subcortical structures including the basal ganglia, hypothalamus (pale olive green), cerebellum, amygdala (purple), and tegmental area (pink) of the midbrain with a third level in the suprabulbar cortical swallowing center and insula (green). The cranial nerves (CN) required for the motor process of feeding and swallowing include CN V and VII to move the jaw and facial muscles, CN XII for tongue movement, CN V, IX, and X for movement of the epiglottis, expansion of the uvula and elevation of the hyoid bone and larynx, and CN X for peristaltic movement of the esophageal muscles.

stages of 3–5 around 34 weeks PMA, less experience will delay this progress (51, 64).

The preterm infant must also coordinate the pharyngeal and esophageal phases. The timing of pharyngeal peak pressure and the relaxation of the upper esophageal sphincter (UES) must evolve through both maturation and experience as well. Usually by the time a preterm infant is 34 weeks PMA, given enough experience, pharyngeal pressure is at its peak and the UES is able to fully and rapidly relax open. Younger preterm infants are at risk for dysphagia until this time because the pharyngeal pressure is lower and the UES is slower to relax open and does not open completely (67).

There is relatively little known about NNS in preterm infants in large part because it does not necessarily have an implication for NS performance until about 38 weeks PMA (44, 65, 68, 69). It is important, however, as a therapeutic action for the infant to help promote regulation of state (calm, sleepy, alert, fussy, crying, etc.) and lessen distress (39, 44). Similarly to NS, NNS is present around 28 weeks PMA and the frequency, volume, and negative pressure increases as the preterm infant ages (69). The pauses between bursts during NNS become shorter and more regular (less variation) and the bursts have increased frequency of sucks and longer duration with increasing PMA (39).

ASSESSMENTS

Routinely for many decades, clinicians, often speech therapists or nurse feeding specialists, have used a gloved finger and inserted it into the infant's mouth to gauge their sucking ability by considering the strength, rhythmicity, frequency and duration of sucks and bursts (14). This method is used to assess if an infant is ready to orally feed; whether they are able to get nutrition or if there is another issue causing clinical symptoms (such as failure-to-thrive). It is also used by lactation consultants to evaluate latch and sucking to aid in successful breast-feeding. Yet, this is a subjective judgement highly dependent upon the clinician's experience, tactile sensitivity, and how long the infant sucks on their finger. Going one step further, the Infant-Driven Feeding Scale was developed in an attempt to quantify the subjective assessments of the rater (70).

The Neonatal Oral-Motor Assessment Scale (NOMAS), developed in the mid-1980s, is a common observational tool used to assess jaw and tongue movement with qualitative results of normal sucking, disorganized sucking, or dysfunctional sucking pattern (71–74). A dysfunctional pattern is believed to be a sign of neurological impairment (75, 76), however it is controversial (71, 74). One problem lies in the NOMAS relying purely on the training and experience of the rater performing the scale because it is only an observation of how the infant feeds. A second problem arises when the NOMAS is compared to a later neurologic assessment. There are many different neurologic assessments done at different ages, and depending on which of them the NOMAS is compared to (BSID most commonly, early motor repertoire, or MOS, CRIB, Dubowitz, and NNNS to name a few), this can change how well the NOMAS score predicts the outcome of the neurologic assessment. A third problem comes from the variable chronological and gestational ages of the infants and/or preterms used in each study; there is not a routine age when the NOMAS is performed, nor are there consistent longitudinal scores taken for each infant in each study. Clinicians are in need for objective measures of the sucking pattern of each neonate in order to tailor therapies to improve primary measures along with improving secondary outcomes, such as weight gain or increase in feeding volume.

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ADDENDUM L

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Suck/Swallow/Breath Model

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René de Bruin
Occupational Therapist
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ADDENDUM M

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Institution name	University of the Free State
Expected presentation date	Oct 2024
Portions	Figure1. Mid-saggital T1 MR images of (a) neonate (of 39.5 weeks GA at birth that was 1-day old at the time, p 165
The Requesting Person / Organization to Appear on the License	Rene Anna De Bruin
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ADDENDUM N

Consent form for Parents/Legal guardians

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For 2021 and Addendum for 2024

87157 Date:2024/02/08 Bed:IZ13 Age:00m00d
KHOABANE,MISS N (NALA)
DR NESER JP Prac#:0320000876739
DOB.:2024/02/08 ID#:240208
MISS ML MVUSI (H) 0782986986
28 WEST CLIFT COMPLEX (W)
SIERAAD STREET,FLEURDAL,BLOEMFONTEIN,9301
BESTMED (196047906)

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INFORMATION LEAFLET AND PATIENT CONSENT FORM

for the Participants of a Research Project

The Research Project:

A project aimed to determine if the self-regulation behaviour of babies in a neo-natal intensive care unit (NICU) can be improved with the use of the Octo-Sense aid.

Reference Number:

You are invited to participate in the above-mentioned research project. Please ensure that you read and understand the basis of your participation and if anything is unclear, or if you have any questions about any part of the study, you may contact R. de Bruin at 082 559 9121. 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. You are free to withdraw from the study at any point, even if you did agree to participate.

This study has been approved by the **Health Sciences Research Ethics Committee (HSREC) at the University of the Free State** and will be conducted according to accepted and applicable national and international ethical guidelines and principles, including those of the International Declaration of Helsinki as well as South African Guidelines for Good Clinical Practice and the Medical Research Council's (MRC) Ethical Guidelines for Research.

Where will the research be conducted?

The research will be conducted in Unit I, neo-natal intensive care unit (NICU) and Unit J, paediatric intensive care unit (PICU), Mediclinic Private Hospital, Bloemfontein. Babies recruited for the study according to the research parameters and inclusion criteria will remain as part of the study, even if they were admitted to unit I and then later on transferred to unit J.

Should you agree to participate in the study, you will be required to do the following:

- Provide written consent for your infant to receive and use the Octo-Sense aid while in the neo-natal intensive care unit during the period of the study.
- Adhere to the standard practices of the neonatal intensive care unit.

What is an Octo-Sense aid?

The Octo-Sense aid is a non-toxic and easily sterilised dummy or pacifier in the shape of an ocotopus and was developed as a tool to help a baby to self-calm when not being held or coddled and to practise its sucking, swallowing and breathing skills during the periods between feedings.

Potential benefits of the study:

- This study will help the researcher to establish if the Octo-Sence aid improves the self-regulation behaviour of babies in neonatal intensive care units.
- The placement of one of the tenticles of the octopus-shaped dummy in the hand of the baby while it sucks on the dummy may lessen the chance of the baby pulling on the lines, tubes and cables attached to its body.
- The tentacles of the Octo-Sense dummy resemble the umbilical cord and this familiarity may assist in calming the baby.

Note: There is no financial benefit to you for participating in this research study.

Are there any risks associated with your participation in this research?

There are no normal risks assosciated with your participation in the study. If the baby does not respond favourably to the Octo-Sense, the observational study will be stopped immediately and the nurse working with the baby as well as its paediatrician will be informed. The necessary steps will be taken to ensure the baby's wellbeing and safety at all times.

Who will have access to your medical records?

All information collected will remain confidential. If it is used in a publication or thesis, the identity of the participants will remain anonymous. The researcher is the only person who will have access to the identity of the babies. The two occupational therapists will only know the babies by the numerical number allocated to them. Likewise, only these numbers will be used for statistical data interpretation purposes.

Is there anything else that you should know or do?

- If you have any concerns or complaints that have not been adequately addressed by your study researcher, you may contact the Health Sciences Research Ethics Committee of the University of the Free State at 051-401-7794/5.
- You will receive a copy of this information leaflet and the consent form for your records.

Principal investigator: René A. de Bruin

Address: Department of Occupational Therapy

University of the Free State

Bloemfontein

Contact number: 082 559 9121

CONSENT TO PARTICIPATE IN RESEARCH

TITLE: A project aimed to determine if the self-regulation behaviour of babies in a neonatal intensive care unit (NICU) can be improved with the use of the Octo-Sense aid.

REFERENCE NUMBER:

Declaration by Participant

By signing below, I Miranda Londi Maus.

agree to take part in this research study.

I declare that:

- I have read the attached information leaflet and agree that it is written in a language which I fully comprehend.
- I have been allowed to ask questions, which have been adequately answered.
- I understand that participation in this study is **voluntary** and that I have not been pressurised in any way to take part.
- I understand that I have the right to withdraw from this study at any point in time without penalty or prejudice.
- I accept that the researcher has the right to remove me from this study at any point in time, specifically If I do not adhere to the research guidelines. The interest of the baby's wellbeing will take preference.

Signed at (place) Medi clinic on (date) 10/02/2024

Signature of Participant

Declaration by Investigator

I (name) ..René de Bruin..... declare that:

- I explained the information in this document to ..Miss Nvusi..... who is the parent/legal guardian of the baby.
- I encouraged him/her to ask questions and took adequate time to answer them.
- I am satisfied that he/she adequately understand all aspects of the research, as discussed in the document.
- I did/did not use an interpreter. (If an interpreter was used then the interpreter must sign the declaration below).

Signed at (place) .....Bloemfontein..... on

(date) .....10 Feb 2024.....

.....RdB..... .....

Signature of Investigator **Signature of Witness**

Declaration by Interpreter

I (name) ..... declare that:

- I assisted the researcher (name) ..... to

explain the information in this document to (name of participant)

....., using the language medium of Afrikaans/English, Sotho.

- We encouraged him/her to ask questions and took adequate time to answer them.
- I conveyed a factually correct version of what was related to me.
- I am satisfied that the participant fully understands the content of this informed consent document and has had all his/her questions satisfactorily answered.

Signed at (place) ..... on

(date) .....

No interpreter used 24/02/10

....

Signature of Interpreter **Signature of Witness**

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1 June 2024

ADDENDUM TO ORIGINAL CONSENT FORM FOR THE STUDY:

Self-regulation of preterm infants in the Neonatal Intensive Care Unit while engaged with Sensory Integration-informed intervention and Octo-Sense technology

Conducted by: René de Bruin, Occupational Therapist

(082 55 99 1221 – renedebruinot@gmail.com)

The Protection of Personal Information Act of 2018 (POPIA) applies to research activities involving individuals or organisations' identifiable personal information. Considering the impact that research has on participants' right to privacy is not just a POPIA obligation; it is also an integral part of research ethics.

Parents/legal guardians of preterm infants signed the consent forms between 2021 and 2022. Unfortunately, these consent forms were not POPIA compliant. The researcher did not mention that she would use videos from NICU infants, Mediclinic Bloemfontein. Therefore, the new consent form.

With this new consent form, parents/legal guardians consent that the researcher may use these videos and photos taken between 2021 and 2024 in her study. The researcher shared the videos with two observers appointed to watch the videos to complete the observational checklists used in the study. The researcher will not share information on social media. The researcher saved the videos, raw data, and analysis on Figshare, the University of the Free State's platform, which allows data safekeeping for ten years.

The Octo-Sense pacifier (silicone octopus) used in the study is a new assistive device that Mr Brandon Halasz developed before the study. Mr Brandon Halasz owns the Intellectual Property (IP). The previous consent form mentioned that infants in the control group would use the standard pacifier, and infants in the experimental group would use the Octo-Sense pacifier.

There is a possibility that the researcher will publish the results of the study in academic journals.

`

ADDENDUM O

Vision of Preterm infants in the NICU

Email from Alice Skelton

Research Fellow

The University of Sussex

Vision of preterm babies in NICU

3 messages

Rene de Bruin <renedebruinot@gmaii.com> Mon, Oct 5, 2020 at 7:49 AM
To: babylab@sussex.ac.uk

Good day

I am an Occupational therapist, doing my Master in Sensory Integration. I work in the NICU and would like to know if premature infants can see black and white? I am developing an assistive technology that I would like to use in NICU, but do not know what colour it should be.

If possible, could you assist?

Kind regards

René

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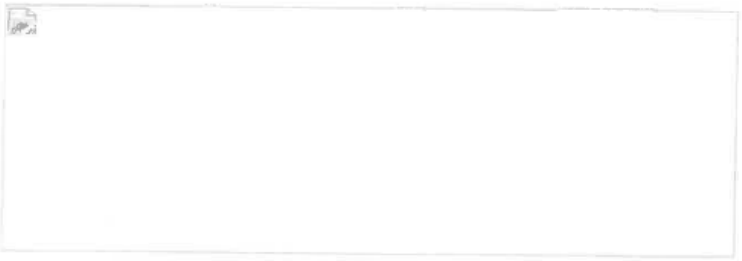

Sussex Baby Lab <Babylab@sussex.ac.uk> Mon, Oct 19, 2020 at 3:45 PM
To: Rene de Bruin <renedebruinot@gmail.com>

Hi René,

Thank you very much for getting in touch with us. Sorry for our delay in getting back to you.

Usually when babies are born they can see in some colour (e.g. they can tell apart a red and a white light at birth, but not a blue and a white light), and it continues to develop over the first few months of life. The development of premature infants colour vision is a bit harder to unpick, but all infants can see high contrast images (like black and white, or a similarly high contrast red vs white) from birth.

If you'd like more detailed information, please do let us know.

Many thanks,
Alice

Alice Skelton
Research Fellow
School of Psychology
The University of Sussex
Falmer, Brighton
BN1 9RH
✉ a.e.skelton@sussex.ac.uk
BabyLab : Facebook | Twitter | Website

Vision of preterm babies in NICU

3 messages

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Kind regards

René

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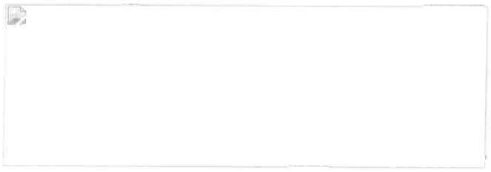

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If you'd like more detailed information, please do let us know.

Many thanks,
Alice

Alice Skelton
Research Fellow
School of Psychology
The University of Sussex
Falmer, Brighton
BN1 9RH
✉ a.e.skelton@sussex.ac.uk
BabyLab : Facebook | Twitter | Website

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ADDENDUM P

Checklist for Possible Inclusion

CHECKLIST FOR POSSIBLE INCLUSION

PARTICIPANT	
TODAY'S DATE	

Primary diagnosis					
Secondary diagnosis					
Date of birth					
Chronological age					
Adjusted age					
Birth weight	g	**Normal birth weight**		**Low birth weight**	
Current weight	g	**Normal for gestational age**		**Low for gestational age**	
Non-invasive positive pressure ventilation	**Room air**	**Nose-cannula**	**CPAP**	**SiPAP**	
Vital sign assessment of the preterm infant					

Parameter	**Normative reference values**	**Value for infant**
Heart rate	120 – 160 beats per min	
Oxygen saturation	89 – 94%	
Respiratory rate	35- (40 – 60)- 65 breaths per min (Normal)	
Body temp (abdominal probe)	36.5 – 37.5 degrees Celsius	
Physiologically stable based on above assessment	**YES**	**NO**

Gestational age	**Normal birth weight (NBW)**	**Prolonged Ventilation?**		**Date of video**
32 weeks	1 007g			1
33 weeks	2 000g	**Prolonged NPO?**		**2**
34 weeks	2 100g			**3**
35 weeks	2 400g	**PDA?**		**4**
36 weeks	2 600g			**5**

`

ADDENDUM Q

Consent form for Parents/Legal Guardians

in

English

Afrikaans

South-Sotho

For 2021 and Addendum for 2024

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- This study will help the researcher to establish if the Octo-Sence aid improves the self-regulation behaviour of babies in neonatal intensive care units.
- The placement of one of the tenticles of the octopus-shaped dummy in the hand of the baby while it sucks on the dummy may lessen the chance of the baby pulling on the lines, tubes and cables attached to its body.
- The tentacles of the Octo-Sense dummy resemble the umbilical cord and this familiarity may assist in calming the baby.

Note: There is no financial benefit to you for participating in this research study.

Are there any risks associated with your participation in this research?

There are no normal risks assosciated with your participation in the study. If the baby does not respond favourably to the Octo-Sense, the observational study will be stopped immediately and the nurse working with the baby as well as its paediatrician will be informed. The necessary steps will be taken to ensure the baby's wellbeing and safety at all times.

Who will have access to your medical records?

All information collected will remain confidential. If it is used in a publication or thesis, the identity of the participants will remain anonymous. The researcher is the only person who will have access to the identity of the babies. The two occupational therapists will only know the babies by the numerical number allocated to them. Likewise, only these numbers will be used for statistical data interpretation purposes.

Is there anything else that you should know or do?

- If you have any concerns or complaints that have not been adequately addressed by your study researcher, you may contact the Health Sciences Research Ethics Committee of the University of the Free State at 051-401-7794/5.
- You will receive a copy of this information leaflet and the consent form for your records.

Principal investigator: René A. de Bruin

Address: Department of Occupational Therapy

University of the Free State

Bloemfontein

Contact number: 082 559 9121

CONSENT TO PARTICIPATE IN RESEARCH

TITLE: A project aimed to determine if the self-regulation behaviour of babies in a neonatal intensive care unit (NICU) can be improved with the use of the Octo-Sense aid.

REFERENCE NUMBER:

Declaration by Participant

By signing below, I .....

agree to take part in this research study.

I declare that:

- I have read the attached information leaflet and agree that it is written in a language which I fully comprehend.
- I have been allowed to ask questions, which have been adequately answered.
- I understand that participation in this study is **voluntary** and that I have not been pressurised in any way to take part.
- I understand that I have the right to withdraw from this study at any point in time without penalty or prejudice.
- I accept that the researcher has the right to remove me from this study at any point in time, specifically If I do not adhere to the research guidelines. The interest of the baby's wellbeing will take preference.

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

.....

Signature of Participant

Declaration by Investigator

I (name) ..... declare that:

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

Signed at (place) ..... on

(date) .....

....

Signature of Investigator **Signature of Witness**

Declaration by Interpreter

I (name) ..... declare that:

- I assisted the researcher (name) ..... to

explain the information in this document to (name of participant)

....., using the language medium of Afrikaans/English, Sotho.

- We encouraged him/her to ask questions and took adequate time to answer them.
- I conveyed a factually correct version of what was related to me.
- I am satisfied that the participant fully understands the content of this informed consent document and has had all his/her questions satisfactorily answered.

Signed at (place) ..... on

(date) .....

....

Signature of Interpreter **Signature of Witness**

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INLIGTINGSBLAD EN TOESTEMMINGSVORM

Vir Deelnemers aan 'n Navorsingsprojek

Die navorsingsprojek:

Hierdie projek beoog om te bepaal of die selfregulerende gedrag van babas in 'n neonatale intensiewesorgeenheid (NISE) met behulp van die Octo-Sense hulpmiddel bevorder kan word.

Verwysingsnommer:

U word genooi om aan die bogenoemde navorsingsprojek deel te neem. Maak asseblief seker dat u die omvang van u deelname lees en verstaan. Indien enigiets onduidelik is of u enige vrae het oor enige deel van hierdie studie, kan u vir R. De Bruin op 082 559 9121 skakel. Deelname aan die studie is **volkome vrywilliglik**. As u besluit om nie deel te neem nie, sal dit u geensins negatief beïnvloed nie. U kan uself ook enige tyd van die studie onttrek, selfs al het u aanvanklik ingestem om deel te neem.

Hierdie studie is deur die **Navorsingsetiekkomitee van Gesondheidswetenskappe aan die Universiteit van die Vrystaat** goedgekeur. Dit sal gedoen word volgens aanvaarde en toepaslike nasionale en internasionale etiese riglyne soos voorgeskryf deur die Internasionale Verklaring van Helsinki en die Suid-Afrikaanse Riglyne vir Goeie Kliniese Praktyk asook die Mediese Navorsingsraad (MNR) se Etiese Riglyne vir Navorsing.

Waar sal hierdie studie gedoen word?

Die studie sal in Eenheid I van die neonatale intensiewesorgeenheid (NISE) en in Eenheid J van die pediatriese intensiewesorgeenheid (PISE) van Medi-Clinic Privaathospitaal, Bloemfontein gedoen word. Babas wat aan die perke vir hierdie spesifieke navorsing en insluitingskriteria voldoen sal deel bly van die studie, selfs as hulle eers in Eenheid I opgeneem is en later na Eenheid J geskuif word.

Indien u toestemming gee om aan die studie deel te neem, sal die volgende van u verwag word:

- Om geskrewe toestemming te gee dat u baba tydens die studietydperk die Octo-Sense hulpmiddel mag ontvang en te gebruik terwyl hy/sy in die neonatale intensiewesorgeenheid opgeneem is.
- Om ten alle tye aan die standaard-gebruike van die neonatale intensiewesorgeenheid te voldoen.

Wat is 'n Octo-Sense hulpmiddel?

Die Octo-Sense is 'n niegiftige fopspeen/tiet in die vorm van 'n seekat wat vinnig en maklik gesteriliseer kan word. Dit is ontwikkel as 'n hulpmiddel om babas te help om hulself te kalmeer wanneer hulle nie vasgehou of vertroetel word nie en ook om hulle suig-, sluk- en asemhalingsvaardighede tussen voedingstye te oefen.

Voordele wat die studie mag inhou:

- Hierdie studie sal die navorser help om te bepaal of die Octo-Sense hulpmiddel babas wat in neonatale intensiewesorgeenhede is se self-regulerende gedrag bevorder.
- Deur een van die seekat se tentakels in die baba se hand te sit terwyl hy/sy aan 'n ander tentakel suig, mag keer dat die baba aan die lyne, buise en kabels wat aan sy/haar liggaam vas is sal trek.
- Die tentakels van die seekat kom baie ooreen met 'n naelstring en hierdie bekendheid mag help om die baba te kalmeer.

Neem kennis: U sal geen finansiële vergoeding ontvang om aan die studie deel te neem nie.

Is daar enige risiko's wat met u deelname aan die navorsing gekoppel kan word?

Daar is geen normale risiko's wat met u deelname aan die navorsing gekoppel kan word nie. Indien die baba nie gunstig op die Octo-Sense reageer nie sal die waarnemende studie dadelik gestaak word en die betrokke verpleegster en die baba se pediater onmiddellik in kennis gestel word. Alle nodige stappe sal gedoen word om u baba se veiligheid en gesondheid ten alle tye te verseker.

Wie sal toegang tot u mediese rekords hê?

Alle inligting wat ingesamel word sal vertroulik bly. Indien die inligting in 'n tesis of publikasie gebruik word sal die identiteit van die deelnemers anoniem bly. Die navorser is die enigste persoon wat ooit toegang tot die babas se identiteit sal hê. Die twee arbeidsterapeute sal slegs die babas as numeriese nommers wat aan hulle toegeken is kan herken. Soortgelyk, sal slegs hierdie nommers vir statistiese data-analise gebruik word.

Is daar enigiets anders wat u moet weet?

- Indien u enige bedenkings of klagtes het wat nie genoegsaam deur die studienavorser beantwoord of aangespreek is nie, kan u die Komitee vir Navorsingsetiek van Gesondheidswetenskappe van die Universiteit van die Vrystaat op 051-401-7794/5 skakel.
- U sal 'n afskrif van hierdie inligtingsblad en die toestemmingsvorm vir u eie stawing ontvang.

Hoofnavorser: René A. De Bruin

Adres: Departement van Arbeidsterapie

Universiteit van die Vrystaat

Bloemfontein

Kontaknommer: 082 559 9121

TOESTEMMING OM AAN NAVORSING DEEL TE NEEM

TITEL: 'n Projek wat beoog om te bepaal of die selfregulerende gedrag van babas in 'n neonatale intensiewesorgeenheid (NISE) met behulp van die Octo-Sense hulpmiddel bevorder kan word.

VERWYSINGSNOMMER:

Verklaring deur Deelnemer

Met die ondertekening van hierdie dokument onderneem ek,

.....

om deel te neem aan hierdie navorsingstudie.

Ek verklaar dat:

- Ek die gepaardgaande inligtingsblad gelees of aan my laat voorlees het en dat dit in 'n taal geskryf is wat ek ten volle verstaan.
- Ek geleentheid gehad het om vrae te stel en dat al my vrae bevredigend beantwoord is.
- Ek verstaan dat deelname aan hierdie studie **vrywilliglik** is en dat daar geen vorm van druk op my geplaas is om deel te neem nie.
- Ek myself enige tyd aan die studie kan onttrek en dat ek nie op enige wyse daardeur benadeel sal word nie.
- Ek aanvaar dat ek enige tyd gevra mag word om van die studie te onttrek voordat dit afgehandel is, indien die navorser van mening is dat dit in my baba se beste belang is, of indien ek nie die ooreengekome navorsingsplan volg nie.

Geteken te (plek) .....op (datum) .....

....

Handtekening van Deelnemer **Handtekening van Getuie**

Verklaring deur Navorser:

Ek (naam) ..... verklaar dat:

- Ek die inligting in hierdie dokument aan

..... wat die ouer/wettige voog van die baba is, verduidelik het.

- Ek hom/haar aangemoedig het om vrae te vra en voldoende tyd daaraan spandeer het om dit te beantwoord.
- Ek tevrede is dat hy/sy al die aspekte van die navorsingsprojek soos hierbo bespreek, voldoende verstaan.
- Ek 'n tolk gebruik het/nie gebruik het nie. *(Indien 'n tolk gebruik is, moet die tolk die onderstaande verklaring teken.)*

Geteken (plek) ..... op (datum) .....

....

Handtekening van Navorser **Handtekening van Getuie**

Verklaring deur Tolk

Ek (naam) ..... verklaar dat:

- Ek die navorser (naam) ..... bygestaan het

  om die inligting in hierdie dokument in .....
  Afrikaans/Engels/Sesotho

  aan (naam van ouer/voog) .....
  te verduidelik.
- Ons hom/haar aangemoedig het om vrae te vra en voldoende tyd daaraan spandeer het om dit te beantwoord.
- Ek 'n feitelik korrekte weergawe van wat aan my vertel is, oorgedra het.
- Ek tevrede is dat die deelnemer die inhoud van hierdie dokument ten volle verstaan en dat al sy/haar vrae bevredigend beantwoord is.

Geteken te (plek) ..... op (datum) .....

....

Handtekening van Tolk **Handtekening van Getuie**

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LEQEPHE LA DINTLHA LE FOROMO YA TUMELLO YA MONKAKAROLO

Bakeng sa Bankakarolo ba Projeke ya Diphuputso

Projeke ya Diphuputso:

Projeke e reretswe ho fumana kamoo boitshwaro ba tlhaho ba masea ka hara yuniti ya masea ya *neo-natal intensive care unit (NICU)* bo ka ntlafatswang ka teng ka tshebediso ya *Octo-Sense aid.*

Nomoro ya referense:

O memilwe ho ba le seabo projekeng ya diphuputso e boletsweng ka hodimo. Ka kopo etsa bonnete ba hore o bala le ho utlwisisa sepheo sa hao sa ho ba le seabo mme haeba ho na le ntho e sa hlakang, kapa haeba o na le potso efe kapa efe mabapi le karolo efe kapa efe ya diphuputso, o ka ikopanya le R. de Bruin ho 082 559 9121. Ho ba le seabo ha hao ke **boithaopo ba hao ka botlalo** mme o na le bolokolohi ba ho hana ho ba le seabo. Haeba **o** re tjhe, hona ha ho na o ama hampe ka letho ka tsela efe kapa efe. O na le tokelo ya ho ikgula diphuputsong tsena ka nako efe kapa efe leha o ne o se o dumetse ho ba le seabo.

Thuto ena ya diphuputso e amohetswe ke ***Health Sciences Research Ethics Committee (HSREC)*** **mane Yunivesithing ya Freistata** mme di tla tsamaiswa ho ya ka maano le melawana ya tataiso le boitshwaro e amohetsweng e sebediswang ya naha le matjhaba, ho kenyeletswa le eo ya *International Declaration of Helsinki* esita le *South African Guidelines for Good Clinical Practice and the Medical Research Council's (MRC) Ethical Guidelines for Research.*

Diphuputso di tla etsetswa hokae?

Diphuputso di tla etsetswa *Unit I, neo-natal intensive care unit (NICU)* le *Unit J, paediatric intensive care unit (PICU), Mediclinic Private Hospital, Bloemfontein.* Masea a batlilweng bakeng sa diphuputso ho ya ka ditaelo tsa diphuputso le mekgwa ya kenyeletso a tla dula e le karolo ya diphuputso, leha ba ne ba amohetswe ho yuniti ya I mme hamorao ba fetisetswa ho yuniti ya J.

Haeba o dumela ho ba le seabo diphuputsong tsena, o tla tshwanela ho etsa tse latelang:

- Fana ka tokomane e ngotsweng ya tumello ya hore lesea la hao le fuwe le ho sebedisa *Octo-Sense aid* ha ba ntse ba le yuniting ya *neo-natal intensive care unit* nakong ya diphuputso tsena.
- Dula ka ho tsepama tshebetsong tse tlwaelehileng tsa *neonatal intensive care unit.*

***Octo-Sense aid* ke eng?**

Octo-Sense aid ke tami e se nang tjhefu e fediswang mahloko habobebe e sebopehong sa *octopus* mme e entswe jwaloka sesebediswa sa ho thusa lesea ho ithodisa haeba le sa nkuwa la thodiswa le ho ithuta diketso tsa ho nyanya, ho hlafuna le ho phefumoloha pakeng tsa dinako tsa ho fetjwa.

Melemo e ka bang teng diphuputsong tsena:

- Diphuputso tsena di tla thusa mofuputsi ho fumana hore *Octo-Sence aid* e ntlafatsa boitshwaro bo itlhahelang feela ba masea ha a le diyuniting tsa *neonatal intensive care units*.
- Ho ba teng ha manakana ana a tami e kang *octopus* letsohong la lesea ha le nyanya tami a ka nna a fokotsa monyetla wa hore lesea le nne le hule dikgwele, ditjhupu le dikgwele tse hoketsweng mmeleng wa lona.
- Manakana ana a tami ya *Octo-Sense* a batla a tshwana le mokgubu mme ho tshwana hona ho ka etsa hore lesea le kgutse le be bonolo.

Hlokomela: Ha ho na molemo kapa monyetla wa tjhelete bakeng sa ho ba le seabo ha hao thutong ena ya diphuputso.

Na ho na le kgonahalo ya dikotsi tse amanang le ho ba le seabo ha hao diphuputsong tsee?

Ha ho na dikotsi tse tlwaelehileng tse amanang le ho ba le seabo ha hao diphuputsong tsena. Haeba ngwana a sa kgema hantle le *Octo-Sense*, thuto ena ya tekolo e tla emiswa hanghang mme mooki ya sebetsanang le lesea hammoho le setsebi sa *paediatrician* ba tla tsebiswa. Ho tla nkuwa dikgato tse tshwanelehang ho etsa bonnete ba hore boiketlo ba lesea le tshireletso ya lona di ba teng ka nako tsohle.

Ke mang ya tla fihlella direkoto tsa hao tsa bongaka?

Dintlha tsohle tse bokeletsweng di tla bolokwa e le sephiri. Haeba di sebediswa ka hara phatlalatso kapa diphuputso tse ngotsweng, boitsebahatso ba bankakarolo bo tla dula e le sephiri. Ke mofuputsi feela eo e leng motho a le mong ya tla ba le tumello ya ho fihlella boitsebahatso ba masea. Ditsebi tse pedi tsa bongaka tsa *occupational therapists* di tla tseba masea ka dinomoro feela tseo masea a di filweng. Ka tsela e jwalo, ke dinomoro tsena feela tse tla sebediswa bakeng sa merero manollo ya dintlha tsa dipalopalo.

Na ho na le ntho e nngwe hae eo o lokelang ho e tseba kapa ho e etsa?

- Haeba o na le dipelaelo kapa ditletlebo tse sa kang tsa sebetswa ka tshwanelo ke mofuputsi wa hao wa thuto ena ya diphuputso, o ka ikopanya le *Health Sciences Research Ethics Committee* ya Yunivesithi ya Freistata ho 051-401-7794/5.
- O tla fumana khopi ya leqephe lena la dintlha le foromo ya tumelo bakeng sa direkoto tsa hao.

Mofuputsi e moholo: René A. de Bruin

Aterese: Department of Occupational Therapy

University of the Free State

Bloemfontein **Nomoro ya boikopanyo:** 082 559 9121

TUMELO YA HO BA LE SEABO DIPHUPUTSONG

SEHLOOHO: Projeke e reretswe ho fumana kamoo boitshwaro ba tlhaho ba masea ka hara yuniti ya masea ya *neo-natal intensive care unit (NICU)* bo ka ntlafatswang ka teng ka tshebediso ya *Octo-Sense aid.*

NOMORO YA REFERENSE:

Phatlalatso ka Monkakarolo

Ka ho saena mona ka tlase, Nna .....

Ke dumela ho ba le seabo thutong ena ya diphuputso.

Ke phatlalatsa hore:

- Ke badile leqephe la dintlha le qhwaelletsweng mme ke dumela hore e ngotswe ka puo eo ke e utlwisisang hantle.
- Ke dumeletswe ho botsa dipotso mme di arabilwe ka botlalo.
- Ke utlwisisa hore ho ba le seabo ke **boithaopo** le hore ha ke a qobellwa ka tsela efe kapa efe ho ba le seabo.
- Ke utlwisisa hore ke na le tokelo ya ho ikgula thutong ena ya diphuputso ka nako efe kapa efe ka ntle ho kahlolo kapa tsheollo.
- Ke a dmela hore mofuputsi o na le tokelo ya ho ntlosa diphuputsong tsena ka nako efe kapa efe, haholoholo haeba ke sa kgema le ditataiso tsa diphuputso. Ditakatso tsa boiketlo ba lesea di tla ananelwa ho tla pele.

E saenetswe mane (sebaka) .....ka (letsatsi) .....

.....

Tshaeno ya Monkakarolo

Phatlalatso ka Mofuputsi

Nna (lebitso) ..... ke phatlalatswa hore:

- Ke hlalositse dintlha tsa tokomane ena ho .....
  eo e leng motswadi /mohlokomedi wa molao wa lesea.
- Ke mo kgothaleditse ho botsa dipotso mme ka ipha nako e lekaneng ya ho di araba.
- Ke kgotsofetse hore o utlwisisa dintlha tsohle tsa diphuputso ka botlalo jwalokaha di hlalositswe tokomaneng ena.
- Ke sebedisitswe / ha ke a sebedisa motoloki. (haeba motoloki a sebedisitswe, yena motoloki o lokela ho saena phatlalatso ena mona ka tlase).

E saennwe mane (sebaka) ..... ka la

(letsatsi) .....

....

Tshaeno ya Mofuputsi **Tshaeno ya Paki**

Phatlalatso ka Motoloki

Nna (lebitso) ..... ke phatlalatsa hore:

- Ke thusitse mofuputsi (lebitso) ..... ho

hlalosa dintlha tse tokomaneng ena ho (lebitso la monkakarolo)

....., ka ho sebedisa puo ya Afrikaans/English, Sesotho.

- Re mo kgothaledise ho botsa dipotso mme ra ipha nako e leaneng ya ho di araba.
- Ke fane ka lehlakore la dintlha tse nepahetseng la seo ke se boleletsweng.
- Ke kgotsofetse hore monkakarolo o utlwisisa ka botlalo dikateng tsa tokomane ena ya tsebiso ya tumello mme ke entse hore dipotso tsohle di arajwa ka botlalo ka tsea e kgotsofatsang.

E saenetswe mane (sebaka) ..... ho

(letsatsi) .....

.....	.....
Tshaeno ya Motoloki	**Tshaeno ya Paki**

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1 June 2024

ADDENDUM TO ORIGINAL CONSENT FORM FOR THE STUDY:

Self-regulation of preterm infants in the Neonatal Intensive Care Unit while engaged with Sensory Integration-informed intervention and Octo-Sense technology

Conducted by: René de Bruin, Occupational Therapist

The Protection of Personal Information Act of 2018 (POPIA) applies to research activities involving individuals' identifiable personal information. Research's impact on participants' right to privacy is not just a POPIA obligation but also an integral part of research ethics.

Parents/legal guardians of preterm infants signed the consent forms between 2021 and 2022. Unfortunately, these consent forms were not POPIA compliant. The researcher did not mention that she would use videos from NICU infants, Mediclinic Bloemfontein. Therefore, the new consent form.

With this new consent form, parents/legal guardians consent that the researcher may use these videos taken between 2021 and 2022 in her study. The researcher shared the videos with two observers appointed to watch the videos to complete the observational checklists used in the study. The researcher will not share the videos with anyone other than the two observers or on any public platform. The researcher transferred all data to Figshare. The researcher permanently deleted the Google Drive folder she used to save the data during the data-gathering period. Figshare, the University of the Free State's platform, has allowed data safekeeping for ten years, after which the platform would automatically archive the data. The researcher shredded all the hard copies of all the data sheets.

The Octo-Sense pacifier (silicone octopus) used in the study is a new assistive device that Mr Brandon Halasz developed before the study. Mr Brandon Halasz owns the Intellectual Property (IP). The previous consent form mentioned that infants in the control group would use the standard pacifier, and infants in the experimental group would use the Octo-Sense pacifier.

As soon as the researcher included an infant in the study, the infant was de-identified by giving a randomised number provided by the biostatition's randomised list. The researcher continued to use randomised numbers throughout the study.

The researcher may publish the study's results in academic journals. However, the videos used to gather data for the observational checklist will not be published.

Herby consent is given to use the photo that was taken in the NICU, Mediclinic, Bloemfontein in the dissertation. This document is for the researcher's supervisors and examinators.

I, ...

(Name and surname)

(parent/legal guardian) of .....

(infant's name and surname)

give consent for videos from 2021 to 2022 to be used in the Occupational Therapist René de Bruin studies.

....

Signature or parent/legal guardian Date

Researchers contact information:

René de Bruin

Occupational Therapist/Researcher

082 559 9121

renedebruinot@gmail.com

Supervisor's contact information:

Mrs Monique Strauss

Department of Occupational Therapy

051-401-2829

To lodge a complaint against the researcher, contact HSREC at:

HSREC Administration
T: +27 51 401 2352
E: ethicsfhs@ufs.ac.za

HSREC Administration
T: +27 51 401 9860
E: ethicsfhs@ufs.ac.za

All correspondence addressed to:
The Chair: Health Sciences Research Ethics Committee
Block D, Rooms D115 and D112
Francois Retief Building
Po Box 339 (G40)
Nelson Mandela Drive
Faculty of Health Sciences
University of the Free State
Bloemfontein
9300

University of the Free State – Sasol Library

051-401-2989

Ufslibrary@ufs.ac.za

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ADDENDUM R

Randomised List compiled by the Biostatistician

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RANDOMIZED LIST

1	Gender = F; gestation= 32- 32/6 delayed oral feeding due to prolonged null per os (NPO)= Yes and/or prolonged invasive ventilation= Yes PDA=Yes
2	Gender = F; gestation= 32- 32/6 delayed oral feeding due to prolonged null per os (NPO)= No and/or prolonged invasive ventilation= Yes PDA=Yes
3	Gender = F; gestation= 32- 32/6 delayed oral feeding due to prolonged null per os (NPO)= No and/or prolonged invasive ventilation= No PDA=Yes
4	Gender = M; gestation= 32- 32/6 delayed oral feeding due to prolonged null per os (NPO)= Yes and/or prolonged invasive ventilation= Yes PDA=Yes
5	Gender = M; gestation= 32- 32/6 delayed oral feeding due to prolonged null per os (NPO)= No and/or prolonged invasive ventilation= Yes PDA=Yes
6	Gender = M; gestation = 32- 32/6 delayed oral feeding due to prolonged null per os (NPO)= No and/or prolonged invasive ventilation= No PDA=Yes
7	Gender = F; gestation= 32- 32/6 delayed oral feeding due to prolonged null per os (NPO)= Yes and/or prolonged invasive ventilation= Yes PDA=No
8	Gender = F; gestation= 32- 32/6 delayed oral feeding due to prolonged null per os (NPO)= No and/or prolonged invasive ventilation= Yes PDA=No
9	Gender = F; gestation= 32- 32/6 delayed oral feeding due to prolonged null per os (NPO)= No and/or prolonged invasive ventilation= No PDA= No
10	Gender = M; gestation= 32- 32/6 delayed oral feeding due to prolonged null per os (NPO)= Yes and/or prolonged invasive ventilation= Yes PDA= No
11	Gender = M; gestation= 32- 32/6 delayed oral feeding due to prolonged null per os (NPO)= No and/or prolonged invasive ventilation= Yes PDA= No
12	Gender = M; gestation= 32- 32/6 delayed oral feeding due to prolonged null per os (NPO)= No and/or prolonged invasive ventilation= No PDA= No
13	Gender = F; gestation= 33- 33/6 delayed oral feeding due to prolonged null per os (NPO)= Yes and/or prolonged invasive ventilation= Yes PDA=Yes
14	Gender = F; gestation= 33- 33/6delayed oral feeding due to prolonged null per os (NPO)= No and/or prolonged invasive ventilation= Yes PDA=Yes
15	Gender = F; gestation=33- 33/6 delayed oral feeding due to prolonged null per os (NPO)= No and/or prolonged invasive ventilation= No PDA=Yes
16	Gender = M; gestation= 33- 33/6delayed oral feeding due to prolonged null per os (NPO)= Yes and/or prolonged invasive ventilation= Yes PDA=Yes
17	Gender = M; gestation= 33- 33/6delayed oral feeding due to prolonged null per os (NPO)= No and/or prolonged invasive ventilation= Yes PDA=Yes
18	Gender = M; gestation= 33- 33/6delayed oral feeding due to prolonged null per os (NPO)= No and/or prolonged invasive ventilation= No PDA=Yes
19	Gender = F; gestation= 33- 33/6 delayed oral feeding due to prolonged null per os (NPO)= Yes and/or prolonged invasive ventilation= Yes PDA=No
20	Gender = F; gestation= 33- 33/6 delayed oral feeding due to prolonged null per os (NPO)= No and/or prolonged invasive ventilation= Yes PDA=No
21	Gender = F; gestation= 33- 33/6 delayed oral feeding due to prolonged null per os (NPO)= No and/or prolonged invasive ventilation= No PDA= No

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22	Gender = M; gestation= 33- 33/6 delayed oral feeding due to prolonged null per os (NPO)= Yes and/or prolonged invasive ventilation= Yes PDA= No
23	Gender = M; gestation= 33- 33/6 delayed oral feeding due to prolonged null per os (NPO)= No and/or prolonged invasive ventilation= Yes PDA= No
24	Gender = M; gestation = 33- 33/6 delayed oral feeding due to prolonged null per os (NPO)= No and/or prolonged invasive ventilation= No PDA= No
25	Gender = F; gestation= 34- 34/6 delayed oral feeding due to prolonged null per os (NPO)= Yes and/or prolonged invasive ventilation= Yes PDA=Yes
26	Gender = F; gestation= 34- 34/6delayed oral feeding due to prolonged null per os (NPO)= No and/or prolonged invasive ventilation= Yes PDA=Yes
27	Gender = F; gestation= 34- 34/6delayed oral feeding due to prolonged null per os (NPO)= No and/or prolonged invasive ventilation= No PDA=Yes
28	Gender = M; gestation= 34- 34/6delayed oral feeding due to prolonged null per os (NPO)= Yes and/or prolonged invasive ventilation= Yes PDA=Yes
29	Gender = M; gestation= 34- 34/6 delayed oral feeding due to prolonged null per os (NPO)= No and/or prolonged invasive ventilation= Yes PDA=Yes
30	Gender = M; gestation= 34- 34/6 delayed oral feeding due to prolonged null per os (NPO)= No and/or prolonged invasive ventilation= No PDA=Yes
31	Gender = F; gestation= 34- 34/6 delayed oral feeding due to prolonged null per os (NPO)= Yes and/or prolonged invasive ventilation= Yes PDA=No
32	Gender = F; gestation= 34- 34/6 delayed oral feeding due to prolonged null per os (NPO)= No and/or prolonged invasive ventilation= Yes PDA=No
33	Gender = F; gestation= 34- 34/6 delayed oral feeding due to prolonged null per os (NPO)= No and/or prolonged invasive ventilation= No PDA= No
34	Gender = M; gestation= 34- 34/6 delayed oral feeding due to prolonged null per os (NPO)= Yes and/or prolonged invasive ventilation= Yes PDA= No
35	Gender = M; gestation= 34- 34/6 delayed oral feeding due to prolonged null per os (NPO)= No and/or prolonged invasive ventilation= Yes PDA= No
36	Gender = M; gestation = 34- 34/6 delayed oral feeding due to prolonged null per os (NPO)= No and/or prolonged invasive ventilation= No PDA= No
37	Gender = F; gestation= 35- 35/6 delayed oral feeding due to prolonged null per os (NPO)= Yes and/or prolonged invasive ventilation= Yes PDA=Yes
38	Gender = F; gestation= 35- 35/6 delayed oral feeding due to prolonged null per os (NPO)= No and/or prolonged invasive ventilation= Yes PDA=Yes
39	Gender = F; gestation= 35- 35/6 delayed oral feeding due to prolonged null per os (NPO)= No and/or prolonged invasive ventilation= No PDA=Yes
40	Gender = M; gestation= 35- 35/6 delayed oral feeding due to prolonged null per os (NPO)= Yes and/or prolonged invasive ventilation= Yes PDA=Yes
41	Gender = M; gestation= 35- 35/6 delayed oral feeding due to prolonged null per os (NPO)= No and/or prolonged invasive ventilation= Yes PDA=Yes
42	Gender = M; gestation= 35- 35/6 delayed oral feeding due to prolonged null per os (NPO)= No and/or prolonged invasive ventilation= No PDA=Yes
43	Gender = F; gestation= 35- 35/6 delayed oral feeding due to prolonged null per os (NPO)= Yes and/or prolonged invasive ventilation= Yes PDA=No

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44	Gender = F; gestation= 35- 35/6 delayed oral feeding due to prolonged null per os (NPO)= No and/or prolonged invasive ventilation= Yes PDA=No
45	Gender = F; gestation= 35- 35/6 delayed oral feeding due to prolonged null per os (NPO)= No and/or prolonged invasive ventilation= No PDA= No
46	Gender = M; gestation= 35- 35/6 delayed oral feeding due to prolonged null per os (NPO)= Yes and/or prolonged invasive ventilation= Yes PDA= No
47	Gender = M; gestation= 35- 35/6 delayed oral feeding due to prolonged null per os (NPO)= No and/or prolonged invasive ventilation= Yes PDA= No
48	Gender = M; gestation = 35- 35/6 delayed oral feeding due to prolonged null per os (NPO)= No and/or prolonged invasive ventilation= No PDA= No
49	Gender = F; gestation= 36- 36/6 delayed oral feeding due to prolonged null per os (NPO)= Yes and/or prolonged invasive ventilation= Yes PDA=Yes
50	Gender = F; gestation= 36- 36/6 delayed oral feeding due to prolonged null per os (NPO)= No and/or prolonged invasive ventilation= Yes PDA=Yes
51	Gender = F; gestation= 36- 36/6 delayed oral feeding due to prolonged null per os (NPO)= No and/or prolonged invasive ventilation= No PDA=Yes
52	Gender = M; gestation= 36- 36/6 delayed oral feeding due to prolonged null per os (NPO)= Yes and/or prolonged invasive ventilation= Yes PDA=Yes
53	Gender = M; gestation= 36- 36/6 delayed oral feeding due to prolonged null per os (NPO)= No and/or prolonged invasive ventilation= Yes PDA=Yes
54	Gender = M; gestation= 36- 36/6 delayed oral feeding due to prolonged null per os (NPO)= No and/or prolonged invasive ventilation= No PDA=Yes
55	Gender = F; gestation= 36- 36/6 delayed oral feeding due to prolonged null per os (NPO)= Yes and/or prolonged invasive ventilation= Yes PDA=No
56	Gender = F; gestation= 36- 36/6 delayed oral feeding due to prolonged null per os (NPO)= No and/or prolonged invasive ventilation= Yes PDA=No
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58	Gender = M; gestation= 36- 36/6 delayed oral feeding due to prolonged null per os (NPO)= Yes and/or prolonged invasive ventilation= Yes PDA= No
59	Gender = M; gestation= 36- 36/6 delayed oral feeding due to prolonged null per os (NPO)= No and/or prolonged invasive ventilation= Yes PDA= No
60	Gender = M; gestation = 36- 36/6 delayed oral feeding due to prolonged null per os (NPO)= No and/or prolonged invasive ventilation= No PDA= No

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ADDENDUM S

Observational checklist during Sensory Integration-Informed Therapy WITHOUT Octo-Sense Technology

and

Observational checklist during Sensory Integration-Informed Therapy WITH Octo-Sense Technology

1. Observational checklist during SI-Informed intervention **WITHOUT** Octo-Sense Technology

Number: _____

Date: _____

Video: _____

Observer | A | B

Mark the corresponding behaviour with an X

Time in min	0-1	1-2	2-3	3-4	4-5	5-6	6-7	7-8	8-9	9-10
Crying 										
Active awake 										
Quiet awake (Face open) 										
Drowsy 										
Active sleep 										
Quiet deep sleep 										

Time in min	0-1	1-2	2-3	3-4	4-5	5-6	6-7	7-8	8-9	9-10
Manifestations observed in motor system										
Regulated: Flexed arms										
Flexed legs										
Grasping										
Unregulated: Flaccid arms										
Flaccid legs										
Extended arms										
Extended legs										
Arching neck										
Arching back										
Finger splaying										
Toe splaying										
Stop sign										
Fisting										
Location: Crib										
Open incubator										
Closed incubator										
Tube Feeding: No										
Nasogastric tube										
Orogastric tube										

Comments:

Observational checklist during SI-Informed intervention WITHOUT Octo-Sense Technology										
Time in min	0-1	1-2	2-3	3-4	4-5	5-6	6-7	7-8	8-9	9-10
Holding pacifier in mouth										
Actively sucking pacifier										

Adapted from:
NIDCAP Observation Sheet,
Als, H.,etal.(1986).
Little Steps, www.littlesteps.co.za

2. Observational checklist during SI-Informed intervention **WITH** Octo-Sense Technology

Number: _____

Date: _____

Video: _____

Observer | A | B

Mark the corresponding behaviour with an X

Time in min	0-1	1-2	2-3	3-4	4-5	5-6	6-7	7-8	8-9	9-10
Crying 										
Active awake 										
Quiet awake (Face open) 										
Drowsy 										
Active sleep 										
Quiet deep sleep 										

Time in min	0-1	1-2	2-3	3-4	4-5	5-6	6-7	7-8	8-9	9-10
Colour: Jaundice										
Pink										
Pale										
Mottled										
Visceral: Spit up										
Gag										
Burp										
Sigh										
Hiccup										
Face: Tongue extension										
Hand(s) to face										
Mouthing										
Suck search										
Sucking: Hand										
Finger										
Attention: Fuss										
Yawn										
Sneeze										
Frown										
Eyes closed										
Face/ Eyes open										
Made eye contact										
Looked at camera										
Avert										
Head: Right										
Left										
Middle										
Posture: Prone										
Supine										
Left side										
Right side										
Nest: Yes										
No										

2

Time in min	0-1	1-2	2-3	3-4	4-5	5-6	6-7	7-8	8-9	9-10
Colour: Jaundice										
Pink										
Pale										
Mottled										
Visceral: Spit up										
Gag										
Burp										
Sigh										
Hiccup										
Face: Tongue extension										
Hand(s) to face										
Mouthing										
Suck search										
Sucking: Hand										
Finger										
Attention: Fuss										
Yawn										
Sneeze										
Frown										
Eyes closed										
Face/ Eyes open										
Made eye contact										
Looked at camera										
Avert										
Head: Right										
Left										
Middle										
Posture: Prone										
Supine										
Left side										
Right side										
Nest: Yes										
No										

Time in min	0-1	1-2	2-3	3-4	4-5	5-6	6-7	7-8	8-9	9-10
Manifestations observed in motor system										
Regulated: Flexed arms										
Flexed legs										
Grasping										
Unregulated: Flaccid arms										
Flaccid legs										
Extended arms										
Extended legs										
Arching neck										
Arching back										
Finger splaying										
Toe splaying										
Stop sign										
Fisting										
Location: Crib										
Open incubator										
Closed incubator										
Tube Feeding: No										
Nasogastric tube										
Orogastric tube										

Observational checklist during SI-Informed intervention WITH Octo-Sense Technology

Time in min	0-1	1-2	2-3	3-4	4-5	5-6	6-7	7-8	8-9	9-10
Holding pacifier in mouth										
Sucking pacifier										
Holding on to tentacle/s with one hand										
Holding on to tentacle/s with both hands										

Affordance of Octo-Sense:	Yes	No
Touch-able		
Hold-on-able		
Grab-able		

Comments:

Any other affordances observed:

Adapted from:
NIDCAP Observation Sheet,
Als, H.,etal.(1986).
Little Steps, www.littlesteps.co.za

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ADDENDUM T

Observational checklist used in the Pilot Study

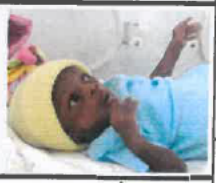
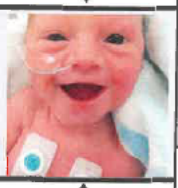
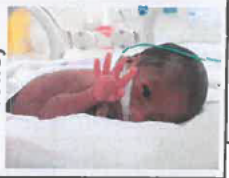
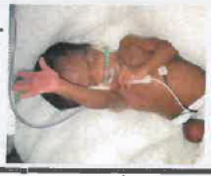
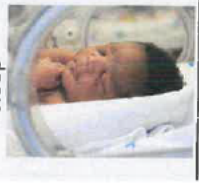
Observational checklist during Sensory Integration-informed Intervention WITH and WITHOUT Octo-Sense

1

Observational Checklist during SI-Informed Intervention WITH and WITHOUT Octo-Sense Technology

Mark the corresponding behaviour with an X

Number:	
Date:	
Day:	
Time:	
Observer	A / B

Behavioural State	Time in min	0-1	1-2	3-4	5-6	7-8	9-10
 Crying							
 Active awake							
 Quiet awake (Face open)							
 Drowsy							
 Active sleep							
 Quiet deep sleep							

Time in min	0-1	1-2	3-4	5-6	7-8	9-10
Colour: Jaundice						
Pink						
Pale						
Mottled						
Visceral: Spit up						
Gag						
Burp						
Sigh						
Hiccup						
Face: Tongue extention						
Hand to face						
Mouthing						
Suck search						
Sucking: Hand						
Finger						
Attention: Fuss						
Yawn						
Sneeze						
Face open						
Avert						
Frown						
Head: Right						
Left						
Middle						
Nest: Yes						
No						
Posture: Prone						
Supine						
Left Side						
Right side						

Time in min	0-1	1-2	3-4	5-6	7-8	9-10
Manifestations observed in motor system						
Regulated: Flexed arms						
Flexed legs						
Grasping						
Unregulated: Flaccid arms						
Flaccid legs						
Extended arms						
Extended legs						
Arching neck						
Arching back						
Finger splay						
Stop sign						
Fisting						

Location: Crib	
Open incubator	
Closed incubator	
Tube Feeding: No	
Nasogastric tube	
Orogastric tube	

Comments:

Observational checklist during SI-Informed intervention WITH Octo-Sense Technology

Time in min	0-1	1-2	3-4	5-6	7-8	9-10
Holding pacifier in mouth						
Sucking pacifier						
Holding on to tentacle/s with one hand						
Holding on to tentacle/s with both hands						
Eyes closed						
Eyes open						
Infant made eye-contact: YES/NO If yes, with whom/what:						

Affordances of Octo-Sense:

Touch-able	
Twirl-able	
Hold-on-able	
Grab-able	
Look-at-able	

Any other affordances observed:

Adapted from: NIDCAP Observation Sheet, Als, H.,etal.(1986). Little Steps, www.littlesteps.co.za

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ADDENDUM U

Operational Management of COVID-19 within MCSA Hospitals

Policy C.1.1

OPERATIONAL MANAGEMENT OF COVID-19 WITHIN MCSA HOSPITALS

POLICY MCSA.C.1.1

1. Purpose

This COVID-19 Policy is an amalgamation of all policies relating to the operational management of COVID-19 in MCSA hospital as of 19th May 2021. It covers 3 broad Sections:

1. Management of Patients
2. Management of Healthcare Workers
3. Management of Visitors

Version 1 – UPDATES 28 May 2021

Updates include latest evidence and literature related to the impact of vaccination and diagnostic tests on the management of COVID-19 in patients, Healthcare Workers and visitors.

ACCESS CONTROL

- Number of access control points may be determined by the hospital, but must be limited during a surge.
- Hospitals should consider using trained security personnel at access control.
- A designated person to co-ordinate access control must be determined at hospital level.

TESTING AND DIAGNOSIS

- With our existing international knowledge on the impact of vaccination on patients, our current view on diagnostic testing for COVID-19 **remains in place** until further local or international guidance is available.
- **No change to pre-admission PCR testing requirements with vaccination.**
- Use of Rapid Antigen Testing, either laboratory or Point of Care test, may be used on symptomatic patients for rapid diagnosis and appropriate placement.
- Doctors' guideline: Ideal timing before elective surgery is 7 weeks post-acute COVID-19 infection. Doctor and patient to evaluate the risk and benefits of surgery when determining the urgency thereof.
- Doctors' guideline: Please indicate "Mediclinic pre-admission" on the laboratory request form: Location section. This is to be done for patients for surgery, as well as patients who are being seen as outpatients, during a surge. It will allow automated import of the results into the ICNet systems and then Notifiable Medical Conditions reporting to the NICD.
- COVID-19 Notifiable Medical Condition (NMC) reporting remains in place, no matter which testing method has been used. The reporting is now automated with the NICD for all patients who are loaded on ICNET, thereby removing duplicate reporting effort for IPC managers.

IPC PRACTICES PPE

- Current guidance from the WHO and the NICD on SARS-CoV-2 transmission routes has not changed. Therefore application of precautions, in addition to universal masking and eye protection,

remains applicable based on the two known routes of transmission (via droplet and contact transmission routes). Aerosols may be generated when in close proximity to specific procedures and airborne precautions with the use of an N95, or equivalent respirator, is indicated.

- A disposable gown: Only indicated if a significant or expected exposure risk to fluids is anticipated which includes aerosol generating procedures and not routinely on an ongoing basis. Initially gowns were adopted when COVID-19 began. However, a gown is not required for ongoing care activities and healthcare workers are adequately protected by wearing a plastic apron.
- A plastic apron should be used when in close contact with COVID-19 patients.
- Gloves: Only when indicated for contact with non-intact skin, mucous membranes, blood and body fluid.
- Aprons (or gown) and gloves used must be removed before leaving the immediate patient area (patient zone).

HEALTHCARE WORKER SURVEILLANCE

- Access control for healthcare workers (HCWs), via the Health Professional Clearance App, continues and now includes symptoms and risk factors linked to their vaccination status,
- The following principles apply when interpreting symptoms or exposure in HCWs who are vaccinated:
    a. HCW with any symptoms immaterial of vaccination status, should be investigated and managed as per normal protocols
    b. HCW with high risk exposure immaterial of vaccination status, should quarantine and be tested on return on day 5. They should be monitored for symptoms by INCON (designated nurse where Incon is not present) and registered on the HCW monitoring app.
- With the roll out of the vaccination program for Healthcare workers, random staff testing is no longer required. Only targeted testing in outbreaks or for symptomatic HCWz is needed.

VISITING HOURS:

- Visiting hours are only stopped in situations of surge (of COVID-19 occupancy) to protect the HCWs, patients and visitors from spread.
- Where hospitals have lower COVID-19 occupancy, visitors to COVID-19 and non-COVID-19 patients should be allowed under specific circumstances as generously as possible.
- Normal provisions continue for terminal, long stay, vulnerable, maternity and paediatric patients.
- Virtual visitation is encouraged under all circumstances.
- Visitors who have been fully vaccinated (all required doses) and more than 30 days post-vaccination should be allowed to access the hospital if they are symptom free to visit COVID-19 positive patients.

This is a dynamic document which changes as the NICD case definition and guidance changes, the COVID-19 related regulations are promulgated and the pandemic waves evolves. It is effective at the time of issue and may be updated or changed at any time.

2. Definitions

ABBREVIATION	DEFINITION	DESCRIPTION
AGP	Aerosol generating procedures	Aerosol generating procedures, where mechanical force during intubation, cardiopulmonary resuscitation, tracheotomy and bronchoscopy increase the risk of exposure and contamination.
COVID-19	Coronavirus disease 2019	Coronavirus disease is the infectious disease and illness caused by the novel SARS-CoV-2 virus.
EC	Emergency Centre	
HCW	Healthcare worker	HCW refers to Mediclinic employees, contract workers, agency staff, volunteers and ancillary healthcare workers, doctor and their staff.
MDRO	Multi Drug Resistant Organisms	Multi Drug Resistant Organisms are defined as microorganisms, predominantly bacteria, that are resistant to one or more classes of antimicrobial agents.
NICD	National Institute for Communicable Diseases	The National Public Health Institute of South Africa providing reference to microbiology, virology, epidemiology, surveillance and public health research, to support government's response to communicable disease threats.
PCR	Polymerase chain reaction	PCR is reverse transcriptase polymerase chain reaction (RT-PCR) molecular test for the identification of Sars CoV2 virus.
SARS-CoV-2	Severe acute respiratory syndrome coronavirus 2	The name given to the novel (newly identified) enveloped virus which is part of the Coronavirus group of viruses.
RTW	Return to work	

3. Responsibilities

Role	Responsibility
Hospital General Manager	• Ultimately accountable for the compliance with the minimum standards held within this policy. • Implementation of the requirements in this policy whilst adapting them to the specific situation and operational needs of the hospital. • Communicate the needs of this with doctors in the facility and ensure compliance.
Nursing Manager/Hospital Clinical Manager/ IPC and PSM	• Communicate and assist with the implementation of the policies and ensure compliance by all HCWs in the hospital.
All Health Care Workers including Medical Practitioners	• Ensure compliance with the requirements in this policy.

MANAGEMENT OF COVID-19 PATIENTS

The following key requirements must be implemented for all MCSA hospitals whilst the country has declared a Disaster and Disaster Management regulations are enacted.

1. Access control for all people accessing a facility

Access control must be implemented to limit risk of spread to patients and HCWs. The following needs to be in place whilst the Disaster Management Act is enforced:

a) Access control applies to every single person who visits or works in the hospital.
b) Access control at hospital entrances is to be implemented 24 hours a day, seven days a week.
c) Co-ordination of the access control function must be decided upon at hospital level and a dedicated person should be identified who can review and engage with Corporate Office on any update/improvements to this policy.
d) Hospital to determine the most suitable number of access control points in order to allow for the control of people entering the hospital. These may have to be limited when a surge occurs in order to control flow through the hospital.
e) A dedicated entrance for HCWs during shift change, over times, must be implemented. The goods access point is only for goods and not people.
f) The person/s manning the access points must be trained to understand the process and have access to a nurse well versed in the criteria for diagnosing COVID-19 where needed. Hospitals should consider utilising trained security personnel and use the electronic access applications wherever possible. Use of trained volunteers (within the parameters set out by HR) at access control points should also be considered.
g) For surgical, medical and obstetric admissions access is clinically based – these patients cannot be denied access as they need admission. However, in order to protect other patients and healthcare workers, they will need to be directed and managed in a dedicated area if they screen 'red'.
h) All patients and visitors to doctors rooms must have their temperature monitored, using either thermal or hand held temperature scanners. There is no need to record the temperature. Should their temperature be >38 degrees, they will need to assessed by a nursing professional and appropriately directed.
i) Placement of thermal cameras and hand held scanners needs to be reviewed in order to allow sufficient access points and reduce queues. Hospital to determine suitable placement of these, based on access control points.
j) All persons older than two years old entering the facility must wear a mask.
k) A parent with a child for admission, are seen as a single unit and are admitted together.
l) Signage: Way-finding signage needs to be in place, posters in the access control points must reflect the process that needs to be followed in this area and direct patients and visitors to the appropriate electronic application. These should include instructions to use the electronic access control app.
m) Physical distancing (indicate by markings on the floor) and hand hygiene have to be applied in the access control area. Ensure that alcohol hand rub is available and hand hygiene posters are displayed.
n) Paper based access control questionnaires should be kept for 3 months.
o) Access to the EC is only via the EC access control point which may be situated just inside/outside the EC pedestrian entrance. Ambulance access will still occur via the ambulance entrance.
The EC access control point may need to be moved outside the EC during a COVID-19 surge as the number of patients accessing the EC might limit the ability to safely social

distance in the EC waiting room. The EC triage point can also be moved outside the EC during a COVID-19 surge in order to utilise the triage room as a clinical area.

Patients will have two modes of gaining access:

- At the main entrance on the day of admission – this can be by using the WhatsApp Bot or paper based, or
- Surgical patients will require a risk assessment online, 24 hours prior to admission via the Engage platform SMS system. If they do not complete this, they will follow the WhatsApp Bot or paper based version at the entrance on the day of admission.

2. Pre-admission symptom screening and access control for surgery patients

Pre-admission symptom screening and access control for all patients for elective surgery is a requirement utilising the Engage platform to streamline access on day of admission:

a) Doctor/practice rooms should be encouraged to guide all elective patients to complete the ENGAGE pre-admission risk screening process.
b) Risk assessment should occur 24 hours before their day of admission whereby the patient will complete their online risk assessment on the secure website (Engage).
c) Outcomes of the risk assessment are communicated to the patient and doctor.
d) The results of the risk assessment must be available as a "flag" on the theatre bookings list with each patient's risk assessment status. This should be available for relevant staff in the hospital to see.
e) Patients screening with symptoms or risk factors ("red status") must be reviewed by the surgeon or admitting doctor for COVID-19 test results and risk of proceeding with the procedure.
f) The doctor/practice rooms must contact the theatre scheduling clerk to confirm or cancel the patient with a "red status" and this information should be indicated on the theatre slate.
g) Patients who do not complete their preadmission screening via Engage will need to complete screening at access control on the day.
h) Ideally no "red" status patient or one with a positive COVID-19 test result should turn up on the day of surgery. However, if they do, the staff at access control should check if the patient is still on the theatre slate. If they are on the slate, they should continue to be admitted with the patient placed in the suitable ward in the hospital.

3. Daily symptom monitoring

A process must be followed to assess admitted non-COVID-19 patients on a daily basis to allow for early identification of the development of any signs or symptoms which may indicate COVID-19 infection. Upon identification, further action to review, test and isolate the patient, pending an outcome should occur. Daily symptom monitoring must be completed as per the COVID-19 Daily Symptom Screening document (N0800). This applies to:

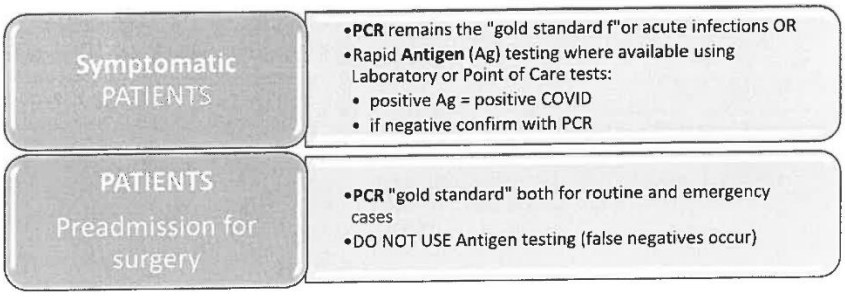
- All in patients identified as 'COVID-19 negative' from day 1 of admission until discharge.
- All maternity partners.
- All parents with children admitted.

4. COVID-19 diagnosis and testing

a) PCR remains the "gold standard" test for COVID-19 for patients prior to surgery.
b) All surgical patients must have a PCR testing 48-72 hours prior to surgery.
c) Symptomatic patients may have PCR or Rapid Antigen testing performed. In such patients a positive PCR or Antigen is considered diagnostic of COVID-19.

d) PCR may remain positive for up to 90 days and therefore repeat testing within this period is not needed. Alternative diagnoses should be considered and a respiratory PCR panel (either viral or bacterial) may assist with alternative diagnostics.
e) If after 90 days a PCR test is positive, then reinfection should be considered and reported to the NICD.
f) Patients with repeated short stay admissions should have an initial baseline PCR test performed and thereafter daily symptom monitoring. If they develop symptoms, rapid antigen testing may be utilised.
g) COVID-19 negative patients admitted for extended periods of stay should have a repeat COVID-19 test, if more than 5 days have passed since admission. If they develop symptoms at any point in time, an Antigen test or COVID-19 PCR should be performed.
h) Current knowledge on the impact of the COVID-19 vaccination on patients who require surgery is insufficient to change this policy so PCR testing prior to admission remains a requirement.
i) Additional international guidance on ideal timing for surgery indicates that where possible, elective surgery should be delayed for at least 7 weeks following SARS-CoV-2 infection. Patients with ongoing symptoms ≥ 7 weeks from diagnosis may benefit from further delay. It is for the doctor and patient to weigh up risks and benefits of surgery and determine the urgency, as the risk of mortality is as high at 23.8% whilst pulmonary complications occurred in 51% of patients.
j) Antibody serology testing is currently of limited value in diagnosing infection and documenting immunity post-vaccination or infection due to the challenges with interpretation of the results.

Figure 1 – Summary of testing methods



5. IPC practices

a) Current guidance from the WHO and the NICD on SARS-CoV-2 transmission routes has not changed therefore application of standard and transmission based precautions, in addition to universal masking and eye protection, remain applicable based on the two known routes of transmission of SARS-CoV-2 (via droplet and contact transmission routes). Aerosols may be generated when in close proximity to specific procedures and airborne precautions with the use of an N95 or equivalent respirator is indicated
b) Effective Hand Hygiene, ventilation, distancing and masks are the cornerstones to preventing its spread in the healthcare setting.
c) Standard precautions should be always adhered to. This always includes the use of a surgical mask. Eye protection should be worn in addition, when caring for suspected or confirmed COVID-19 patients.
d) Transmission based precautions are based on the route of transmission.

There are two known routes of transmission:

Zones in summary are:

- **COVID-19 positive ward (Red):** Patients with a confirmed positive result can be cohorted in one ward.
- **Suspected patient/high risk (Orange):** Patients with clinical signs and symptoms of COVID-19, or a history of contact with a confirmed or suspected case, are regarded as high risk of having COVID-19 and should be placed in an isolation room.
- If no isolation rooms are available, patients with respiratory symptoms can be cohorted.
- **Low risk/COVID-19 negative (Green):** The placement of patients in this group, should be based on risk stratification taking other IPC risks and history of MDROs into consideration:
  i. Patients without clinical signs and symptoms of COVID-19, and without a history of contact with a confirmed or suspected case, are regarded as low risk of having COVID-19 and can be cohorted with other patients if no single room is available.
  ii. Patients with prior positive tests, who have completed the required isolation period and are now symptom free, or fully vaccinated patients who are more than 30 days post-vaccination can also be placed in the green zone.

7. Personal protective equipment

a) Universal masking is required by all staff throughout MCSA hospitals. If the prevalence in the community is greater than 5%, visors must be added as universal PPE.
b) Mask and visors should be worn in COVID-19 red zones.
c) All PPE should be worn as appropriate according to IPC protocols. Table below provides an overview of the type of PPE that should be worn in each zone and based on the type of precautions needed.

Table 1: PPE use in zones

	PPE use for HCWs in each zone		
	Droplet precautions	**Contact Precautions**	**Airborne for AGPs**
COVID-19 Positive Patients	Mask Visor	Apron Gloves when indicated*	N95 or similar respirator Visor Disposable gown and/or plastic apron Gloves
Suspected or High Risk Patients	Mask Visor	Apron Gloves when indicated*	N95 or similar respirator Visor Disposable gown and/or plastic apron Gloves
Low risk and Negative Patients	Mask Visor when indicated	Only when indicated (e.g. risk of MDROs)	N95 or similar respirator for all AGPs Visor Gloves
	Universal Mask and visor		

* Contact with non-intact skin, mucous membranes, blood and body fluid

- Droplet route: Via respiratory droplets produced via sneezing, coughing or directly inhaled during close contact with the affected person.
- Contact route: Via respiratory droplets landing on environmental surfaces surrounding the infected person (also known as the patient zone and the health zone) which are then transferred through contact with contaminated hands to a person's face and mucous (eyes, nose and mouth).

e) It is possible during certain procedures, referred to as aerosol generating procedures (AGP), for example intubation, cardiopulmonary resuscitation, tracheotomy or bronchoscopy, where mechanical force disperses secretions that smaller, finer droplets, known as aerosols may disperse. For this reason, when in close proximity, airborne precautions (the use of an N95 respirator) will be required, in addition to eye protection.

f) Principles relating to standard precautions and utilisation of PPE and their applicability in the COVID-19 setting include:
   - **Hand Hygiene**: This remains the cornerstone of preventing transmission in the healthcare setting and must be performed according to the 5 Moments of Hand Hygiene. Mediclinic Corporate Policy: Hand Hygiene: MCSA.C.IPC.1.6. http://intranet/sites/Policies/Records/Hand%20Hygiene.pdf.
   - **Gloves** are used per patient during care as indicated by standard precautions and removed and discarded immediately after each use before leaving the patient zone. Contaminated gloves pose a risk and can transmit the virus and other multidrug resistant organisms to the other critical body sites on the same patient, to the environment and other patients.
   - **Aprons** should be used during activities where there is a possibility of exposure to body fluids to provide a waterproof barrier and discarded after each patient intervention. They should be removed and discarded when leaving each individual patient zone.
   - **Disposable gowns** are only indicated when a procedure is performed where there is a heightened risk for exposure to blood and body fluids, which includes aerosol generating procedures. Initially gowns were adopted when COVID-19 began. However, based on the route of transmission of SARS-CoV-2, a gown is not required for ongoing care activities and healthcare workers are adequately protected by wearing a plastic apron.

g) Environmental cleaning: SARS-CoV-2 can remain on certain surfaces (such as plastic and stainless steel) for up to 9 days. Therefore, cleaning of the environment is paramount. Increase the frequency of routine cleaning rounds to 3 times per day, with additional cleaning of frequently touched areas, especially in dedicated COVID-19 wards.

h) Equipment: Do not share equipment (as far as possible) amongst patients and ensure dedicated equipment for (isolated) patients, wherever possible. If equipment is shared, ensure that it is adequately cleaned and disinfected after use.

i) Social distancing: Maintain a distance from other people of 1.5 - 2 meters. SARS-Cov-2 droplets are heavy and do not normally travel more than 1 meter. Ensure that social distancing is maintained in tearooms and during hand over and ward rounds.

6. COVID-19 zones:

a) When COVID-19 patients volumes are low, hospitals can place patients within existing wards based on the risk-assessment and history done upon admission, i.e isolate COVID-19 positive or suspected patients, taking other multidrug-resistant organisms and infectious diseases into consideration. Dedicated zones are not required in such instances.

b) Dedicated COVID-19 and non-COVID-19 zones must be implemented during surge periods and patients placed based on their risk, into either a dedicated COVID -19 positive area, suspected patient area or negative areas. Staff need to wear the appropriate universal and additional PPE in these areas.

8. COVID-19 treatment

A separate guidelines details Mediclinic's preferred care process models and flow of patients between the Emergency Centre, wards/ICU and palliative care. This includes the admission and discharge criteria for each level of care and guides on best evidence available for medication and oxygenation treatment options and choices. It covers awake proning and links to the specific care and treatment of COVID-19 critical care, maternity and paediatric patients, as well as the management of COVID-19 patients in theatre.

9. Reporting and notification of COVID-19

The following are the COVID-19 reporting requirements for all hospitals with COVID-19 patients:

a) **COVID-19 Notifiable Medical Condition (NMC):** According to regulations, any healthcare provider (doctor or nurse) who makes a diagnosis of COVID-19 must immediately report the case to the district communicable disease co-ordinator, using one of the NMC platforms (either via the NMC App or by electronic submission of forms). This is currently being automated for all patients who are loaded on ICNET, removing duplicate reporting requirements from the IPC managers.

b) **Death certification and reporting of COVID-19 patients:** Based upon the NDOH Circular of the 21st of July 2020, by the Director General, the treating doctor must complete death certificates in a specific manner to allow for identification of COVID-19 related deaths. In addition, all patients with positive COVID-19 results who demise in a hospital are centrally and automatically reported, based on PAS discharge status codes (automated DATCOV reporting).

10. Surge management

When hospitals have become capacity and resources constrained, additional surge management principles may be implemented for the surge. The hospital should revert to normal operating principles as soon as safe to do so. Refer to COVID-19 Guidelines for the management of COVID-19 for details.:

a) **Care Areas**

i. Plan for efficient patient flow through the hospital (all patient movement to be coordinated through the hospital command centre when activated).

ii. Plan for escalation and de-escalation of all patients based on standardised assessment criteria (care process models).

iii. Attempt to group patients with similar care needs and acuity together.

iv. Movement of patients to different levels of care areas might take time, so consider the creation of a high-dependency area, a palliative care area and a discharge/lounge area.

v. Critical care and high care units will both function as critical care units.

vi. Plan to accommodate increasing and decreasing numbers of patients per care area. (need to have a Plan A, plan B and plan C based on volumes), e.g. the palliative area could be a room initially and eventually a whole ward.

vii. Plan to manage growing volumes of patients with decreasing availability of staff: Think of how to re-purpose permanent and agency staff and to rationalise patient care.

viii. Ensure that all staff are aware of the staff planning principles and rationalised documentation to be implemented during this scenario, as per guideline: 'Minimum staffing.'

ix. Educate staff and plan appropriately regarding the rational use of PPE and conservation strategies that kicks in if the PPE supplies run low.

x. Plan for different scenarios of how the hospital is going to support healthcare workers in the hospital based on risk of exposure, including PPE usage, rest areas and meal serving.

b) **Patient flow**

The following guidelines support optimal patient flow through care areas:

i. All patients seeking emergency care enter the hospital through the Emergency Centre, where patients are assessed (COVID-19 or non-COVID-19). Except for elective admissions with negative tests, in which case normal admission channels can be used.

ii. Based on the patient's condition, a decision is made on the appropriate level of care the patient should be admitted to.

iii. All ward patients (COVID-19 and non-COVID-19) will be assessed daily by the medical team, using a standardised approach. All information will be sent through to the clinical management team. Patients needing up- or down escalation of care, will be managed accordingly.

iv. All ICU patients/patients needing critical care from the wards or Emergency Centre will be assessed by the Triage Team. This information will be sent through to the clinical management team.

v. The clinical management team will then decide which patients need to be moved to a different care area as they have an overview of bed availability in the hospital.

c) **Establish the structures**

i. Ensure a well-established triage team for consistent decision making around the allocation of critical care resources, using the latest guidelines from the Critical Care Society of Southern Africa.

ii. Ensure a well-established Triage Escalation Support Team (TEST) is in place to support the decisions of the triage teams and the clinical management team structures in equitable allocation of scarce resources.

d) **Staffing Levels**

The hospitals should plan for safe staffing to accommodate severe staff absenteeism and/or a surge of patients. The following assumptions underpin minimum staffing:

i. Oversight and doctors' involvement

- Healthcare staff will be redistributed and allocated as decided by the clinical management team.
- Both the physician teams and the nursing teams will report to the clinical commander who can resolve challenges that cannot be resolved at unit level.
- An emergency medical response team (crash/resuscitation team) should be available for assessment and/or intubation of deteriorating patients.
- Staff should be allocated to communicating with patients and next-of-kin as required, e.g. the doctor, patient experience manager and shift lead.
- Doctors' rounds will be re-designed, e.g. pre-planning of rounds including the UM/shift lead will be done before daily rounds (in person or virtually).

e) **Patient care**

i. Patients will not be moved out of the unit for procedures or investigations if possible.

ii. The donning/doffing of PPE creates additional workload and pre-planning of care (e.g. getting all items needed while with the patient in PPE; using a runner/scribe; using a buddy).

iii. Patient care record keeping to be minimised.

iv. Non-essential care activities to be omitted.

f) **Staff allocation**
   i. The care team model will be expanded, with task shifting or task sharing, and relevant changes in responsibility.
   ii. Staff will be authorised to act outside their scope of practice (depending on their ability to perform such acts with reasonable skills and safety, based on education, training and experience) and will be legally protected to do so, e.g.:
      - One Professional Nurse to handle Schedule 5/6 drugs.
      - Enrolled Nurse to administer IV/SC medication.
      - Enrolled Nursing Assistant (or person in the room) to give oral drugs (set out by Enrolled Nurse/Professional Nurse).
      - Enrolled Nursing Assistant handling/changing IV bags and reconnecting lines.

g) **Staff competencies**
   i. Re-purposed and upskilled staff (e.g. theatre and recovery staff, care workers) will be included in care teams, appropriately trained and information to be available to support clinical management of COVID-19-19 patients.
   ii. On-the-job training will be provided whilst working under the guidance of a more experienced nurse.

h) **Support staff**
   i. Appropriate unit administrative assistance will be provided (administration and stock control), additional to the patient care team.

i) **Team based doctor care models**

These should be considered to support the physicians involved in daily care. Alternative support for specialists can include GPs appointed for evenings or wards. Each hospital to determine their suitable team, based approach or doctor support, discuss and agree any financial and governance implications of these, with their Regional Operations Executive.

j) **Rationalised record keeping**

Measured against the disaster situation, disaster plan and general circumstances, the following legal principles pertaining to record keeping are applicable during a surge:

   i. The records should be sufficient to communicate relevant information amongst healthcare workers.
   ii. Looking back (e.g. a year later), all the information needed should be available.
   iii. This requires documents to be rationalised and shortened to ensure care is provided without additional administrative burden on staff.

k) **Charting of surgical stock in nursing units**
   i. There is an expectation that the charting of stock in the current manner might become challenging during a COVID-19 surge scenario.
   ii. The current stock replenishment system should not be changed, although the way in which the charge sheets are completed, could be adjusted, while not compromising the accuracy of stock charting and adherence to IPC principles.
   iii. A contingency plan needs to be in place should key staff be absent, with urgent training of staff for stock replenishment roles, before a surge of patients or increased staff absenteeism is experienced.
   iv. Re-allocated staff, allocated to stock replenishment in the nursing units, should preferably have knowledge of stock, e.g. theatre nursing staff, theatre/pharmacy stock controllers or other nurses.
   v. The suggestion is therefore that hospitals consider changing the way the daily charge sheet per patient is completed, at surge and in their specific context. Examples are provided in the guidelines.

MANAGEMENT OF HEALTHCARE WORKERS

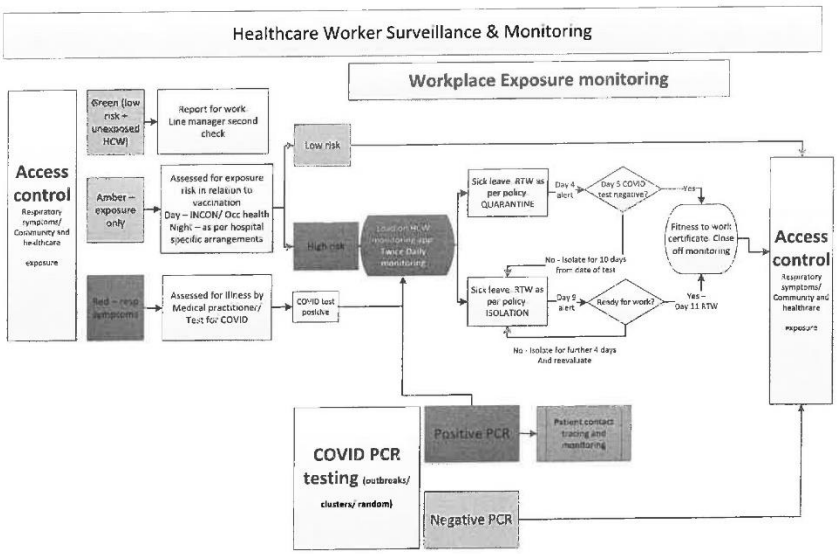
The principles for the surveillance and monitoring of all HCWs1 who are exposed to COVID-19 in the workplace is to ensure:

i. A team-based approach with the Human Resource Business Partners (HRBPs) as lead.

ii. Accurate implementation and management of the three healthcare worker surveillance and monitoring methods, namely (see figure 2 below):

- 'Access Control' to monitor all HCWs entering the hospital (low risk contacts, HCW who have completed their quarantine/isolation periods or unexposed) and govern access control to the facility by identifying respiratory symptoms/community and healthcare exposure.
- 'Workplace Exposure Monitoring' to identify and follow up on high risk contacts to ensure their wellbeing and actively manage their return to work process.
- 'COVID-19 Testing' for the SARS-CoV-2 virus which can be performed as part of clusters or outbreak management or when a HCW has symptoms.
  - Accurate and regular monitoring of the HCWs health.
  - Accurate and timeous data on the number of HCWs absent due to being in isolation or quarantine due to infection or high risk exposure to the SARS-CoV-2 virus.

Figure 2 – Healthcare Worker Surveillance and Monitoring



[1] Healthcare workers include Mediclinic employees, contract workers, agency staff, volunteers and ancillary healthcare workers, doctors and their staff.

1. Access control

Healthcare worker symptom reporting at access control must occur daily:

a. All HCWs who require access to the hospital premises, may do so online using the Health Professional Clearance App or using a paper based questionnaire system https://mediclinicforms.datafree.co/Clearance
b. Only those with a green outcome may be allowed to enter the hospital.
c. HCWs screening amber must be followed up by INCON/Occupational health services and those who screened red must be assessed for COVID-19 infections by a healthcare practitioner.
d. Hospital to determine the most suitable number of access control points to allow for the control of HCWs entering the hospital. These may have to be limited when a surge occurs to control flow through the hospital.
e. The entrance must be manned by designated staff members with access to a Nurse (e.g. L&DF, Patient Safety Manager, Clinical Facilitator, etc.) if the HCW is amber or red.
f. Hospitals should encourage the use of the electronic access applications wherever possible.

2. Workplace exposure monitoring

a. HCW with high risk contacts or exposure must be assessed and monitored.
b. Any person who has had close contact with a confirmed case, 2 days prior to a positive result or symptom onset until 14 days since onset of the symptoms of a case, should be carefully monitored for signs of respiratory symptoms (WHO contact tracing).
c. The names of all exposed healthcare workers must be recorded on the "contact line list" accessible on the Mediclinic intranet: http://intranet/communities/ClinicalServices/IPC/Guidelines/Forms/CoronaView.aspx.
d. High risk contacts must be monitored for 5 days after first exposure as required by the NICD and added to the Mediclinic Healthcare worker (HCW) monitoring application.
e. With our existing knowledge and current vaccination levels, any vaccinated HCW and has a high risk exposure should quarantine as per normal rules and test at day 5 on PCR.
f. If high risk HCWs are not responding on the HCW monitoring app, they should be followed up telephonically as per the "COVID-19 Procedure Monitoring of HCWs, 31st August 2020".
g. Low risk contacts do not need to be added on the HCW application but monitor themselves through the daily screening and do not have to be followed up actively by HRBPs.

   A high risk contact (close contact) in a healthcare setting is defined as a person having had face-to-face contact (<1 meter) or has been in a closed space with a confirmed COVID-19 case for at least 15 minutes without wearing the appropriate PPE. This includes exposure within a household which is close contact for long durations of time.
   Low risk contact (casual contact) - A healthcare worker or other person providing direct care for a confirmed COVID-19 case, while wearing recommended PPE.

h. All line managers should do a daily "check in" of staff on duty to ensure that no symptomatic people are at work.
i. Access control should be monitored daily and all staff who failed access control should be followed up immediately by their line manager and HRBP.

3. COVID-19 Testing for HCWs

a. HCW will only be tested if they exhibit symptoms of COVID-19, immaterial of their vaccination status.
b. Each employee will provide consent at the time of testing which includes that their details[2] are provided to a laboratory service provider for them to conduct the COVID-19 test and submit the required regulatory information to the National Institute for Communicable Diseases (NICD).
c. PCR testing remains the "gold standard" for staff testing. However, antigen testing may be used for symptomatic staff only.
d. With the roll out of the Vaccination program for healthcare workers, random staff testing is no longer required. Only targeted testing in outbreaks or for symptomatic patients is needed.

4. Return to work following COVID-19 infection for HCWs.

a. This policy is based upon the existing regulations and guideline documents from South Africa and internationally [1] [2]. Duration of leave is based upon the type of infection or exposure the HCW had.
b. Currently the research doesn't indicate if symptomatic vaccinated individuals are able to transmit the virus onto unvaccinated staff. Therefore the following principles apply when interpreting symptoms or exposure in HCWs:
    i. HCW with any symptoms immaterial of vaccination status, should be investigated and managed as per normal protocols, knowing that symptoms in the first three days are possibly vaccine sick effect related;
    ii. HCW with high risk exposure immaterial of vaccination status, should quarantine and be tested on return on day 5. They should be monitored for symptoms by INCON (designated nurse where Incon is not present) and registered on the HCW monitoring app.

c. The return to work guidelines have therefore not been updated with the impact of vaccination. They remain in summary as follows:
    i. **HCW COVID-19 Positive with or without symptoms**: Isolate and RTW 10 days after onset of symptoms or positive test.
    ii. **HCW with High risk exposure – immaterial of vaccination status**: quarantine and RTW after 5 days and a medical evaluation and a negative COVID-19 PCR test.
    iii. **HCW Low Risk exposure**: Continue working whilst wearing appropriate PPE and daily access control symptom monitoring.

MANAGEMENT OF VISITORS

1. Access control screening

a. Every opportunity should be provided to allow visitors to see their loved ones in hospital, without compromising their safety, that of the HCWs and that of the patients.

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[2] Employee details include the employees name, surname, identification number, age, gender, race, contact details and address.
[1] NICD Clinical management of suspected or confirmed COVID-19 disease. Version 5 (19th August 2020)
[2] CDC Criteria for Return to Work for Healthcare Personnel with Suspected or Confirmed COVID-19 (10th August 2020). https://www.cdc.gov/coronavirus/2019-ncov/hcp/return-to-work.html.
Strategies to mitigate healthcare worker shortages (19th July 2020). https://www.cdc.gov/coronavirus/2019-ncov/hcp/mitigating-staff-shortages.html

b. Visitors of patient, visitors for doctors' rooms and partners of obstetric admissions, must have their clinical symptoms or contact risk evaluated as part of access control on a per entry basis. Anyone considered high risk will be denied access to the hospital, unless for seeking medical treatment.
c. Whilst the Disaster Management Act is still enforced in South Africa, all visitors will have two modes of gaining access to the hospital or doctors' rooms:
    iv. Using a WhatsApp Bot for online completion of symptoms and risk factors. They will receive a clearance notice on their phones. This allows access control to be completed prior to arriving at the hospital and is valid for the calendar day
    v. Paper based questionnaire at the entrance.
d. **Temperature screening**: All visitors to have their temperature checked prior to entry. There is no need to record the temperature.
e. **Visitor's with a temperature in excess of 38°C**: Visitor needs to be assessed by a clinical professional before access will be allowed. If they have a doctors' appointment, that doctor's practice/rooms should be contacted to inform them of the patient's temperature and seek further guidance on access.
f. **Visitors who have been fully vaccinated (all required doses) and more than 30 days post-vaccination should be allowed to access the hospital if they are symptom free to visit COVID-19 positive patients.**

2. COVID-19 Visitation Policy

Principles

a. Wherever possible, visitation should be facilitated for the wellbeing of patients and families and to make admission for elective surgery less daunting for patients.
b. Visitors will not be routinely permitted to visit COVID-19 patients. However, this should be considered where it will not pose heightened exposure risk to the visitor or other patients, or if the visitor has been fully vaccinated (all doses required and is more than 30 days post-vaccination). Adherence to prevention measures including wearing of masks and the appropriate PPE remains a requirement.
c. The policy must be maintained uniformly across all hospitals.
d. Every effort must be made to facilitate visitation of terminal and/or long stay patients, as well as vulnerable/special needs patients. This is irrespective of the COVID-19 status of the patient. This should be facilitated after an appropriate risk assessment and the necessary PPE should be worn.
e. At all levels of visitation, partners of obstetric patients must be allowed; as well as in the case of paediatric patients (the parent and child regarded as a unit). For Neonatal ICU, both parents may be allowed in at the same time if they are COVID-19 negative.
f. All visitation is subject to access control screening.
g. **Where visitation is not allowed**: Window visits must be facilitated where possible with patient rooms being accessible on the ground floor.
h. Where visits are not possible for COVID-19 or non-COVID-19 patients, a minimum of one virtual visit should be facilitated per day.
i. Should virtual visitation not be possible or by choice of the family, at least one daily update should be given to the family.
j. One person should be allowed to accompany a patient into the EC.

With the above in mind the visitation guidelines are as follows:

Option 1	**No visitation except for those mentioned above.** Recommended when the COVID-19 occupancy of the hospital is greater than 30% of occupied beds.
Option 2	**Visitation for non-COVID-19 patients in all "mixed" wards (where there are both COVID-19 and non-COVID-19 patients)** is restricted to 1 visitor per day (multiple entries) between 10h00 and 20h00. COVID-19 patients may be accommodated according to the principles above. Recommended for occupancies of less than 30% of occupied beds.
Option 3	**Visitation for non-COVID patients in all wards where there are no COVID-19 patients** - restricted to 1 visitor at a time between 10h00 and 20h00. Recommended for occupancies of less than 30% of occupied beds
Option 4	**Original Flexible Visiting Hours policy**. Recommended "back to normal".

In all cases, the above will be the official stance of the hospital. The appropriate documentation will be available from the Patient Experience Managers for speedy changeover and updating of the website information accordingly.

More generous visitation is encouraged if a hospital can safely facilitate same.

3. ASSOCIATED DOCUMENTS AND RECORDS

TITLE	LOCATION
COVID-19 Guidelines for the Management of COVID-19 in MCSA	Intranet
Guideline for the Clinical Management of COVID-19 patients	Intranet

4. HISTORY AND VERSION CONTROL

History

VERSION NO	EFFECTIVE DATE	AUTHOR	DETAILS OF UPDATE
1	28 May 2021	Dr Kim Faure	Consolidation of all prior COVID-19 operational and management policies

New version

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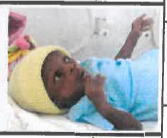
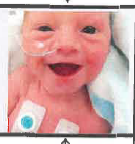
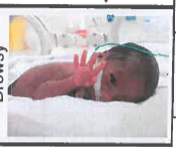
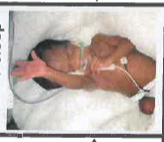
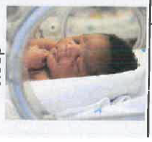
1

Observational Checklist during SI-Informed Intervention WITH and WITHOUT Octo-Sense Technology

Mark the corresponding behaviour with an X

Number:	
Date:	
Day:	
Time:	
Observer	A / B

Behavioural State

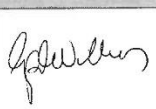
Time in min	0-1	1-2	3-4	5-6	7-8	9-10
 Crying						
 Active awake						
 Quiet awake (Face open)						
 Drowsy						
 Active sleep						
 Quiet deep sleep						

Time in min	0-1	1-2	3-4	5-6	7-8	9-10
Colour: Jaundice						
Pink						
Pale						
Mottled						
Visceral: Spit up						
Gag						
Burp						
Sigh						
Hiccup						
Face: Tongue extention						
Hand to face						
Mouthing						
Suck search						
Sucking: Hand						
Finger						
Attention: Fuss						
Yawn						
Sneeze						
Face open						
Avert						
Frown						
Head: Right						
Left						
Middle						
Nest: Yes						
No						
Posture: Prone						
Supine						
Left Side						
Right side						

	Dr Stefan Smuts	Doctor Relationship & Stakeholder Management Executive
	Kevin Seaman	National Patient Experience Manager
	Amanda Appelgryn	Patient Experience Operations Specialist
Author	Dr Kim Faure	Clinical Performance Manager
Details of update	Consolidation of prior policies	
Version number	1.1	
Effective date	2021 May 28th	
Next review date	2026 May	

5. APPROVAL AND SIGN-OFF

Approved by

DEPARTMENT	REPRESENTATIVE NAME	SIGNATURE	DESIGNATION	DATE SIGNED
Clinical	Dr Gerrit de Villiers		Chief Clinical Officer	08 June 2021
Operations	Wimpie Aucamp		Chief Operations Officer	

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ADDENDUM V

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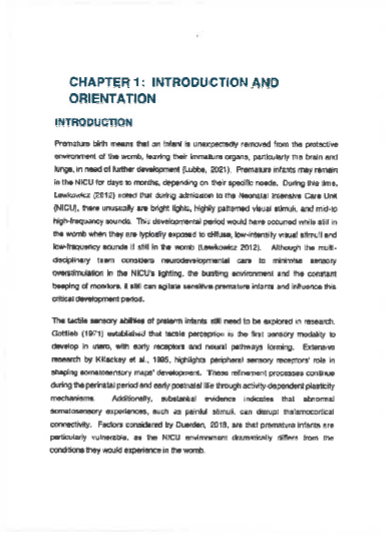

CHAPTER 1: INTRODUCTION AND ORIENTATION

INTRODUCTION

Premature birth means that an infant is unexpectedly removed from the protective environment of the womb, leaving their immature organs, particularly the brain and lungs, in need of further development (Lubbe, 2021). Premature infants may remain in the NICU for days to months, depending on their specific needs. During this time, Lewkowicz (2012) noted that during admission to the Neonatal Intensive Care Unit (NICU), there unusually are bright lights, highly patterned visual stimuli, and mid-to high-frequency sounds. This developmental period would have occurred while still in the womb when they are typically exposed to diffuse, low-intensity visual stimuli and low-frequency sounds if still in the womb (Lewkowicz 2012). Although the multi-disciplinary team considers neurodevelopmental care to minimise sensory oversimulation in the NICU's lighting, the bustling environment and the constant beeping of monitors, it still can agitate sensitive premature infants and influence this critical development period.

The tactile sensory abilities of preterm infants still need to be explored in research. Gottlieb (1971) established that tactile perception is the first sensory modality to develop in utero, with early receptors and neural pathways forming. Extensive research by Kilackey et al., 1995, highlights peripheral sensory receptors' role in shaping somatosensory maps' development. These refinement processes continue during the perinatal period and early postnatal life through activity-dependent plasticity mechanisms. Additionally, substantial evidence indicates that abnormal somatosensory experiences, such as painful stimuli, can disrupt thalamocortical connectivity. Factors considered by Duerden, 2018, are that premature infants are particularly vulnerable, as the NICU environment drastically differs from the conditions they would experience in the womb.

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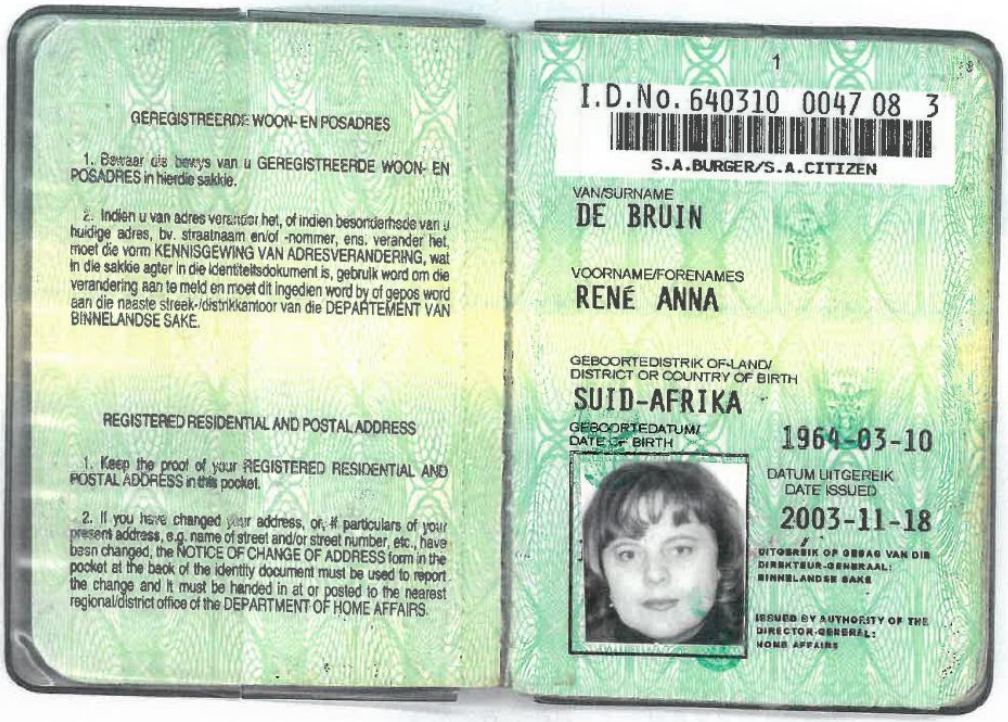
ADDENDUM W

South African Identification Document

René Anna de Bruin

196403100047083



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