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Emerging Minds podcast episodes

- The lived experience of infants in neonatal intensive care – Part One
  In the first episode of this two-part podcast, neonatologist Dr Natalie Duffy shines a spotlight on the key infant mental health concepts that guided her PHD research into the lived experience of infants in NICU.

Further Reading – please see these articles attached

- Duffy, N., Hickey, L., Treyvaud, K., & Delany, C. (2020). The lived experiences of critically ill infants hospitalised in neonatal intensive care: A scoping review. Early Human Development, 151, 105244. https://doi.org/10.1016/j.earlhumdev.2020.105244

- Duffy, N., Hickey, L., Treyvaud, K., & Delany, C. (2024). 360-Degree Phenomenology: A Qualitative Approach to Exploring the Infant Experience of Hospitalisation in Neonatal Intensive Care. https://doi.org/10.2139/ssrn.4678312

- Nicolson, S., Carron, S., & Paul, C. (2022). Supporting early infant relationships and reducing maternal distress with the newborn behavioral observations: A randomized controlled effectiveness trial. Infant Mental Health Journal, 43(3), 455–473. https://doi.org/10.1002/imhj.21987

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The lived experiences of critically ill infants hospitalised in neonatal intensive care: A scoping review

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ABSTRACT

Background: Neonatal intensive care saves lives, but the environment in which this occurs is complex and has been shown to negatively disrupt some aspects of an infant's early development. Identifying these negative effects has relied on measuring physiological and behavioural responses. Little research has sought to understand and learn from what an individual infant can communicate about their lived experience.
Aim: To examine what is known of the lived experiences of infants hospitalised in neonatal intensive care.
Study design: A scoping review using the revised Arksey and O'Malley framework was undertaken. Relevant studies, exploring an infant's experience of hospitalisation were identified through a comprehensive, systematic literature search.
Results: 4955 articles were retrieved, 88 full texts reviewed, and 23 studies included. We identified no studies that assessed the experience from the infant's perspective. The infant experience was explored using quantitative methodology, characterising, and describing the experience in measurable physiological, behavioural, and neurodevelopmental terms or through the lens of medical outcomes. The environment is described as too loud and too bright and infants are exposed to high levels of medical handling, impacting on physiology, behaviour, sleep, feeding, and both short- and longer-term outcomes.
Conclusion: The studies captured in this review focused on quantitative, measurable outcomes as a proxy for the experience as it might be felt, interpreted, and processed by an infant. Medical focus has been crucial to advance the field of neonatology, but the review highlights an important gap; the need to explore and better understand the infant's experience through their eyes.

1. Introduction

The neonatal intensive care unit (NICU) provides care for premature and critically ill infants. Progressive advancements in both perinatal and neonatal intensive care have led to dramatic improvements in the survival of premature infants and those with congenital anomalies. However, despite improved survival rates, poorer neurodevelopmental outcomes persist amongst infants hospitalised in the newborn period [1–5].

Early childhood is the most critical and vulnerable time in any child's development. It is a time when the cumulative effects of both positive and negative experiences on brain growth are remarkably profound and can strongly shape future health outcomes [6,7]. Research has demonstrated that while the skills, knowledge and actions of neonatal staff coupled with sophisticated medical technologies are capable of providing extraordinary lifesaving measures following birth, the unique NICU environment and the infant's experience of hospitalisation may be disruptive to several key aspects of early development [8].

It was previously assumed that newborns were not sensitive to their environment and hence not capable of interaction [9]. However, it is

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now evident that infants respond to their environment, utilising their sensory experiences as a platform for learning and so the intensity of sensory stimuli within the NICU environment has become a focus of interest [10]. A complex interplay of environmental factors within the NICU setting, including long periods of separation from their parents, inconsistent caregivers, the sound and light environment, touch and handling from clinical staff, and acute and chronic exposure to stressful/painful stimuli have all been shown to impact upon early life experiences, influencing both short- and longer-term outcomes [11].

Research which has examined the broader impacts of the NICU environment has led to significant changes. For example, studies detailing the deleterious effects of the constant noise and bright lights of NICU on infant's physiological and behavioural wellbeing and medical outcomes, have led to recommendations to promote and maintain a healing environment, which aims to minimise sensory overload [12–18]. Another aspect of the NICU environment that has been of particular interest is the infant's experience of pain. A landmark study in 1987 led to significant advancements in the understanding and management of neonatal pain [19]. Evidence has since demonstrated a causal link between repeated exposure to painful, stressful procedures and handling during hospitalisation and changes in brain structure and function, which impact on longer-term neurodevelopmental outcomes [3,20,21].

There is an already well-established body of literature addressing approaches to support the infant during hospitalisation, which place the infant at the centre of care processes within NICU, to ameliorate where possible, the harmful negative effects of hospitalisation on the developing infant and their family [22–24]. Despite these transformative changes, neurodevelopmental disabilities remain the most common, and potentially the most damaging, sequalae of complicated childhood disease [25]. This calls for a potentially new, exploratory area of research within NICU which aims to achieve a deeper understanding of the infant's experience of hospitalisation through the eyes and communication of the infants themselves, hoping to contribute to and enrich the neonatal literature, inform practice and bring about change to the way neonatal care is delivered.

The qualitative research paradigm of phenomenology may provide this alternative means to conduct a comprehensive and child-centred analysis of an individual infant's NICU experience. In simple terms, phenomenology seeks to understand and describe the essence of a lived phenomenon (in this case the human experience of being hospitalised in NICU) [26]. For the purposes of this scoping review, the lived experience, defined in phenomenological terms, is to gather *what* an infant experiences during hospitalisation and *how* they are experiencing life, within the NICU environment [26,27]. Using this definition and scope of interest, this review sought literature which reported or discussed the experience of the individual infant from the perspective of the infant's lived experience. We were interested in papers which analysed an infant's daily encounters, activities, and opportunities for developing connections and relationships with others. We were particularly interested in studies which focused on whether and how an infant communicates what they are experiencing and how those caring for the infant interpret the infant experience. The infant's lived experience, explored in this way, may be the missing piece in neonatal research that compliments family-centred, patient-focused care; proving that hospitalised infants are more than just a pathology, they are individuals with their own capabilities, vulnerabilities, and needs.

The purpose of this scoping review is to examine what is already known of the lived experiences of infants hospitalised in NICU. A scoping review design was chosen as it allows a range of literature to be gathered to provide an overview of what has been written on this topic, including the types of empirical studies that have been conducted and the overall focus of the literature. Our aims are to provide an overview of the infant's personal experience within NICU, identify any salient gaps, and to suggest directions for future research.

2. Method

2.1. Design

The methods for this scoping review were informed by the six-stage framework outlined by Arksey and O'Malley and revised by Levac and colleagues [28,29].

2.1.1. Stage 1: identifying the research question

Following the guideline for scoping reviews, we developed a broad research question for our literature search, asking *what is known of the lived experiences of infants hospitalised in NICU*?

2.1.2. Stage 2: identifying relevant studies

Multiple key search terms were developed and used to capture the breadth of literature pertaining to how an infant experiences hospitalisation (Table 1). These were based on an infant's ability to utilise their senses to explore and experience the world around them, as well as routine infant activities (feeding, sleep) and their emotional needs (bonding, attachment, relationships, mental health). Paediatric intensive care was included in the literature search as young infants may be cared for as part of the general PICU population in some centres, however literature focusing on paediatric intensive care was limited to the neonatal age group only (less than 28 days of age or 44 weeks post-menstrual age at admission). All searches were limited to English language and from 2009 to current day to capture work that focuses on current neonatal care practices, given it is an ever-evolving field. The following electronic databases were searched: MEDLINE, CINAHL (Cumulative Index of Nursing and Allied Health Literature), PubMed and PsycINFO. In addition, manual searching of reference lists was undertaken to ensure identification of any other primary sources.

2.1.3. Stage 3: study selection

In accordance with scoping review methodology, the inclusion criteria aimed to capture studies which met our definition of the infant experience (i.e. reported infant's responses to the environment or daily activities and encounters via direct observation, paid attention to what the infant was conveying about their experience through their behaviours and communication, or reported carer's views of the infant's experience). Articles were excluded if they did not relate back to or focus on the infant's experience or if the authors focused only on the parental or clinician's personal account of their NICU experience. Review articles or studies that investigated an intervention within the NICU environment were also excluded. A summary of the search process is illustrated in Fig. 1.

Table 1
Search terms utilised in the literature search.

Hospital/physical environment	Study population	Components that influence an infant's experience of NICU
Neonatal intensive care, NICU, paediatric intensive care, PICU	Newborn, new-born, newborns, new-borns, baby, babies, neonate, neonates, infant, and infants	Light, vision, visual perception, sound, noise, auditory perception, smell, olfactory perception, touch, touch perception, touch sensation, pain, taste, taste perception, feeding, sensory deprivation, sleep, bonding, relationships, attachment, parent-relations, professional-patient relations, nurse-patient relations, physician-patient relations, stress, mental health, and patient satisfaction

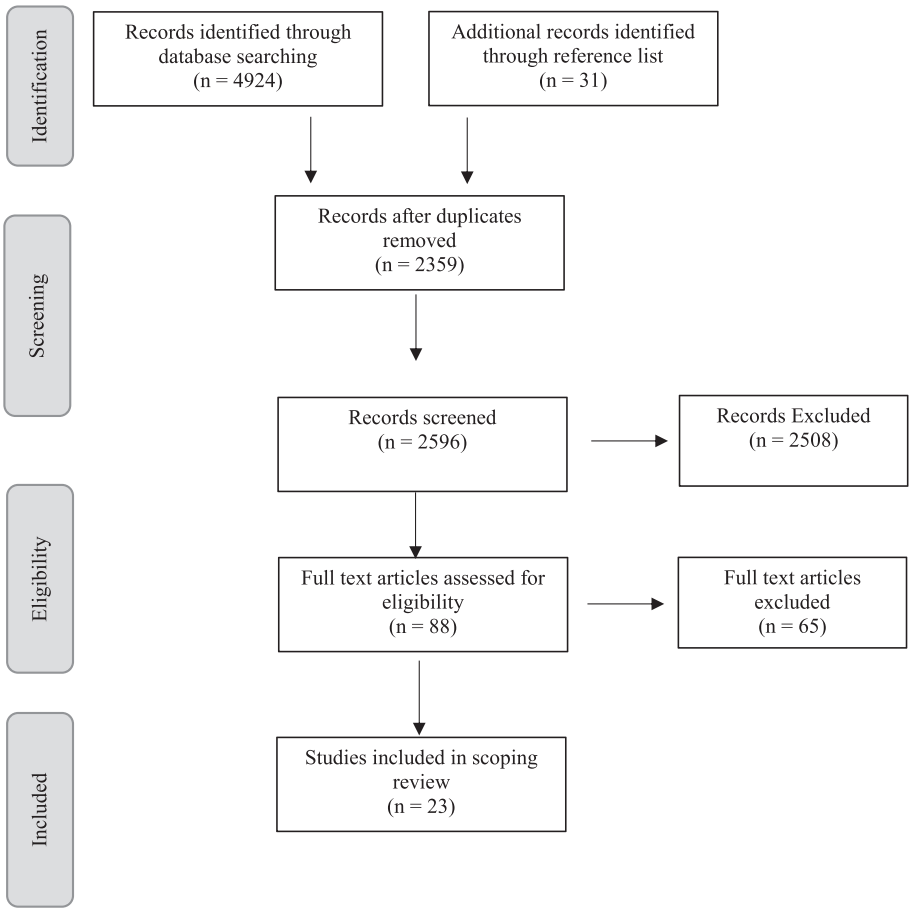

Fig. 1. Study selection flow diagram.

2.1.4. Stage 4: charting the data

In the fourth stage of the review, we charted data, recording pertinent information from eligible studies. Categories included for data extraction were as follows: (a) study demographics (author, year, country), (b) study population, (c) study objective, (d) study design, (e) data collection methods (i.e. how did the author collect data about the infant's experience), (f) key findings, and (g) author recommendations.

2.1.5. Stage 5: collating, summarising, and reporting results

The fifth stage of the review was the most intensive stage of the study where we analysed the data, reported the results, and applied meaning to these results.

3. Results

A total of 4955 articles were identified through database searching and other sources; 2359 duplicates were removed, and the review of the remaining titles and abstracts resulted in the exclusion of a further 2508 records. The most common reason for exclusion was a lack of focus on the infant's experience of NICU as defined by the study objective. Of the selected studies, 88 were submitted to a full text review, following which, 23 studies were deemed eligible for inclusion.

3.1. Study characteristics

Table 2 outlines the characteristics of the 23 publications included in this scoping review [30–52]. Participants included in the reviewed studies were infants born either prematurely (gestational age at birth <37 weeks) or at term gestation. Most of the studies (n = 19) focused solely on preterm infants. Thirteen studies are from the United States, four are European, two are from the Middle East, and four are from South America. Most studies (n = 22) used quantitative research methodologies with a variety of data collection methods and predetermined outcomes. The studies used physiological parameters (respiratory rate, heart rate, blood pressure, temperature, systemic oxygenation saturations, cerebral oxygen saturations), medical outcomes (weight gain, complications of prematurity), neurodevelopmental outcomes, and observations of infant behaviour to infer the infant experience. One study used qualitative research design utilising semi-structured interviews of staff within focus groups and thematic analysis to interpret their findings.

3.2. Study findings

3.2.1. The infant's sensory experience and their response to their physical environment

Seven studies explored the infants' sensory experience and two studies focused on their response to the physical NICU environment [30–38]. Three studies measured the infant's experience using physiological parameters alone [30–32]. Three studies combined physiological measurements with infant behavioural states to infer the infant's sensory experience [33–35]. Caskey and colleagues documented the infant's sound environment [36]. The two studies that focused on the physical NICU space used medical and neurodevelopmental outcomes, relating these to the infant's experience of hospitalisation [37,38].

Multiple studies reported that noise levels within NICU exceed recommendations, irrespective of time of day or location (open bay or single-family room) [30,33,34]. When exploring the infant's experience of sensory stimuli there was an associated stress response (increased heart rate and decreased respiratory rate, peripheral oxygen saturations,

Table 2
The infant's experience of NICU.

Study demographics (author, year, country)	Study population	Study objective	Study design	Data collection methods (i.e. how did the author collect data about the infant experience)	Key findings	Recommendations
The infant's sensory experience						
Sound in NICU						
Cardoso, Kozlowski, Lacerda, Marques and Ribas, 2015, Brazil	n = 61 (weight: 1000–2500 g)	To evaluate the physiological and functional effects resulting from the exposure to noise on low weight infants in incubators in NICU.	Quantitative research design: prospective, observational, exploratory, descriptive study.	Measurements: noise levels (both inside and outside the incubator during "noise" and "sleep" times), HR, SpO_2 and assessment of infant behaviour using the APIB scale.	– Significant increase in HR and decrease in SpO_2 observed during periods of higher environmental noise. – Infants exhibit behavioural change in response to environmental noise.	Instigate noise reduction programs within NICU.
Caskey, Stephens, Tucker and Vohr, 2011, USA	n = 36 (BW ≤ 1250 g)	To determine the sound environment of preterm infant and to test the hypothesis that's infants exposed to more adult language will make more vocalisations.	Quantitative research design: prospective cohort study	Measurements: digital language processor recorded the infant's sound environment: adult speech, child vocalisations, and background noise.	– Most of the sound an infant is exposed to is composed of monitor noises and background noise. – Language, either adult or infant, comprises a small percentage of the sounds to which infants are exposed. – Infant vocalisations are present as early as 32 weeks CGA. – Adult word counts per hour and infant vocalisations per hour increase significantly between 32 and 36 weeks CGA.	Infant directed language should be encouraged as part of neonatal care.
Kuhn, Zores, Pebayle, Hoeft, Langlet, Escande, Astruc and Dufour, 2012, France	n = 26 (GA at birth <32 weeks)	To investigate whether (i) VPIs hear nosocomial sound peaks that are 5–10 dbA and/or 10-15dBA above background noise, (ii) how do they physiologically react to this noise and (iii) does the noise alter infant well-being.	Quantitative research design: prospective observational study	Measurements: sound peaks, environmental sounds, HR, RR, SpO_2, rcO_2, and arousal states (using Prechtl's observational rating system).	– VPIs can detect sound peaks of as little as 5dBA above background noise. – The physiological response noted by VPIs in response to noise included increased HR and decreased RR, SpO_2, and rcO_2.	NICU should have strict criteria to protect infants from the deleterious exposure to noise.
Smith, Ortmann and Clark, 2018, USA	n = 3	To identify the types, rate, and levels of acoustic events that occur in NICU and their potential effects on infant physiological state.	Quantitative research design: descriptive study	Measurements: noise levels, documentation of acoustic events by observer (alarm noise, infant- generated noise, staff/family noise or transient events), RR and HR.	– No correlation could be made between acoustic events and infant physiological state.	Hospital systems should strive to incorporate developmentally appropriate acoustic stimuli into the infant's environment rather than solely focusing on the diminution of all sound.
Williams, Sanderson, Lai, Selwyn and Lasky, 2009, USA	n = 8 (BW < 1000 g)	To measure the correlation between NICU noise levels and ELBW neonate's HR and BP and to determine whether these correlations differ by BW.	Quantitative research design: descriptive, observational study	Measurements: noise levels, HR, and BP.	– The lower BW infants responded to noise events with significant increase in HR. – Higher BW infants experienced a biphasic response to increasing noise levels in NICU (deceleration initially followed by an acceleration in HR).	Reducing noise levels in the NICU may reduce stress for ELBW infants by improving physiological stabilisation in this vulnerable patient group.
Sound, light, and infant handling in NICU						
Peng, Bachman, Jenkins, Chen, Chang, Wang, 2009, Taiwan	n = 37 (GA at birth <36 weeks)	To examine the relationship between environmental stressors (light, sound, and handling) and biobehavioural responses in preterm infants	Quantitative research design: exploratory, descriptive study	Measurements: (i) physiological- HR, RR, and SpO_2, (ii) handling- a Likert scale was used to measure the degree of stimulation in nursing interventions, (iii) behavioural stress responses — sleep-wake	– There was a statistically significant relationship between environmental stressors (both light and sound) and changes in physiological state (increased HR, increased RR, and decreased SpO_2). – There was also a	Early recognition of physiological and behavioural stress responses in relation to environmental stressors is prudent to provide individualised patient care.

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Table 2 (*continued*)

Study demographics (author, year, country)	Study population	Study objective	Study design	Data collection methods (i.e. how did the author collect data about the infant experience)	Key findings	Recommendations
				states, self-regulatory behaviours, and behavioural stress cues.	statistically significant relationship between environmental stressors (light, sound, and handling) and some specific stress behaviours.	
Light in NICU						
Zores, Dufour, Pebayle, Langlet, Astruc, Kuhn, 2015, France	n = 27 (GA at birth <32 weeks)	To understand the response of VPIs to light variation in incubators.	Quantitative research design: prospective, observational study	Measurements: HR, RR, SpO_2 and rcO_2.	– VPIs react to moderate variations to light levels. – Significant increase in RR with mild variations to light levels (delta lux <50). – Significant increase in HR, RR and rcO_2 with larger variations to light levels (delta lux >50).	Preterm infants should be protected from variations in light exposure in NICU to protect physiological stability.
The infant's experience of the physical NICU environment						
Lester, Hawes, Abar, Sullivan, Miller, Bigsby, Laptook, Salisbury, Taub, Lagasse, Padbury, 2014, USA	n = 403 (BW ≤ 1500 g)	To determine whether SFR NICU layout is associated with improved medical and neurobehavioral outcomes.	Quantitative research design: longitudinal, prospective, quasi-experimental cohort study	Measurements: LOS, weight at discharge, CGA at discharge, rate of weight gain, HC at discharge, GA at full enteral feeding, rates of NEC, IVH, PVL, ROP, sepsis, supplemental oxygen use, CPAP use, mechanical ventilation, rates of BPD, assessment of neurobehavioural outcomes using NNNS and pain scores using Premature Infant Pain Profile. Maternal and staff questionnaires.	– Infants cared for in SFR had improved weight gain, reduced infection rates, few medical interventions, and faster transition to enteral feeds – Infants in SFR also demonstrated increased attention, less physiological stress, less hypertonicity, less lethargy, and reduced pain scores.	This study supports the move to SFRs in NICU to improve neurobehavioural and medical outcomes for hospitalised infants but also emphasises the importance of maternal involvement, staff collaboration and developmental support for preterm infants.
Pineda, Neil, Dierker, Smyser, Wallendorf, Kidokoro, Reynolds, Walker, Rogers, Mathur, Ven Essen and Inder, 2014, USA	n = 136 (GA at birth ≤30 weeks)	To evaluate associations between NICU room type (open ward and SFR) and medical outcomes: neurobehaviour, electrophysiology and brain structure at hospital discharge, as well as developmental outcomes at 2 years.	Quantitative research design: prospective, longitudinal cohort study	Measurements: rates of PDA, NEC, ROP, cerebral injury, confirmed sepsis, use of fentanyl, postnatal steroids or inotropes, days on TPN, maximum amount of oxygen, days of intubation, days of CPAP, hours of oxygen therapy, oxygen requirement at CGA 36 weeks, CGA at discharge, LOS. Neurobehavioural outcomes were measured using: Premie Neuro, NNNS, the Dubowitz Neurological Exam and the Neonatal Oral Motor Assessment Scale Additional measurements: aEEG monitoring, brain imaging (MRI).	– There was no difference in baseline or medical factors amongst infants in private rooms compared with open wards. – There was no significant difference observed in the neuro-behavioural scores between infants managed in private rooms versus open bay. – At term equivalent age, there was a trend toward having lower aEEG maturations scores for infants in SFRs. – At age 2 years, infants from SFR had lower language scores and a trend toward lower motor scores which persisted after adjustment for potential confounders.	Individualised, developmental care that encourages parental involvement should be encouraged in NICU. Further research is needed to explore the sensory stimulation infants are exposed to in private rooms.
The infant's experience of medical treatment						
Cong, Wu, Vittner, Xu, Hussain, Galvin, Fitzsimons, McGrath and Henrdson, 2017, USA	n = 50 (GA at birth 28–33 weeks)	To investigate the impact of early life painful/ stressful experiences on neurobehavioral outcomes of preterm infants in the NICU.	Quantitative research design: prospective, longitudinal study	Measurements: early life pain/stress using the NISS, parental contact using a bedside chart which noted the activity and the duration of the activity (recorded SSC,	– Preterm infants experienced a high degree of pain/stressors in the NICU, both in numbers of daily acute events and cumulative times of chronic/stress exposure.	Strategies to reduce both acute and chronic pain in NICU and increase positive experiences are essential to improve infant outcomes.

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Table 2 (*continued*)

Study demographics (author, year, country)	Study population	Study objective	Study design	Data collection methods (i.e. how did the author collect data about the infant experience)	Key findings	Recommendations
				breast feeding holding or cuddling, hand swaddling or touch, talking, singing, reading), neurobehavioural response data was collected at CGA 36–37 week using the NNNS.	– In comparison parental contact time was minimal. – Infants who experienced more daily pain/stressors and daily chronic pain/ stressors had worse neurobehavioural outcomes.	
Jeong, Park, Lee, Choi and Lee, 2014, Korea	n = 145 (all infants admitted to NICU were eligible)	To evaluate the painful procedures encountered in hospitalised infants.	Quantitative research design: prospective survey	Measurements: self-administered survey questionnaire relating to 27 painful procedures in NICU.	– An overall average of 105.6 painful procedures were performed per baby, with a daily average of 7.54 painful procedures and a weekly average of 25. – Oral suctioning was the most frequently performed painful procedure. – Infants born more prematurely and with a lower BW underwent more painful procedures.	Painful procedures should only be executed if deemed essential to patient care.
Orovec, Disher, Caddell and Campbell-Yeo, 2019, USA	n = 242 (GA at birth <37 weeks)	To report on neonatal pain exposure, pain management, and pain assessment/ documentation for a cohort of preterm infants during their hospital stay.	Quantitative research design: retrospective chart review	Measurements: procedure date and time, procedure type, pain scores, pharmacological and non-pharmacological interventions used, and number of attempts required for successful procedure.	– The 242 neonates included in the study underwent a total of 11,191 procedures. – Most common painful procedure was heel lance. – The frequency of painful procedures decreased over the course of the admission. – Only 32.6% of procedures had a documented pain score. – Sucrose was the most widely used pharmacological agent to manage pain. – Non-nutritive sucking was the most widely used non-pharmacological method to manage pain.	Increased efforts are required to promote consistent pain assessment and management to ensure optimal outcomes for vulnerable at-risk infants.
Pereira, Nogueira de Goes, Fonseca, Scochi, Castral and Leite, 2013, Brazil	n = 20 (GA < 37 weeks)	To describe the handling that preterm infants are subjected to over a 24-hour period.	Quantitative research design: observational, descriptive, exploratory study	Measurements: the type, frequency, duration of handling, and time the handling occurred.	– The 20 preterm infants underwent a total of 768 periods of handling and 1341 procedures in a 24-hour period. – The frequency of handling for each infant ranged from 14 to 71 episodes and the frequency of procedures ranged from 59 to 109 in the 24-hour period.	Careful consideration by clinical staff as to the appropriate timing of procedures and need for handling of preterm infants.
The infant's experience of relationships within NICU						
Pineda, Bender, Hall, Shabosky, Annecca and Smith, 2018, USA	n = 81, (GA ≤ 32 weeks	To (i) define predictors of parent presence, any holding, holding in arms, and SSC in the NICU and (ii) investigate the relationship between parent participation and (a) early neurobehaviour and (b) developmental outcomes.	Quantitative research design: oobservational, descriptive study	Measurements: parent presence, medical factors and socio-demographic factors were collated from the medical notes. NNNS and Dubowitz Optimality Scale were performed at CGA 35 weeks. At age 4 to 5 years the ASQ-3 was completed by parents.	– Parents were present an average of 4 days per week and held their infants an average of 2–3 days per week. – Infants whose parents held them more often had better short-term outcomes, with those who were held SSC demonstrating better	Parents should be encouraged to engage in infant care in NICU.

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Table 2 (*continued*)

Study demographics (author, year, country)	Study population	Study objective	Study design	Data collection methods (i.e. how did the author collect data about the infant experience)	Key findings	Recommendations
					short and long-term outcomes overall.	
Reynolds, Duncan, Smith, Mathur, Neil, Inder and Pineda, 2013, USA	n = 81 (GA ≤ 30 weeks	To investigate the effects of parental presence and infant holding in the NICU on neurobehaviour at term equivalent.	Quantitative research design: prospective, longitudinal, cohort study	Measurements: parental presence, NISS scores and NNNS scores.	– The mean hours per week of parent visitation was 21.3 ± 20.9. – Infants were held on average of 2.3 ± 1.5 days per week. – Over the hospital stay, visitation hours decreased, while holding frequency increased. – Parental visits and holding had a positive effect on infant neurobehaviour.	Neonatal staff should support early parent engagement in NICU care.
The infant's experience of feeding in NICU						
Pickler, McGrath, Reyna, Tubbs-Cooley, Best, Lewis, Cone and Wetzel, 2013, USA	n = 87 (CGA 30–32 weeks)	To examine the effect of the NICU environmental characteristics (levels of sound, light, time of day) in open wards and SFRs on oral feeding outcomes in preterm infants.	Quantitative research design: observational study	Measurements: time of day feed occurred, prescribed volume of feed and the volume consumed, infant's wakefulness prior to and at the end of feeding (simple yes/no question), and the nurse's perception of light and sound levels (using a 5-point Likert scale).	– Infant oral feeding was significantly improved by moderate light levels. – Oral consumption was negatively affected by the time of day (i.e. reduced oral intake at the busiest times of the day). – When infants were awake at the start of the feed, they consumed a greater proportion of the prescribed volume. – Infants consumed a greater proportion of their feed in the open bay setting.	Interventions should be put in place to minimise sound and light levels during infant feeding times. There is an ongoing need to train staff in the assessment of infant behavioural states to optimise successful oral feeding.
Tubbs-Cooley, Pickler and Meinzen-Derr, 2015, USA	n = 89 (GA at birth <32 weeks)	To examine the association between missed oral feeding opportunities amongst preterm infants with achievement of full oral feeding and LOS.	Quantitative research design: observational study	Missed oral feeding opportunities were documented by NICU nurses as unrelated to the infant's clinical condition or state of wakefulness at the time of the feed and instead categorised as missed due to "time-management reasons" or "other reasons". Once oral feeding was initiated, data was collected at each scheduled feeding time using a data collection form which allowed the bedside nurse to record a reason why an oral feed was not offered.	– 30 infants experienced one or more missed oral feeding opportunities. – Each 1% increase in the proportion of missed oral feeding opportunities extended the time to achieve full oral feeding by 1.45 days and time to discharge by 1.36 days.	Future research is needed to understand why preterm infants are missing oral feeding opportunities in NICU. If missed feeding opportunities are related to nurse workloads, then system-level interventions are required, which could include staggered staffing times around feeding schedules or policies and environments that promote parental presence and involvement in infant feeding for the duration of the hospital stay.
The infant's sleep experience in NICU						
Sleep and the physical environment						
Kuhn, Zores, Langlet, Escande, Astruc and Dufour, 2013, France	n = 26 (GA at birth <32 weeks)	To evaluate the impact of moderate noise on the sleep of VPIs.	Quantitative research design: observational study	Measurements: sound pressure levels and environmental sounds were recorded using a dosimeter. Arousal states were assessed using Prechtl's observational rating system.	– Moderate acoustic changes can disrupt the sleep of VPIs.	NICUs should employ sound control measures to protect infant sleep.
Orsi, Avena, Lurdes de Cacia, Tsunemi, Machado and	n = 12 (GA at birth <37 weeks and	To describe the impact of the NICU physical environment on infant sleep.	Quantitative research design: observational study	Measurements: infant sleep (PSG), noise levels, light levels, temperature levels and relative air	– Total sleep time for the infants observed in this study was 14.9 h. – Increased light levels	Strategies to promote and protect sleep by decreasing newborns' exposure to excessive

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Table 2 (*continued*)

Study demographics (author, year, country)	Study population	Study objective	Study design	Data collection methods (i.e. how did the author collect data about the infant experience)	Key findings	Recommendations
Pinheiro, 2017, Brazil	BW 1200–2000 g)			humidity. Infants were video recorded to observe handling by clinical staff.	resulted in increased periods of wakefulness.	light should be implemented in NICUs.
Zores, Dufour, Pebayle, Dahan, Astruc and Kuhn, 2018, France	n = 27 (GA at birth <32 weeks)	To determine whether small variations in light levels affect the sleep of preterm infants.	Quantitative research design: observational study	Measurements: arousal states were assessed during periods of different light exposure using Prechtl's observational rating system.	– VPIs can be woken by small variations in light, when the light protection in their incubator is insufficient.	Caregivers should protect vulnerable infants from the potentially deleterious effects of modest changes in light levels.
Caregiving and sleep						
Levy, Hassan, Plague, Sokoloff, Kushwaha, Chervin, Barks and Shellhaas, 2017, USA	n = 25 (GA > 35 weeks at birth)	To (i) determine the frequency and duration of hands-on-care and its impact on sleep and (ii) to assess the incidence of respiratory events associated with handling for a cohort of sick neonates.	Quantitative research design: observational study	Measurements: PSG-defined behavioural states, episodes of handling (direct contact with the infant or manipulation of their immediate environment) and physiological events (hypopnea, apnoea, oxygen desaturations).	– Handling of infants in NICU is frequent and administered across all sleep states, associated with both substantial sleep disruption and potentially consequential respiratory instability.	Strategies to protect sleep and minimise sleep-disordered breathing may improve neonatal outcomes.
Maki, Sbampato Calado Orsi, Tsunemi, Hallinan, Pinheiro and Machado Avelar, 2017, Brazil	n = 12 (BW 1200–2000 g)	To identify the types of procedural handling performed on preterm infants and its effect on infant sleep.	Quantitative research design: observational, correlational study	Measurements: total sleep time, active sleep time, quiet sleep time, wake time and episodes of handling (grouped into categories of monitoring, therapeutic/diagnostic, hygiene/comfort and feeding).	– The newborns were handled an average of 176.4 (±37.9) times during the 24-hour period. – The proportion of total sleep time was 57.2% in 24 h. – Single handling procedures had a strong positive correlation with wake time. – There was no statistically significant correlation between frequency or duration of handling on infant sleep.	Handling should align with the infant's sleep-wake-cycle to minimise disruption to infant sleep.
Clinician's perspective of the infant's experience within NICU						
D'Agata, Couglin and Sanders, 2018, USA	n = 17	To explore the NICU clinician's perceptions of the infant experience and how the terms trauma/ traumatic would impact their clinical roles and practices.	Qualitative research design	Semi-structured focus groups interviews	– Clinicians expressed their perceptions of the infant experience as unpredictable, overstimulating, painful and stressful. – Reluctance to label the NICU hospitalisation as traumatic.	Making explicit the potential trauma of neonatal intensive care hospitalisation and the healing power of social connectedness empowers professional to provide evidence-based trauma-informed care practices.

Note: HR = heart rate, SpO_2 = oxygen saturation, APIB scale = Assessment of Preterm Infant's Behaviour Scale, BW = birthweight, CGA = corrected gestational age, GA = gestational age, VPI = very preterm infant, dBA = A-weighted decibel, RR = respiratory rate, rcO_2 = regional cerebral oxygenation, ELBW = extremely low birthweight, BP = blood pressure, SFR = single family room, LOS = length of stay, HC = head circumference, NEC = necrotising enterocolitis, IVH = intraventricular haemorrhage, PVL = periventricular leukomalacia, ROP = retinopathy of prematurity, CPAP = continuous positive airway pressure, BPD = bronchopulmonary dysplasia, NNNS = NICU Network Neurobehavioural Assessment scale, PDA = patent ductus arteriosus, TPN = total parenteral nutrition, aEEG = amplitude integrated electroencephalography, MRI = magnetic resonance imaging, NISS = NICU Infant Stressor Scale, SCC = skin-to-skin care, ASQ-3 = Ages and Stages Questionnaire-third edition, and PSG = polysomnography.

and cerebral oxygenation saturations) amongst infants when exposed to excessive light and noise [30,32–35]. No correlation was noted between NICU noise levels and infant blood pressure measurements [31].

Caskey and colleagues explored the natural sound environment of NICU [36]. They found that most sound infants are exposed to in the NICU comes from the surrounding technology and background noise. Language, either adult or infant, comprises only a small percentage of the sound infants hear on a day-to-day basis [36]. An infant's ability to communicate and participate in a conversation as measured by infant vocalisations and conversational turns was noted as early as 32 weeks gestational age. There was a positive correlation between parental presence and increased infant directed language and infant vocalisations. Spoken language was also significantly higher during feeding times, again showing a positive response from infants with an increase in infant vocalisations [36].

Lester and colleagues found single family rooms to have favourable outcomes for infants: improved weight gain, reduced infection rates, fewer medical interventions, faster transition to enteral feeds as well as reduction in physiological instability and infant pain scores, and more favourable neurobehavioural outcomes [37]. Lester and colleagues

relate these improvements to increased developmental support and maternal involvement when infants are nursed in single family rooms [37]. Pineda and colleagues however found no difference in medical or neurodevelopmental outcomes at the time of discharge from hospital between room types. They hypothesise that their finding of poorer neurodevelopmental outcomes at 2 years of age for infants nursed in a private room may be attributed to the relative sensory deprivation associated with private rooms, particularly in an urban American NICU setting with low parental visitation rates, leading to reduced language exposure and caregiver contact [38].

3.2.2. The infant's experience of medical treatment

Four studies explored the infant's experience of medical treatment via descriptive studies with quantifiable outcome measures to depict the infant's experience of clinical care [39–42]. Pereira and colleagues used video recordings to examine the types of handling experienced by preterm infants over a 24-hour period in NICU [39]. They reported 768 periods of handling and a total of 1341 procedures. The frequency of handling for each infant ranged from 14 to 71 episodes and the frequency of procedures ranged from 59 to 109 in the 24-hour period [39]. The authors question the necessity of such burdensome handling on the developing infant and recommend tighter adherence to developmental care protocols ensuring the grouping of handling activities and dedicated rest periods for infants [39].

The three articles exploring infant pain in NICU acknowledge the significant exposure to pain and stressful procedures encountered by hospitalised infants during a critical period of brain development [40–42]. Jeong and colleagues studied the first 2 weeks of an infant's admission to hospital using a predetermined checklist of 27 painful procedures [40]. During the studied timeframe they reported an average of 105.6 painful procedures performed per baby, with a daily average of 7.5 painful procedures. In their study, suctioning was the most common painful procedure [40]. Cong et al. investigated whether premature infants born between 28 and 32 + 6 weeks gestational age, subjected to stressful early experiences during their first 4 weeks of hospitalisation would develop an altered neurodevelopmental outcome at 36–37 weeks corrected gestational age [41]. They utilised a validated instrument, the NICU Stressor Scale (NISS), to provide a cumulative measure of infant's exposure to both acute stressful procedures (numbers), such as heel lancing, and chronic stressful exposure (h) such as an indwelling nasogastric tube [41]. During the first 4 weeks of their NICU stay, infants on average experienced a total of 643.2 ± 64.5 acute procedures with a daily average of 23.0 ± 2.3 procedures. There were 1192.5 ± 420.5 h of chronic events with a daily average of 42.6 ± 15.0 h (some infants encountered several chronic procedures at the same time, and since a cumulative hour score was calculated the daily duration of chronic events exceeds 24 h). In comparison parental contact time during the first 4 weeks of hospitalisation in this study was deemed insufficient (skin-to-skin care provided by mothers averaged 13 min daily and fathers 1 min daily) [41]. Using the validated Neonatal Intensive Care Unit Network Neurobehavioural Scale (NNNS) infants underwent neurobehavioural testing at term corrected age. The study concluded that infants who experienced more daily pain/stressors had poorer neurobehavioural outcomes at term corrected age [41]. Orovec and colleagues conducted a retrospective chart review of neonatal pain exposure, pain management, and pain assessment and documentation, for a cohort of preterm infants' entire hospital admission [42]. The 242 infants underwent a total of 10,469 painful procedures (4801 tissue breaking and 5667 non-tissue breaking, with only 56.6% and 12.2% respectively, having a documented pain score) [42]. In this study, heel-lancing was the most common painful procedure. The authors noted that the frequency of painful procedures decreased over the course of the infant's admission. Sucrose and non-nutritive sucking were the most common methods employed to manage pain [42]. All three articles echo the recommendations set out by Pereira et al., calling for the careful consideration of the necessity of handling and painful procedures and, when deemed necessary the appropriate use of pain assessment tools, pain management strategies and parental involvement in care to mediate the cumulative stresses of pain and handling in NICU [39–42].

3.2.3. The infant's experience of relationships within NICU

Two articles reported on parental presence within NICU as a means of inferring the infant's experience of relationships with primary caregivers [43,44]. Pineda et al. found that the median number of days per week a parent was present in NICU with their infant was 4 days. Infants were held by their parents a median number of 2.8 days per week [43]. They also reported on predictors of parental presence on the neonatal ward. More parent participation was observed amongst mothers who were Caucasian, married, employed, or older, and those who had familial support, fewer children, or provided breast milk. Increased parental participation was also observed for infants with fewer medical complications [43]. In this study there was a demonstrable improvement in neurobehavioural outcomes for infants who experienced more holding [43]. These findings were echoed by Reynolds et al. who found a positive correlation between the amount of parental contact and holding and neurobehavioural outcomes [44]. In their study, infants were held on average 2.3 ± 1.5 days per week [44]. Both studies highlight the importance of engaging parents to actively participate in the care of their infants during their hospital stay.

3.2.4. The infant's experience of feeding in NICU

Two articles discussed the infant's experience of feeding in NICU [45,46]. Pickler and colleagues describe the adverse effects exerted by the NICU physical environment on infant feeding and showed that, by reducing light and sound levels and responding to infant feeding cues of readiness to feed, feeding outcomes improve [45]. They also commented that rates of infant feeding were lower during the busier times of day in NICU (i.e. working daytime hours) [45]. Infant characteristics also impacted infant feeding; in this study female infants consumed more than males, healthier infants consumed more than sicker infants, and mature infants consumed more than less mature infants [45]. Tubbs-Cooley et al. in their work explored missed feeding opportunities in NICU revealing that infants who missed out on the experience of oral feeding, despite infant readiness, took longer to achieve full oral feeding and remained in hospital for longer [46]. Both articles recommend the early engagement of parents in neonatal care, especially their active participation at infant feeding times.

3.2.5. The infant's sleep experience in NICU

Five articles describe infant sleep in NICU [47–51]. Three articles explore the impact of sensory stimuli from the NICU environment on sleep, hypothesising that the physical NICU surroundings: bright lighting, high ambient noise levels, frequent alarms, and absence of day-night differentiation in combination with the frequency of interventions and handling for neonatal care, disrupt infant sleep [47–49]. Kuhn et al. evaluated the effect of moderate noise on the sleep of very preterm infants by observing infant behavioural states [47]. They reported that preterm infants are repeatedly exposed to sound pressure levels that exceed recommendations and that repeated and atypical noise is harmful to infant sleep [47]. Using infant observation, Zores and colleagues explored the impact of light on infant sleep. Their study found that small light-level increases led to sleep disruption in very preterm infants [48]. Orsi and colleagues used polysomnography (a non-invasive test considered the gold standard for sleep assessment) to determine how the physical NICU environment, its noxious stimuli and infant handling influenced sleep [49]. The preterm infants studied showed a mean total sleep time of 14.9 h within the 24-hour period. This work again demonstrated that infants are exposed to sound levels greater than that specified by regulatory bodies [49]. However, in this study the sound levels did not influence infant sleep, explained perhaps by the habituation phenomenon, which is characterised by an infant's capacity to diminish his/her behavioural responses when exposed to

frequent and repeated stimuli [49]. The results did show that wakefulness time increased with increasing light levels within the incubator and that the more the infants were handled the more time they spent awake [49].

Using polysomnography, two articles focused on infant handling and its impact on sleep. Levy and colleagues showed that all infants underwent frequent handling [50]. The total duration of hands-on care lasted an average 65.3 ± 33.0 min, or 27% of the 4-hour polysomnography [50]. Contacts were most often initiated for clinical care and were initiated across all behavioural states. They also examined the physiological response of infants to handling during sleep. They found that handling was frequently followed by respiratory events: hypopnoea, apnoea, and desaturation occurred within 60 s on 16%, 8%, and 19.5% of all contacts, respectively [50]. Maki and colleagues also demonstrated high frequency of handling: an average of 176.4 (±37.9) times during the 24-hour period. In this study the proportion of total sleep time was 57.2% in 24 h [51]. There was no statistically significant correlation between frequency or duration of handling and the sleep of preterm infants [51]. Recommendations from these articles include creating an environment that promotes and protects infant sleep. Authors also encourage formal staff training in the assessment of infant sleep-states and behaviour so that routine care is infant-led and cue-based [47–51].

3.2.6. *Parent and clinician perspective of the infant experience of NICU*

No articles discussed parental opinion of the infant's journey through NICU. One article was identified that reported on clinicians' perspective of the infant's experience of NICU. In their qualitative analysis D'Agata and colleagues explored the terminology that best describes the NICU infant experience, through focus group discussion with neonatal healthcare providers [52]. During these focus groups they proposed the use of the word "traumatic" to describe the infant experience. Emergent themes from the focus groups describe the fragility of the infants, parents, and clinicians themselves in the NICU environment [52]. While clinicians expressed their perceptions of the infant experience as unpredictable, overstimulating, painful, and stressful, they were reluctant to label these early lived experiences as traumatic [52]. Hesitations relate to the clinicians' personal concerns that they may be the agents of trauma and the potential negative impact on the already vulnerable families by labelling the admission as traumatic [52].

4. Discussion

Stressful early life experiences in the NICU continue to be an inherent part of the high-technology, lifesaving care for hospitalised infants [41]. The course and length of the NICU experience has been found to be one of the most crucial factors influencing infant neurodevelopment and health outcomes; particularly because this is a modifiable factor that occurs during a critical period of neurodevelopment [53,54].

This review, which aims to interrogate the literature for knowledge of the NICU experience from the infant's perspective, affirms the link between noxious stimuli and the infant stress response both physiologically and behaviourally [30–35,37,38]. Despite environmental guidelines and recommendations, the environment is repeatedly described as too loud and too bright, impacting on physiology, infant behaviour, sleep, feeding, and neurobehavioural outcomes [30–35,37,38,45–49].

Sleep is essential for normal health and development in children. Alterations in sleep can have a negative impact on behaviour and may result in cognitive impairment [55,56]. Disturbances in neonatal sleep have been associated with increased distractibility in later childhood [57]. Disruption of sleep duration and quality in hospitalised patients has been described both in adult and paediatric populations, with patients treated within the intensive care unit setting showing the most profound sleep abnormalities [50]. Despite this there are limited available data on infant sleep in NICU. The five articles described in this review highlight the negative impact of hospitalisation on infant sleep [47–51]. Sleep is yet another aspect of an infant's early life experience which is disrupted with possible long-term implications. More research both acutely and with longer-term outcome data is required to investigate infant sleep in NICU.

Other research highlights an imbalance between negative handling for medical care and positive touch and interaction with caregivers [39–44]. These findings again question a lack of dissemination and implementation of family- and infant-centred models of care.

On one level, this review has identified multiple articles relating to the infant experience of NICU, recognising the negative effects of such an invasive experience for infants. However, when closely analysed, the studies have not focused on trying to understand these experiences from the infant's perspective, and neonatal research utilising qualitative methodologies is scarce. Shrouded by both pathology and technology, the infant as a real person can be lost both in the medical quest to save their life as well as in the literature. The infant too often being the object of research instead of an active participant.

This response from a neonatal clinician captures, openly and honestly, the complexity of the modern NICU.

"*We've all experienced the days where you almost just want to run and put your head in a corner because it's just… there's just stuff going on everywhere. Bells and whistles and alarms and beeping and people…ah! And it's like I can't imagine what these little babies are feeling like…* (**MD**)" [52].

A growing body of literature describes the physical NICU environment and the multiple stressors it exerts on the developing infant, implicating the environment as an independent risk factor for poorer developmental outcomes. Perhaps more importantly however, this review highlights the gap within neonatal literature, understanding the essence of the infant's experience by relying on an openness to explore this experience from the infant's perspective.

While infants may not be able to verbalise their experience, they can be "heard" if researchers are willing to utilise other methods of data collection. For example, the Newborn Behavioral Observations (NBO) System is an infant-focused, family-centred relationship-based tool, designed to highlight the full richness of a newborn infant's behavioural repertoire and communication style [58]. The NBO consists of 18 neurobehavioural observations and is designed for use from birth through the third month of life. These items are designed to show that newborn infants possess a wide range of visual, auditory, and perceptual abilities that allow them to explore the world around them and to engage in face-to-face, eye-to-eye mutual exchange [58]. The infant's behaviour is at the centre of the NBO with the clinical focus on the infant's individuality. Through observation and interaction, the NBO allows infants to fully show who they are: their preferences, capacities, and vulnerabilities. In other words, the NBO provides the infant with a "voice" and the baby as a developing person is revealed [58].

Despite the repeated message for healthcare providers to recognise and promote parents as the experts in their infant's needs, their opinions of the infant's experience have not been reported in the literature. D'Agata and colleagues are the first to investigate the clinician's perspective of the infant experience. They propose a conceptual model of infant medical trauma in the NICU (IMTN) that facilities an interdisciplinary approach for studying the infant's experience [8]. We suggest exploring the infant's lived experience through a qualitative lens to provide a rich description and complete picture of life in NICU.

4.1. *Limitations*

The results reported here are subject to certain limitations. Our emphasis in this scoping review was to examine the infant's experience of hospitalisation and therefore, we excluded any work conducted retrospectively following discharge from hospital. We also discounted systematic reviews and intervention studies. Despite these limitations, the results of this review highlight the need for hospital systems to foster an environment more in tune with the individual needs of the infant, strongly encouraging and facilitating parental involvement wherever possible.

5. Conclusion

This scoping review aimed to explore the lived experiences of infants hospitalised in neonatal intensive care. The studies captured in this review focused on quantitative, measurable outcomes as a proxy for the experience as it might be felt, interpreted, and processed by an infant. Much is known about the effects of the environment on the developing infant, but little research has sought to understand the experience from the infant's perspective. By employing qualitative methodology to explore the lived experience of infants in NICU the baby becomes an active agent in research and the process of data collection is modelling (and based on) a fundamental orientation to the baby's interpretation and response to stimuli. Collecting data "on" the baby may in effect be perpetuating an essential problem or gap in neonatal research: the baby as a subject not a person actively involved with their own voice and story to tell. Future qualitative studies would add an increased understanding of the lived experience of infants hospitalised in NICU and give greater descriptive meaning to the quantitative data already published.

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Natalie Duffy: Supervision, Conceptualization, Investigation, Formal analysis, Writing - original draft, Writing - review & editing. **Leah Hickey:** Conceptualization, Investigation, Validation. **Karli Treyvaud:** Conceptualization, Investigation, Validation. **Clare Delany:** Conceptualization, Investigation, Validation.

Declaration of competing interest

None declared.

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360-degree phenomenology: A qualitative approach to exploring the infant experience of hospitalisation in neonatal intensive care

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ABSTRACT

This paper describes the development and justification of a qualitative methodology aimed at exploring the infant's personal experience of hospitalisation in the neonatal intensive care unit (NICU). We begin by briefly reviewing existing methods for documenting and recording infant experiences. These methods focus on the clinical needs of the infant predominantly through quantifiable medical outcome data. Research understanding their experience of receiving clinical care is lacking. By exploring newborn infant behaviour, cues, and communication strategies we assert the infant as a capable participant in neonatal research. We then describe the methodology and methods which we have named 360-degree phenomenology that draws directly from the capabilities and knowledge of the infants themselves. We propose this methodology will address the gap in the literature by enabling a rich and comprehensive overview of the early life experiences of infants hospitalised in NICU.

1. Introduction

An experience can be described as "something that happens to you that affects how you feel" [1].

The research paradigm of phenomenology originated from the works of German philosopher, Edmund Husserl (1913) but it was Alfred Schutz, a colleague of Husserl, who was instrumental in introducing phenomenology into scientific research (1972) [2]. Phenomenology focuses on the study of an individual's lived experience. Lived experience, as it is explored and understood in qualitative research is a representation and understanding of how a person encounters and interacts with the world around them [2]. It privileges the experience of the person who is undergoing an event, valuing the insights and learnings that only that person can offer. The goal of phenomenology is to describe the meaning of these experiences-both in terms of *what* was experienced and *how* it was experienced [3].

The neonatal intensive care unit (NICU) provides care for premature and critically ill infants. Progressive advancements in both perinatal and neonatal intensive care have led to dramatic improvements in the survival of premature infants and those with congenital anomalies. However, despite improved survival rates, poorer neurodevelopmental outcomes persist amongst infants hospitalised in the newborn period [4–9].

Early childhood is the most critical and vulnerable time in any child's development. It is a time when the cumulative effects of both positive and negative experiences on brain growth are remarkably profound, shaping future health outcomes [10,11]. Research has demonstrated that whilst the skills, knowledge and actions of neonatal staff coupled with sophisticated medical technologies are capable of providing extraordinary lifesaving measures, the unique NICU environment and the infant's experience of hospitalisation may be disruptive to several key aspects of early development, such as cognitive impairment and social and emotional challenges in later childhood [6,12,13]. Much of this current literature is focused on quantitative accounts of "*life in*

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NICU". These measurable outcomes act as a proxy for the experience as it might be felt, interpreted, and processed by an infant, resulting in a lack of understanding of the infant's personal perspective of their experience [14].

Other studies in the NICU context have focused on parents and infants' experiences. Parents of hospitalised infants experience high levels of distress, symptoms of depression and anxiety, sleep disturbance and fatigue as they journey with their infants through NICU [15]. Research suggests that hospitalised infants spend 80 % of their time alone in NICU [16]. Specifically, for an average 19 h a day, the infant's primary developmental environment is provided by non-human technology (i.e., incubator, monitor wires, ventilation devices) with the remaining hours consumed mostly with clinical interactions [16]. Clinicians describe the infant's experience as unpredictable, overstimulating, painful, and stressful [17]. A systemic review of painful procedures, for example, indicates newborn infants are exposed to 7–17 painful procedures a day, over the first two weeks of their hospital admission [18]. However, there is very little reference to how the infants cope with these procedures, what they may feel and how they communicate these emotions to their caregivers.

Given the body of evidence linking the importance of early life experiences and future health outcomes there is increasing interest in the lived experience of infants hospitalised in NICU. A sustained focus on the experience of the infants as told by the infant themselves is essential. This gap in understanding the infant's experience through the eyes and communication of the infant themself is increasingly being recognised as a significant omission in the field of neonatal care. One may even argue that there is an ethical imperative to obtain the voice and experience of the infant undergoing neonatal care to complement and better inform research about clinical pathology as well as hospital policies and guidelines, which rely heavily on consumer engagement. Opening a window into their emotional and relational health through a qualitative lens will add an increased understanding of the subjective experience of infants hospitalised in NICU and give greater descriptive meaning to the quantitative data already published. The infant's lived experience, explored in this way, is a missing piece in neonatal research that compliments patient-focused, family-centered care; highlighting that hospitalised infants are individuals with their own capabilities, vulnerabilities, and needs, beyond their physiological pathology, providing future focus for strategies to improve their early life experiences, to better their long-term health outcomes.

2. Understanding newborn infant behaviour

Attempts to systematically observe and record infant behaviour can be traced to the 1950s and were primarily clinician-led for use in clinical and health settings. Peter Wolff made a foundational contribution to our understanding and appreciation of the complexity and competencies of the human newborn. In 1959 he identified that newborns have six behavioural states and infant behaviour has an organised structure. It was his observation of newborn behavioural states that laid the groundwork for Berry Brazelton's work in developing the Neonatal Behavioural Assessment Scale (NBAS, 1973), and Heinz Prechtl's efforts to develop a standardised neurological examination for neonates (1977). Dr. Brazelton contributed an entirely new understanding of newborn infants—their behaviour, their temperament, and their interactions with family and other caregivers. He moved away from the traditional pathology-based approach and instead focused on the strengths of the individual infant. A colleague of Brazelton's, Dr. Heidelese Als expanded this work, focusing her attention to the behavioural repertoire of premature infants. Observing these infants for hours at a time she found patterns and meaning to their behaviour and responses to environmental stimuli. She developed the conceptual Synactive Theory as a framework for understanding human, and especially young infant, behaviour and in 1982 co-authored the Assessment of Preterm Infant Behaviour (APIB), a comprehensive neurobehavioral assessment [19]. In 1984 she introduced the first comprehensive neonatal model of care, the Newborn Individualised Developmental Care and Assessment Program (NIDCAP) into NICU.

After decades of work with the NBAS and NIDCAP both clinically and in research, Dr. Kevin Nugent and colleagues, in 2007, published the Newborn Behavioural Observations (NBO) system [20]. The NBO is an infant-focused, family-centred relationship-based tool, designed to highlight the full richness of a newborn infant's behavioural repertoire and communication style and unlike the other tools relies on direct parental involvement with the infant guiding the interaction [20]. The NBO consists of 18 neurobehavioral observations and is designed for use from birth through the third month of life. These items showcase that newborn infants possess a wide range of visual, auditory, and perceptual abilities that allow them to explore the world around them and to engage in face-to-face, eye-to-eye mutual exchange with caregivers [21]. The infant's behaviour is at the centre of the NBO with the focus on the infant's individuality. Through observation and interaction, the NBO allows infants to fully show who they are: their preferences, capacities, and vulnerabilities. In other words, the NBO provides the infant with a "*voice*" and the infant as a developing person is revealed [21].

The NBO although a powerful tool, will not capture the infant's complete experience of hospitalisation. To fully understand the complexities these infants must endure during their hospital stay there is a need for new methods of research in NICU.

2.1. Using 360-degree phenomenology in NICU to understand the infant's lived experience

Over the last 70 years we have learned much about the behavioural repertoire and capabilities of the newborn infant. Clinicians and researchers alike have used a variety of methods and observational tools to demonstrate that infants are born with a sense of self, and a sense of others, and possess inherent capacities for engagement, reciprocity, exploration, and discovery [22]. Their preverbal stage of development is no longer considered a barrier to including infants in research about matters which directly concern them. Placing the infant at the centre of our research allows those experiencing neonatal care to have their subjective opinion explored, guaranteeing space is made to see, hear, and consider the viewpoint of the infant [23]. Bringing an infant-led approach to research requires placing the infant at the forefront of the researcher's mind and practice. It is about truly being present in observing the infant, providing space to "*imagine*" and reflect on what it might feel like and be like for the infant in the moment [23].

To accomplish our aim of providing an infant-centred, rich understanding, and comprehensive analysis of the NICU experience through the eyes and communication of the infants themselves we devised a particular combination of methods underpinned by the research paradigm of phenomenology. For the purposes of this project, the lived experience, defined in phenomenological terms, is the infant's situated, immediate activities and everyday first-hand encounters within the NICU environment [24].

We drew also from case study methodology and utilised a variety of methods to explore the lived experience of infants in NICU [25]. As depicted in Fig. 1, the "*infant experience*" is our central focus, with each infant forming their own individual case study, respecting each infant's individuality and unique perspective. We began with infant involvement and infant data collection, drawing on what the infants themselves communicate, observing their hospital journey, and then interviews with the significant caregivers adds another perspective of the infant's lived experience. This 360-degree approach allowed us to utilise every possible lens to gain insight into what the infant is experiencing; infant, parent, care-team, and researcher. Methodological triangulation also increases the internal validity of the study (i.e. the extent to which the method is appropriate to answer the research question and the trustworthiness of the research findings) [25–29].

Data collection methods comprised recording the infant's daily

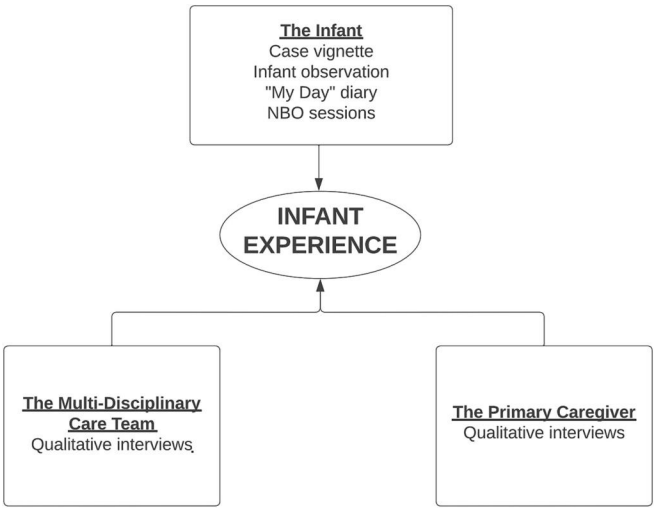

Fig. 1. Illustrates a visual representation of the data collection strategy.

encounters, activities, and opportunities for developing connections and relationships with others with a particular focus on how an infant communicates what they are experiencing and how those caring for the infant interpret the infant experience. The infant's lived experience, explored in this way, allows the infant to become an active agent in neonatal research, with their own "*voice*" and story to tell, and the process of data collection is modelling (and based on) a fundamental orientation to the infant's interpretation and response to stimuli.

This exploratory 360-degree phenomenology approach facilitates a closer, more granular perspective of an infant's experience in NICU, addressing the gap in the literature about how to know about and better understand what a NICU patient experiences.

3. Setting and participants

The research project has been granted ethical approval and is being conducted on a quaternary neonatal unit with 35 beds and approximately 800 admissions per year, caring for infants with complex medical and surgical conditions. Most infants cared for on this unit are born at or near-term gestation ($\geq$ 37 weeks gestation) with an average length of stay being 18 days, however infants with complex pathology can spend months in NICU. For feasibility inclusion criteria included term infants with an expected minimum length of hospital admission of >7 days. Exclusion criteria included diagnosis of congenital heart disease requiring surgery in the neonatal period (these infants are co-managed between two hospital units) or infants being cared for on a palliative care pathway.

Infants are enrolled following written, informed consent by their parents. For each infant key members of their clinical team are also approached to participant in private interviews. Infants participate for their entire hospital admission or for a maximum of 12 weeks.

4. Data collection methods

There are multiple data collection methods as shown in Fig. 1 and described in detail below. As mentioned, we are focused on term infants, but the following methods could be adopted to better understand the experience of preterm infants in NICU.

4.1. Case vignette

The infant's health record sets the scene for their hospital admission. A timeline of the key events taking place during the infant's hospital journey based on data from the health record is documented.

4.2. Infant observation

Utilising infant observation at the bedside we build a complete and empathic understanding of an infant's collective real time experience of everyday life in NICU. The goal of the observation being to describe, in concrete terms, the infant's environment and their behaviours whilst cataloguing their daily activities, interactions, and relationships. The observer, whilst immersed in the complex NICU environment simultaneously reflects on the events unfolding in front of them, "*imagining*" what it may be like to experience these things from the infant's perspective. These observation sessions are informed by the Tavistock Model of Infant Observation developed by Esther Bick [30]. This method of collecting data involves a disciplined process whereby the observer unobtrusively but keenly watches the interactions of the infant within their caregiving world and immediately post session writes up meticulous notes on what was seen from the beginning to the end of the observation session [31].

4.3. "My day" diary

A bedside dairy is used to capture a "*day in the life of an infant in NICU*" during times when infant observation is not possible. The diary details time spent with family, such as skin-to-skin care and medical and/or nursing caregiving interactions over a 24-h period. Any pain scores which are recorded as part of routine NICU care are also recorded. For ease of completion the diary includes a predetermined list of common NICU activities and encounters e.g. blood taking, medical examination, nappy change, as well as space for free text for both staff and families to add further detail. Any person interacting with the infant is encouraged to contribute to the bedside diary.

4.4. NBO session

The NBO permits direct interaction between the researcher, the infant, and their caregiver at the bedside, allowing the infant to showcase their individuality, strengths, and areas that may require support (Figs. 2 and 3 illustrate snapshots from a NBO session with an infant in NICU). These sessions allow the researcher to explore, fine tune and add greater meaning to behaviours that have already been observed at the bedside. The 18 items included in the NBO focus on the infant's motor system including quality of movements, tone, and activity level; capacity for self-regulation (including crying and consolability); response to stress (indices of the infant's threshold for stimulation); and visual, auditory, and social-interactive capacities (degree of alertness and response to both human and non-human stimuli) [20]. The researcher and parents work together during these sessions to fully understand the infant in front of them.

4.5. Qualitative interviews

Using qualitative interviews, we explore how the adults surrounding the infant describe, account for, justify and rationalise the infant's hospital experience. Parents or primary caregivers are interviewed at two different time points in the infant's hospital journey. Members of the multidisciplinary care team are invited to attend one private interview. The interviews explore not only the physical environment and its impact on the developing infant but the activities and encounters the infants are exposed to. There is a particular focus on the infant's developing relationships. Using a semi-structured interview guide, the researcher sensitively explores the interviewee's ability to reflect and mentalise on the infant experience, as if in the infant's "*shoes*". Interviews are recorded, and then transcribed verbatim for data analysis.

5. Data analysis

Data will be analysed using inductive content analysis (ICA). ICA is a

Fig. 2. NBO session demonstrating the infant's responsiveness. Picture 1 demonstrates response to face and voice. He can engage in mutual eye-to-eye exchange with the NBO clinician. He can track both face and voice. Picture 2 demonstrates visual tracking with a red ball. These interactions highlight a growing awareness of the environment and the capacity to respond and engage in social interaction.

Fig. 3. NBO session demonstrating the infant's organisation of state and ability to cope with stress. Picture 1 demonstrates the infant's ability to habituate to light and protect sleep. In picture 2, we see that the infant was disturbed by sound; awakening from sleep. The infant has pursed lips and a facial frown/grimace. He also developed hiccups. The NBO clinician holds him in a containment hold, bringing his arms to his chest, to help him to return to a regulated, stress-free state.

method of qualitative data analysis well-suited for use in health-related research that has direct relevance for practice and policy [32]. As stated, each infant will form their own case study. Data analysis will occur in two phases, firstly a detailed account of each case will be developed; this is known as in-case analysis. Secondly, analysis across all cases is carried out, referred to as a "cross-case analysis" [33].

5.1. Phase 1

Data will be analysed using the principles of Vears and Gillam's ICA [32]. ICA is an *inductive process* and involves *iterative coding* meaning that the codes used to label the data are developed during the process of coding, based on the actual content of the data set [32]. The codes are identified by the researcher within the data itself. Iterative coding means that the process of coding is not done only once for each document/transcript but is refined based on comparison between documents/transcripts and then repeated. Each document/transcript is coded several times in more refined iterations each time [32].

As described by Vears and Gillam, analysis will take place in five phases, beginning with familiarisation with the data, and then initially coding the data into basic stand-alone segments of text relevant to the phenomenon under study [32]. Content will then be identified, reviewed, and refined. Lastly synthesise and interpretation allows connecting the categories to create a narrative for the reader that gives an overall explanation of the phenomena under study [32].

5.2. Phase 2

Comparing data between cases will be an integral part of data analysis to draw conclusions about the infant's lived experience in NICU.

Data will be managed in NVivo software and presented using visual schema and content categories exemplified with quotations. Quotations will never be presented with identifiable participant information.

6. Conclusion

Early life experiences have a lifetime's influence, laying the foundations for all aspects of development and functioning: physical, social, emotional, and cognitive. Hospitalisation in the newborn period poses a significant challenge to the developing infant by virtue of the varied experiences they encounter.

Despite a notable focus on the importance of early life experiences, research has omitted to include the perspective of the infants undergoing neonatal care. Infants are born with an armoury of behavioural cues and communication strategies to engage with the world around them. Drawing on this skillset we propose a novel, infant-focused methodology, which we have named 360-degree phenomenology to better understand, from the infants themselves their early life experiences in hospital, permitting them a voice in matters that directly relate to them.

Such a focused exploration of the infant experience may uncover gaps in models of care or areas for improvement in the way neonatal care can be delivered to improve the early lived experiences of hospitalised infants. We hope the findings will then lay the foundation for future research, which ultimately strives to improve long-term health outcomes for this vulnerable patient group.

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Natalie Duffy: Writing – review & editing, Writing – original draft, Resources, Project administration, Methodology, Conceptualization. **Leah Hickey:** Supervision, Writing – review & editing. **Karli Treyvaud:** Supervision, Writing – review & editing. **Clare Delany:** Supervision, Writing – review & editing.

Declaration of competing interest

None declared.

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RESEARCH ARTICLE

WILEY

Supporting early infant relationships and reducing maternal distress with the Newborn Behavioral Observations: A randomized controlled effectiveness trial

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Abstract

Research points to the significant impact of maternal distress on the parent-infant relationship and infant development. The Newborn Behavioral Observations (NBO) is a brief intervention supporting the infant, the parent and their relationship. This randomized controlled trial examined the effectiveness of the NBO in a population with antenatal distress and risk of postnatal depression (PND). Pregnant, first-time mothers with current anxiety or depression symptoms or past mental illness were recruited from two Australian hospitals. Participants received three NBO sessions in the first month of life plus treatment as usual (TAU), or, TAU-only. Outcomes assessed at infant age 4 months included mother-infant interaction quality; maternal anxiety and depression symptoms; and depression diagnosis. Of 111 pregnant individuals randomized, 90 remained eligible and 74 completed the trial (82.2% retention). There were intervention effects on emotional availability $F(6, 67) = 2.52$, $p = .049$, Cohen's $d = .90$, with higher sensitivity and non-intrusiveness in the intervention group ($n = 40$) than the comparison group ($n = 34$). There was an intervention effect approaching significance for anxiety symptoms at 4 months ($p = .06$), and a significant effect over time ($p = .014$), but not for depression symptoms. Anxiety and depression symptoms significantly reduced to sub-clinical levels within the intervention group only. There were fewer depression diagnoses ($n = 6$) than expected across groups, with no observed intervention effect. No adverse intervention effects were seen. Exploratory analysis of sensory processing sensitivity suggested differential susceptibility to distress and intervention benefits. The NBO was accepted and exerted meaningful effects on relationship quality and distress; and may enhance the infant's interaction experience and maternal emotional adjustment in at-risk populations.

KEYWORDS
clinical trial, depression, infant development, infant, newborn, parent-child relationship, psychological distress

1 | INTRODUCTION

The early years are critical to infant and child development, and the primary influence during this period is the caregiving relationship (Sroufe et al., 2005). Worldwide, one of the most prevalent factors to compromise caregiving relationships is maternal distress; an umbrella term encompassing depression, anxiety and stress in the transition to motherhood (Kingston et al., 2012; Vehmeijer et al., 2019). Maternal distress can profoundly impact the mother, family and infant, and addressing it is considered one of the most effective ways to reduce delays in early child development (Kingston et al., 2012, 2015).

The developmental impacts of maternal distress are multi-faceted and mediated by a complex interplay of fetal programming, parent-infant interaction quality, infant-attachment security, and neuroendocrine effects on brain structural and functional development (Glover et al., 2018; Murray et al., 2018; Vehmeijer et al., 2019). Impacts are not inevitable, and depend on the distress itself, family circumstances, parental attachment representations, and genetic susceptibility to the environment (Ellis et al., 2011; MacMillan et al., 2020; McMahon et al., 2006; Stein et al., 2014). Nonetheless, the infant may face significant early interactional relationship difficulties known to impede secure attachment and development, such as maternal withdrawal, insensitivity, intrusiveness and hostility and compromised dyadic contingency processes (Erickson et al., 2019; Murray et al., 2018; Riva Crugnola et al., 2016).

Early identification and treatment of maternal distress, within and beyond psychiatric diagnosis is a crucial area for public health intervention to alter the developmental trajectory for families (Glover, 2020; Heron et al., 2004; Howard & Khalifeh, 2020). Prevention of chronic, severe postnatal depression (PND) is particularly pressing (Netsi et al., 2018); but internationally, too few women have their distress acknowledged or access adequate help (Sambrook Smith et al., 2019).

Since 2018, the Australian Government has funded screening to identify women with perinatal distress and psychosocial risk factors for PND, creating a unique opportunity for intervention. Positive screening within obstetric and maternal and child health (MCH) services prompts referral for individual pharmacological treatment and psychotherapy, however converting distress identification to help-seeking and effective care remains challenging and reflects multiple barriers to accessing care such as stigma (Holt et al., 2017). The optimum, feasible front-line intervention approach to maternal distress and its impacts is not established (Belkin et al., 2017; Howard & Khalifeh, 2020; Rayce et al., 2020). Relationship-focused intervention has been effective in a low socio-economic setting, but the effectiveness has not been replicated in a high-income country (P. Cooper et al., 2015; P. J. Cooper et al., 2009). In Australia, an effective, brief perinatal relationship-focused intervention within existing universal services could minimize stigma, provide an integrated front-line response to distress in the family system, and be an entrée to additional support (O'Brien et al., 2017; White, 2018).

One brief relationship-focused intervention of interest is the Newborn Behavioral Observations (NBO). This semi-structured intervention reveals the infant's capacities for state regulation, sleep protection, response to stress and ease of settling, motor and perceptual abilities, and social responsiveness (Nugent et al., 2007). With a clear focus on the infant, while attuned and responsive to the parents, the NBO aims to influence interaction quality by helping parents to see, emotionally accept, and respond to their infant's communication. Adherence to the therapeutic model includes more than "doing a set of items" (Nugent et al., 2022). A stated goal is for a brief, therapeutic experience that builds the intimate relationship between infant and parent, establishes a collaborative relationship between parents and therapist, and encourages further engagement with services.

Diverse health and lay professionals use the NBO worldwide in daily practice, but research supporting widespread community use is limited (Dawson & Frost, 2018; Gibbs, 2015; Schilling et al., 2018). A recent meta-analysis found very low-quality evidence that the NBO supports infant development and parent-infant relationship quality, and called for NBO stand-alone effectiveness trials in at-risk populations (Barlow et al., 2018). Subsequently, an early intervention study for vulnerable newborns reported positive developmental effects, and a pilot study for vulnerable mothers reported on feasibility and acceptability overseas (Greve et al., 2018; McManus et al., 2020). However, no studies in Australia have trialed the NBO as a standalone intervention or in comparison to existing perinatal care for clinical populations.

To address these concerns and examine the therapeutic role of the NBO in an Australian population, the

Understanding your Newborn and Adapting to parenthood (UNA) study was developed for infants, and their first-time mothers identified during pregnancy with distress and risk for PND. The *primary objectives* were to determine whether the intervention was acceptable; and whether it enhanced the quality of the mother-infant interactive relationship, decreased PND diagnoses, and decreased distress in early infancy. *Secondary objectives* were a preliminary assessment of NBO impacts on early infant development, an exploration of possible differential maternal susceptibility to the intervention, and an exploration of factors predicting PND and adverse parent-infant interaction within the population.

KEY FINDINGS

1. This randomized controlled trial in a "real world" setting showed positive effects of the Newborn Behavioral Observations (NBO) intervention, in a population of young infants and their first-time mothers identified with antenatal maternal distress and a risk of postnatal depression.
2. The NBO reduced maternal distress symptoms and enhanced relationship quality but did not prevent depression diagnosis. Very early, integrated infant-parent mental health intervention can support the infant's interactional experiences of the mother and the mother's emotional adjustment.
3. The NBO may provide acceptable and effective preventative care for vulnerable new families identified with maternal distress.

RELEVANCE OF THIS RESEARCH TO THE FIELD OF INFANT AND EARLY CHILDHOOD MENTAL HEALTH

The quality of the infant-caregiver relationship impacts early infant development and maternal wellbeing, and can be adversely affected by maternal distress. Detecting maternal distress in pregnancy and subsequent very early relationship intervention has the potential to alter this trajectory. This is the first Australian study examining the impact of the Newborn Behavioral Observations (NBO) as a stand-alone infant-parent mental health intervention, and the first international study reporting objective NBO intervention effects in this at-risk population.

2 | MATERIALS AND METHODS

A randomized controlled clinical trial (RCT) design examined the effectiveness of the NBO plus treatment as usual (TAU), compared with TAU-only.

2.1 | Recruitment

Participants were recruited from a larger observational study examining the psycho-social and emotional health of first-time mothers and fathers ($n = 327$). The larger study recruited participants between August 2017 and March 2018 from a tertiary metropolitan hospital and a regional hospital in the state of Victoria. These government-funded hospitals provide free services to Australian residents. The Human Research and Ethics Committees (HREC) at each site approved the study. Women were eligible if nulliparous, less than 36 weeks gestation at recruitment, aged 20 or over, able to speak and respond to a questionnaire in English, and living within 40 min drive of their recruitment site. Women became ineligible during the trial if they had a baby born at term with a severe disability, their baby was born before 36 weeks, or they moved away from their recruitment site.

2.2 | Procedure

2.2.1 | Screening

Eligible pregnant women ($n = 295$) were invited to participate in the larger trial. Of 295 approached, 254 agreed to participate (86.1%) and were screened for current distress symptoms (anxiety and depression) and risk of PND. Refusers ($n = 41$) gave the following reasons: lack of time ($n = 12$), uncomfortable with video ($n = 6$), not interested ($n = 10$), not wishing to provide reason ($n = 9$); started but did not complete screen ($n = 4$). Recruits who screened "negative" formed the broader observational study cohort (G0), which was not randomized but continued to receive routine maternity care (see Figure 1). A "positive" screen was defined as one or more of: significant current distress symptoms of depression and anxiety, identified as a score of ≥10 on the Edinburgh Postnatal Depression Scale (EPDS); significant current distress symptoms of anxiety, identified as a score of ≥26 on the Perinatal Anxiety Screening Scale (PASS); significant history of mental illness for

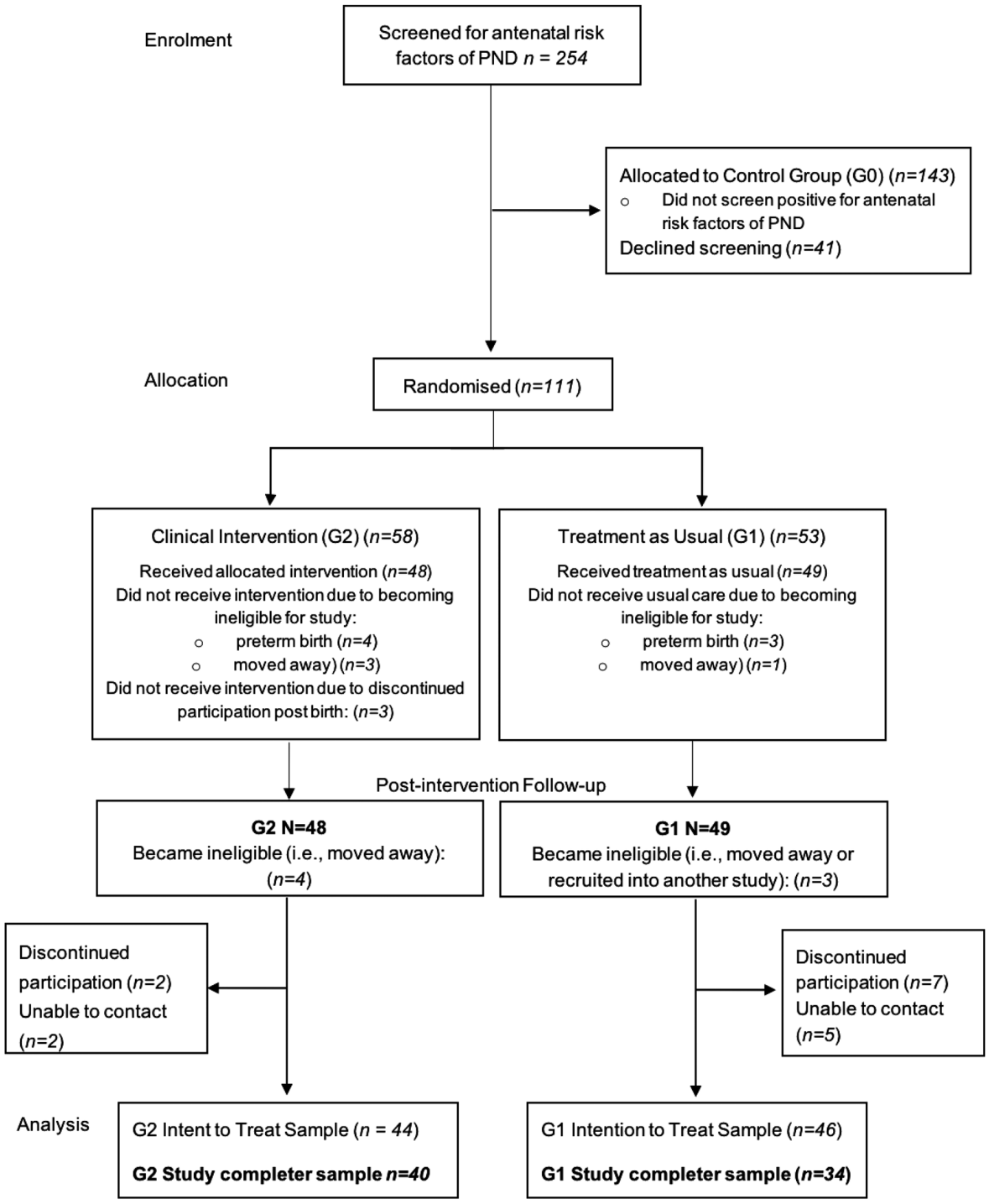

FIGURE 1 CONSORT diagram of participant flow and attrition. PND = post-natal depression

which they had sought professional support, identified via the Antenatal Risk Questionnaire (ANRQ).

Of 254 screened participants, 111(43.9%) screened "positive" for the randomization criteria and formed the at-risk subpopulation for the current study. Randomization was initially based on EPDS scores alone, but the criteria were expanded in an early protocol amendment with HREC approval. This amendment was a response to increasing evidence that past mental illness, perinatal anxiety symptoms and depression symptoms independently and consistently predict PND, and that the PASS enhances detection of perinatal anxiety (Guintivano et al., 2018; Heron et al., 2004; Milgrom et al., 2008; Somerville et al., 2014). The proportion of participants identified and randomized with current distress in pregnancy and risk of PND increased from 10% of the first 40 women screened (EPDS only) to

TABLE 1 Reasons for randomization ($n = 111$)

Randomization criteria met in pregnancy	*n* (%)
Past mental illness only (ANRQ)	39 (35.1)
Current symptoms depression only (EPDS≥10)	16 (14.4)
Current symptoms anxiety only (PASS≥26)	7 (6.3)
Current symptoms anxiety + depression	13 (11.5)
Current symptoms anxiety + past mental illness	3 (2.7)
Current symptoms depression + past mental illness	13 (11.5)
All three criteria[a]	20 (18.0)[a]

Abbreviations: ANRQ, ante natal risk questionnaire; EPDS, Edinburgh postnatal depression scale; PASS, perinatal anxiety screening scale.

[a]Six of these individuals were regional recruits (of a total of six regional participants).

over 40% of the women screened (EPDS plus PASS plus past mental illness), the commonest criterion met being past mental illness (35.1%) (see Table 1).

2.2.2 | Randomization

Participants were randomized to the *intervention group (G2)* or the *comparison group (G1)*. A staff member outside the research team executed randomization in advance via computerized sequence generation, and provided sealed envelopes containing group allocations to researchers at the recruitment sites. Group assignment was not discernable from envelope appearance or thickness. It was not possible to blind participants to their randomization condition. However, researchers undertaking the outcome assessments were blinded, and the research coordinator attended to ensure the participant's randomization status was not discussed.

2.2.3 | Intervention

The intervention group (G2) received three NBO sessions and a study endpoint assessment, as well as TAU. Recruits who birthed at the hospital and completed all NBO sessions and the endpoint assessment were considered *intervention completers*. The NBO sessions utilize 18 passive and interactive observations to draw out the baby's neuro-developmental strengths and challenges and caregiving needs and preferences. Sessions take 20–40 min (Nugent et al., 2007). The clinician adjusts the content, pace and order of observations according to the infant's state, stress signs and responsiveness. The clinician also supports parental emotional responses, involvement and insights (Nugent et al., 2022). Fathers and extended family participate if present. The clinician and parent(s) reflect together on the meaning of the baby's observed behaviors and caregiving implications. Sessions are documented in the NBO summary and recording forms.

For this study, participants also completed an NBO feedback form after each session, which was returned to the research team in a sealed envelope. NBO sessions were timed to coincide with routine maternal-infant health care. They included one session in the first week of life in hospital or participants' homes, and two sessions at infant aged 2 and 4 weeks in participants' homes. An NBO-accredited midwife or MCH nurse provided the sessions, and completed an NBO fidelity checklist to record session adherence to NBO aims and content (see Supporting Information, Appendix 1). A fidelity video was recorded during the second session with participant consent and was reviewed in reflective supervision sessions with an NBO master trainer (author SN). At infant age 4 months, a study endpoint assessment was undertaken, with participants receiving a home visit from an assessment-accredited psychologist or occupational therapist. They conducted a filmed mother-infant interaction assessment, an infant developmental assessment, and a diagnostic interview for PND.

2.2.4 | Clinical comparison

Participants randomized to the comparison group (G1) were offered TAU which involves referral to, assessment, and treatment, at the recruitment site's perinatal mental health service. Depending on the women's history and preference, this may involve allocation to an individual psychiatrist/psychologist/mental health nurse, or clinician-facilitated group care. TAU includes review and follow-up after birth as required. Frequency and duration of visits depend upon need and acceptance of mental health support. TAU was unaffected by study participation. Time-equivalent sessions to match the intervention arm's NBO sessions were not provided. However, participants received the same endpoint assessment as the intervention group. Recruits who birthed at the hospital and completed endpoint assessments were considered *TAU-only completers*. For information on routine maternal and newborn care in Victoria, Australia, see Supporting Information, Appendix 2.

2.2.5 | Study retention

To promote retention, recruits received a congratulatory e-card following the birth of their child, two-monthly calls to check contact details were correct and to organize the endpoint visit, and a text message reminder before each

visit. At study completion, participants received an edited video showing moments of mutual mother-infant enjoyment with background music.

2.3 | Data collection

Data were collected at time points T1-T8. See Table 2 for the data collection schedule. Data were gathered from participants' medical records, NBO tools, self-administered questionnaires, videoed interaction and clinical diagnostic interview. Participants completed questionnaires in person at recruitment (T1), and online (in REDCap-Research Electronic Data Capture) at T2, T7, and T8.

2.3.1 | Pre-intervention data (T1-3)

Socio-demographic and psychosocial data were collected at baseline in pregnancy (T1) for all recruits, including age, country of birth, main language, cultural identity, religious identity, education level, partner status, occupation and income status, depression symptoms, anxiety symptoms, and psychosocial risk assessment. To minimize the impost on non-randomized participants, additional psychosocial data were collected at 36 weeks' gestation (T2) for randomized recruits only, including newborn developmental knowledge and sensory processing sensitivity. Obstetric data were collected post-birth (T3) for randomized recruits, including gestation at first antenatal visit, medical/obstetric complications, gestation at birth, mode of birth, infant gender, birth weight and feeding method on hospital discharge.

2.3.2 | Intervention data (T4-6)

Data were collected, from the intervention group only, at intervention time-points infant age <1 week (T4), age 2 weeks (T5) and age 4 weeks (T6), including the NBO parent summary form, NBO recording form and NBO parent feedback form. Clinicians completed an NBO fidelity checklist at each point, and a fidelity video was recorded at infant aged 2 weeks (T5) only (see Table 2).

2.3.3 | Post-intervention data (T7-8)

Data for the intervention and comparison groups were collected 2 weeks post-intervention at infant aged 6 weeks (T7), plus 12 weeks post-intervention at infant aged 4 months (endpoint, T8). Data at T7 included self-reported distress (depression symptoms), consistent with routine perinatal mental health screening in community nursing care. Psychosocial data at T8 included depression diagnosis, self-reported distress (depression symptoms, anxiety symptoms), newborn developmental knowledge. Infant data at T8 included mother-infant interaction quality, infant development and feeding method.

2.4 | Measurements

2.4.1 | NBO-intervention measurements (T4-T6)

NBO fidelity checklist: Developed for this study, this 18-item questionnaire addressed session duration, number of items completed, and putative mechanisms of change for the parent-infant relationship and parenting-related distress. Responses are on a 5-point Likert scale (1 = minimal to 5 = optimal).

NBO parent feedback form: This included six questions from the Brazelton Institute NBO parent questionnaire, addressing helpfulness of the session to feel closer to baby, to feel more confident as a parent, to get to know their baby more, to relate to the clinician, and overall. Responses were on a 4-point Likert scale (1 = very little to 4 = a lot). See Supporting Information Appendix 1.

NBO recording form: This recorded the infant's age, weight, intervention setting and 18 NBO neurobehavioral observations along a 3-point range using a descriptive guide. The observations then generated a profile of the infant's strengths and areas needing support (Nugent et al., 2007). This record helps clinicians form an individualized understanding of the baby's caregiving needs and provides a reference for subsequent sessions.

NBO parent summary form: Completed by the clinician and parent together, this Brazelton Institute form may be kept by the family. It uses lay terminology and describes the infant's observed behavioral strengths; observed signs of dysregulation and support needs; and caregiving affirmation and guidance. See Supporting Information Appendix 1.

NBO fidelity video: The second NBO session was filmed and constituted the fidelity video.

2.4.2 | Parent-infant interaction measures (T8)

EAS (Emotional Availability Scales), 4th Edition: Mother-infant interaction quality was assessed at infant age 4 months/T8, using the EAS (Biringen, 2008). This primary outcome measure was used to examine for treatment-group differences in mother-infant interaction

TABLE 2 Data collection schedule

		Pre-intervention			Intervention			Post-intervention	
Measure	**Target**	**T1 Recruitment**	**T2 36 wks gestation**	**T3 Post-birth**	**T4 infant aged 1–6 days**	**T5 infant aged 2 weeks**	**T6 infant aged 4 weeks**	**T7 infant aged 6 weeks**	**T8 infant aged 4 months**
Baseline socio-demographics	All recruits (G0,G1,G2)	X							
ANRQ	All recruits (G0,G1,G2)	X							
EPDS	Variable	X All recruits (G0,G1,G2)						X (G1+G2 mothers)	X (G1+G2 mothers)
PASS	Variable	X All recruits (G0,G1,G2)							X (G1+G2 mothers)
HSP scale	G1+G2 mothers		X						
NDKQ	G1+G2 mothers		X						X
Obstetric data	G1+G2 mothers			X					
Infant feeding method (breastfed/bottle-fed/both)	G1+G2 mothers			X					X
NBO recording form	NBO clinician				X	X	X		
NBO parent summary form	G2 mothers + NBO clinician				X	X	X		
NBO parent feedback form	G2 mothers				X	X	X		
NBO fidelity checklist	NBO clinician				X	X	X		
NBO fidelity video	G2 mother-infant dyads + NBO clinician					X			
Video interaction: EAS 4th Ed.	G1+G2 mother-infant dyads								X
Clinical Interview SCID-5	G1+G2								X
Bayley III scales of infant development	G1+G2 infants								X

Abbreviations: ANRQ, ante-natal risk questionnaire; EAS, emotional availability scales; EPDS, Edinburgh postnatal depression scale; G0, non-clinical group; G1, clinical comparison group; G2, clinical intervention group; HPS scale, highly sensitive person scale; NBO, newborn behavioral observations; NDKQ, newborn developmental knowledge questionnaire; PASS, perinatal anxiety screening scale; SCID-5, structured clinical interview for DSM disorders 5th edition.

post-intervention. The EAS is widely-used and has predictive and concurrent validity with several attachment measures (Bohr et al., 2018). In the emotional availability (EA) construct, relationships are examined according to how one person in a dyad affects another emotionally, rather than how an individual behaves. Construct validity has been established in longitudinal studies and multi-cultural populations (see Biringen et al., 2014 for a review). Inter-rater reliability ICCs in laboratory and naturalistic settings range from .76 to .92 (Gridley et al., 2019). Short-term test-retest reliability is moderately strong for three-parent dimensions: sensitivity, structuring and non-intrusiveness (Endendijk et al., 2019).

The tool uses video data of ≥20 min free play or other tasks to assess EA across six scales: maternal sensitivity, structuring, non-intrusiveness, and non-hostility; plus, infant responsiveness and involvement. For each scale, a direct global score is generated on a Likert scale (1 = *non-optimal* to 7 = *optimal)* and a total score is generated using seven subscales (range 7–29). Two subscales are rated from 1 = *non-optimal* to 7 = *optimal* and five subscales are rated from 1 = *non-optimal* to 3 = *optimal*. An overall EA score is generated by adding the six direct global scores (range 6–42). Recent Australian research raises unresolved questions about optimum EAS data analysis (Aran et al., 2021). In the current study, direct and total scores for all six scales, plus overall EA scores, are reported for 20-min free play.

Mothers were invited to "be, play and talk as usual with their baby," and given three toys they might use. The researcher left the room during filming. Overseas EAS experts blind-coded the video data. Across 10 (13.5%) double-coded videos, intra-class correlations (ICC) of .77–.86, for the global rating of each domain indicated high inter-rater reliability. Pearson bivariate correlations confirmed direct and total scores highly correlated across all scales ($r = .89–.96$, $p < .001$), indicating that the total score encompassed the scorers overall rating of each dimension, as previously reported (MacMillan et al., 2020).

2.4.3 | Infant development measures (T8)

Bayley-III Scales: This gold-standard measure of infant development (age 1–42 months) was used at infant age 4 months/T8. The Bayley-III directly records infants' observed performance across cognition, communication and motor development scales, and records socio-emotional and adaptive development in two-parent questionnaire scales (Bayley, 2006). Administration takes 30–90 minutes, with the number of items administered determined by infant performance. Items are scored dichotomously (1 = able to complete, 0 = not able to complete). Infants' development is compared with USA norms to yield composite scores, standardized by age (M = 100, *SD* = 15). The Bayley-III has high reliability and validity (Cronbach's alpha >.85 for all subscales). This study used all scales except adaptive development.

NDKQ (Newborn Developmental Knowledge Questionnaire): The NDKQ was developed to assess parental knowledge of the developmental needs of infants aged 0–3 months pre- and post- clinical intervention (Newman, 2006). It was administered at two study timepoints: 36 weeks' gestation (T2), and at infant age 4 months/T8. The tool has 35 items, with five subscales pertaining to communication, visual attention and mutual gaze, tiredness, regulation and verbal and non-verbal expression. Statements are categorized as true/false/unsure. Correct answers score 1 (range = 0–35). Detailed psychometrics are not available, but the tool has demonstrated face validity and scores have been demonstrated to improve following infant development education (personal communication, A Komiti & L Newman, November 22, 2021).

2.4.4 | Maternal psychosocial measures (including maternal distress and PND)

ANRQ (Antenatal Risk Questionnaire): This tool screened at baseline in pregnancy/T1 for a significant mental health history (a randomization criterion) and other psychosocial risk factors for perinatal mental health morbidity. Fourteen items include past mental illness, past abuse, current supports, relationships with partner and mother, recent life stressors, and anxious/perfectionistic traits (Austin et al., 2013). A significant mental health history is defined by positive response to both "Have you ever had 2 weeks or more when you felt particularly worried, miserable or depressed?" and "If Yes, did this lead you to seek professional help?" Categorical (yes/no) and dimensional (1–5) responses yield a total psychosocial risk score 5–67. Performance identifying risk of PND is acceptable (OR = 6.3 [95% CI = 3.5–11.5]; sensitivity = .62; specificity = .64; positive predictive value = .3; negative predictive value = .87). The recommended cut-off score is ≥23, but past mental illness or past abuse increase risk, irrespective of the total score.

EPDS (Edinburgh Postnatal Depression Scale): This 10-item, highly adopted tool screened for perinatal distress at baseline in pregnancy/T1, at infant age 6 weeks/T7 and infant age 4 months/T8 (Cox et al., 1987). Three questions pertain to anxiety symptoms and seven to depression symptoms. Individuals rate how they felt the previous week. Responses are scored 0–3, with higher scores indicating more severe depressive symptoms (maximum score = 30). The EPDS has high reliability (Cronbach's alpha = .87). For commonly used cut-off values of

10 or higher and 13 or higher, sensitivity and specificity are 85% and 84%, and 66% and 95%, respectively, for depression diagnosis; with no differences across subgroups, including pregnant versus postpartum status (Levis et al., 2020). The current study used a cut-off score of 10 at baseline in pregnancy, providing an optimal combination of sensitivity and specificity for depression diagnosis at clinical interview (Bergink et al., 2011). At T7 and T8, a cut-off of 13 provided optimal specificity for concurrent depression diagnosis.

HSP Scale (Highly Sensitive Person Scale): This 27-item tool measured maternal sensory processing sensitivity at 36 weeks' gestation/T2. Items assess individuals' responses to various environmental situations using a 7-point Likert scale (1 = not at all, 7 = extremely) (Aron & Aron, 1997). The total score represents a person's sensitivity to their environment (both to adverse experiences and supportive interventions). The scale has good internal consistency (Cronbach's alpha = .85–.89) and discriminant validity. Categorical analysis is recommended; the top 30% HSP scoring individuals in a population categorized as Highly Sensitive Persons or "orchids," the middle 40% as "tulips" and the lower scoring 30% as "dandelions" (Greven et al., 2019).

PASS (Perinatal Anxiety Screening Scale): This 31-item tool screened for perinatal anxiety symptoms at baseline in pregnancy/T1 and endpoint infant age 4 months/T8. Items are scored from 0 = never to 3 = almost always (Somerville et al., 2014). The PASS has good convergent validity with the EPDS anxiety subscale and the State-Trait Anxiety Inventory (.74–.83). It has four subscales: acute anxiety and adjustment disorder; general anxiety and specific fears; perfectionism, control and trauma; and social anxiety (Cronbach's alpha .90, .89, .86, and .87, respectively). The tool is validated against diagnostic assessment of anxiety disorder administered at clinical interview by psychologists and psychiatrists in English, and against gold-standard diagnostic tools in other languages, with an optimal clinical cut-off score of 26. In the original Australian population, the PASS cut-off correctly identified 68% pregnant and postnatal women diagnosed with an anxiety disorder at clinical interview (sensitivity = .7; specificity = .3), versus 36% women identified using the EPDS anxiety subscale. In an Italian population, the PASS identified 98% women with a diagnosis of anxiety disorder using the SCID, out-performing both EPDS anxiety subscale and HAM-A (Koukopoulos et al., 2021).

SCID-5 (Structured Clinical Interview for DSM-5): This semi-structured interview guide for diagnosing mental illness uses criteria in the Diagnostic and Statistical Manual for Mental Disorders 5th Edition (First et al., 2015). This study used the current major depressive episode modules to diagnose PND at endpoint infant age 4 months/T8. Administered by trained professionals, the SCID is the most reliable semi-structured instrument for assessing DSM diagnoses in research populations (Levis et al., 2019).

2.5 | Data analysis

2.5.1 | Power calculations and sample size

The total sample size was calculated to detect a medium-sized effect (Cohen's $d = .5$) in the outcome measures of mother-infant interaction (EAS), infant development (Bayley Scales), and maternal distress (EPDS) across groups G1 and G2, utilizing G*Power software (Faul et al., 2007). Calculations were based on ANCOVA analyses for the detection of a difference between groups with 1:1 allocation. With alpha set at .05 and accounting for the effects of four covariates (maternal age, education, marital status, history of depression), a total sample size of 73 offered .95 power to detect a difference between the comparison and intervention groups. The study therefore aimed to recruit and randomize 90–100 participants, anticipating attrition of 20%–30% based on a previous Victorian study with a vulnerable population (Nicolson et al., 2013).

2.5.2 | Statistical analyses

Intention-to-treat (ITT) analyses were performed on the ITT sample (G1+G2 = 90). *Study completer* analyses were performed on the corresponding sample (G1+G2 = 74), see Figure 1. Statistical analyses utilized SPSS Version 25, with alpha set at .05 (IBM Corp, 2017). Categorical data were summarized using frequencies and percentages. Continuous variables were inspected for departures from normality. Responses on validated scales were excluded from statistical analyses if ≥15% values were missing. As per CONSORT standards, ITT analysis was conducted for maternal clinical outcomes of depression and anxiety symptoms for which there was pre- and post-intervention data (Moher et al., 2001). Maximum likelihood-based mixed-effects modelling for repeated-measures method (MMRM) confirmed unbiased results in the presence of random missing data at post-intervention follow-up. Missing data were missing completely at random (Little's MCAR test, $\chi^2 = 34.57$, $p = .18$).

Independent samples t-tests for continuous variables, and Chi Square analyses for categorical variables (or Fisher's exact test when expected cell count was <5), examined between group differences in (a) study completers and non-completers, and (b) intervention and comparison groups for endpoint distress characteristics and

breastfeeding data. Repeated measures analysis of covariance (ANCOVA) examined between group differences on primary outcomes of maternal distress (EPDS and PASS). Linear mixed-effects repeated measures modeling analyzed group and time interaction effects for depression and anxiety symptoms. Paired samples t-tests evaluated change in maternal distress symptoms from pre-intervention (T1:baseline) to post-intervention (T8:endpoint) within intervention ($n = 40$) and comparison group ($n = 34$) completers. Multivariate analyses of covariance (MANCOVA) examined between-group differences in the EAS. Analysis of variance (ANOVA) examined between group differences on endpoint psychosocial, and infant development measures. Effect sizes are expressed as Cohen's d (CI = 95%). Exploratory ANOVA examined differential susceptibility (using categorized HSP scores) to the intervention in relation to primary outcomes of maternal distress (EPDS and PASS) in the intervention group only. Exploratory multiple linear regression examined for likely baseline predictors of PND and mother-infant interaction quality (age, partner support, past mental illness, current anxiety/depression symptoms in pregnancy,) in the comparison group only.

3 | RESULTS

3.1 | Study population

A total of 111 pregnant women were randomized, with 90 remaining eligible after childbirth and forming the ITT sample. Of those, 74/90 completed the study (overall retention rate 82.2%); with 34 completers in the comparison group (retention rate 73.9%), and 40 completers in the intervention group (retention rate 90.9%) (see Figure 1). Of the six regional hospital recruits, all remained eligible after birth and five completed the study. A baseline comparison of study completers versus non-completers found younger mothers were less likely to complete the study ($p = .002$), and non-completers were more likely to have had a vaginal delivery (87.5%; $\chi^2(2, 90) = 8.65$ $p = .000$) and less likely to have had a caesarean delivery (12.5%; $\chi^2(2, 90) = 20.57$ $p = .000$). There were no significant differences across psychosocial risk and distress variables, mean gestation at first antenatal visit, birth weight or gestation at birth. For details, see Table 3. As per CONSORT guidelines, baseline analyses for between group differences were not conducted (Moher et al., 2010). Data were examined for heterogeneity with the intent to adjust results through multivariate analysis as required, but no heterogeneity required statistical correction. Intervention (G1) and comparison (G2) study completers appeared reasonably balanced across all baseline demographic, obstetric, distress and psychosocial risk variables (see Supporting Information, Appendices 3–5).

3.2 | Demographic and psychosocial characteristics

The mean age of randomized participants ($n = 111$) was 31 ($SD = 4.06$), with 39% born outside Australia and 13.5% speaking a language other than English at home. Sixty-two percent reported Caucasian or European cultural identity, 11.7% identified as Asian, 2.7% as Middle-Eastern and 2.7% as Muslim. Fifty-five percent were married, 37.5% in a de-facto relationship and 4.5% were single. Seventy-two percent had a university degree, 15.2% had a trade or post-school certificate, and 5.4% did not complete senior school. Sixty-three percent had paid employment, 10.7% were unemployed, 7% in home duties and 13.4% other. Students comprised 3.6% of participants. Household income was >AUD$80,000 for 65% of participants and 14.3% of the cohort received a government benefit. Participants' mean scores at baseline were: 9.8 ($SD = 4.7$) for depression symptoms (EPDS); 26.7 ($SD = 16.5$) for anxiety symptoms (PASS); and 28.6 ($SD = 10.3$) for psychosocial risk (ANRQ). Mean scores approached the recommended mid-pregnancy cut-off used for randomization for the EPDS (10), and exceeded the cut-offs for the PASS (26) and ANRQ (23), confirming a clinically at-risk population. See Supporting Information, Appendix 6.

3.3 | Intervention effects on mother-infant relationship at infant 4 months (T8)

At study endpoint, infant age 4 months/T8, the intervention showed an effect on emotional availability in 20 minutes of free play ($n = 74$), $F(6, 67) = 2.52$, $p = .049$, Cohen's $d = .90$. Post-hoc analyses of EA scale total scores revealed between group differences for maternal sensitivity $F(1, 72) = 4.07$, $p = .047$, Cohen's $d = .47$ and maternal non-intrusiveness scales $F(1, 72) = 4.36$, $p = .040$, Cohen's $d = .49$, with the intervention group demonstrating higher sensitivity and non-intrusiveness than the comparison group (see Table 4). There were no adverse intervention effects (see Supporting Information, Appendix 7).

3.4 | Intervention effects on early infancy outcomes: a preliminary assessment

Maternal knowledge of infant development at 4 months/T8 ($n = 66$) was significantly greater in the intervention versus the comparison group, $F(1,64) = 5.22$, $p = .03$, Cohen's $d = .57$. MANOVA analyses (G1 = 29, G2 = 38) showed no significant intervention effect on infant developmental outcomes at 4 months/T8 for cognition,

TABLE 3 Baseline obstetric and psychosocial characteristics for study completers versus non-completers

Variable	Completers ($n = 74$)	Non-completers ($n = 16$)	t	df	Sig (2 tailed) p
Gestation at first antenatal visit, mean (SD)	17.35 (3.15)	18.70 (2.7)	1.58	88	.12
Age of mother at birth of baby, mean (SD)	32.15 (3.9)	28.8 (3.6)	−3.13**	88	.002
Infant birth weight kg, mean (SD)	3.40 (.5)	3.40 (.41)	−.04	88	.97
Gestation at birth weeks, mean (SD)	39.41 (1.31)	39.25 (1.06)	−.44	88	.66
ANRQ, mean (SD)	28.49 (9.8)	29.75 (11.86)	.447	87	.66
EPDS, mean (SD)	9.74 (4.76)	11.19 (5.48)	1.07	88	.29
PASS, mean (SD)	24.97 (15.53)	34.85 (22.34)	1.52	72	.15

Abbreviations: ANRQ, antenatal risk questionnaire; EPDS, Edinburgh postnatal depression scale; PASS, perinatal anxiety screening scale; SD, standard deviation.

TABLE 4 Post-test comparison of the Emotional Availability Scales (EAS 4th edition total scores) ($n = 74$) for the intervention (G2) versus comparison (G1) groups

EAS total scores	G2 NBO ($n = 40$) Mean (SD)	G1 TAU ($n = 34$) Mean (SD)	p-Value (2-tailed)	Cohen's d (95% CI's)
Sensitivity	25.28 (2.93)*	23.76 (3.51)	.047	.47 (.01–.94)
Structuring	23.98 (2.56)	23.56 (2.87)	.143	.16 (−.30–.61)
Non-intrusiveness	26.00 (2.86)*	24.18 (4.58)	.040	.49 (.02–.95)
Non-hostility	26.46 (2.16)	25.81 (3.58)	.178	.22 (−.23–.68)
Child Responsiveness	22.42 (3.32)	23.06 (3.26)	.569	.19 (−.65–.26)
Child Involvement	20.69 (3.61)	21.08 (3.26)	.686	.11 (−.57–.34)

Abbreviations: NBO, newborn behavioral observations; SD, standard deviation; TAU, treatment as usual.
*$p < .05$.

motor, language or socio-emotional development using the Bayley-III $F(5,61) = 1.13$, $p > .05$, Cohen's $d = .63$. Seven babies could not complete the Bayley-III assessment due to feeding, sleeping or distress. See Supporting Information, Appendix 8. Significantly more intervention group infants than comparison group infants were exclusively breastfed at discharge from hospital. At endpoint, 65% of infants from the intervention group for whom data were available (n = 33) and 62% of the comparison group (n = 28) were breastfed, a non-significant difference ($p = .37$). See Supporting Information, Appendix 9.

3.5 | Intervention effects on maternal PND diagnoses and distress symptoms

At infant age 4 months/T8, six of 74 study completers (8%) were diagnosed with PND using the SCID-5. Twenty-five mothers (33.7%) met the PASS clinical cut-off score (26) for probable anxiety disorder; 10 from the intervention group (mean total score = 20.75, $SD = 13.29$) and 15 from the comparison group (mean total score = 20.18, $SD = 10.3$). Thirteen mothers (17.5%) met the EPDS clinical cut-off score (13) indicating probable PND diagnosis, 6 from the intervention group (mean total score = 8.19, $SD = 5.03$) and 7 from the comparison group (mean total score = 7.25, $SD = 4.25$). Interestingly, 8 (10.8%) mothers met both the clinical cut-off for symptoms of anxiety (on the PASS) and for depression (on the EPDS) but were not diagnosed with PND on the SCID-5. Only 3 (4%) mothers who met screening cut-offs for both anxiety and depression were diagnosed with PND.

For the ITT sample (n = 90), interaction effects between group and time approached significance for anxiety symptoms $F(1,137) = 3.55$, $p = .06$, indicating a trend towards an intervention effect in reducing anxiety symptoms over time, but not for maternal depression symptoms $F(1, 84.68) = .37$, $p = .69$. In the study completer sample ($n = 74$), no significant differences were observed between groups in endpoint distress characteristics ($p > .05$). See Table 5. A significant interaction effect was observed of group and time on anxiety symptoms; the intervention group showing a significant reduction in anxiety symptoms over time $F(1, 68) = 6.31$, $p = .014$, Cohen's $d = .59$, but no main effect at study endpoint, $F(1, 68) = .46$, $p = .501$, Cohen's $d = .16$. No significant interaction or main effects were identified for depression symptoms, $F(1, 68) = .09$, $p = .76$, Cohen's $d = .07$. See Figure 2 for changes in mean maternal anxiety and depression symptom scores from baseline to endpoint. Within-group analyses

TABLE 5 Endpoint maternal distress in study completers

Variable	Completers ($n = 74$)	Intervention Group (G2) ($n = 40$)	Comparison Group (G1) ($n = 34$)	Chi-square χ^2 (*df*)	Asymptotic significance (2-sided) (ρ)
PASS≥26	25 (33.7 %)	10 (25 %)	15 (44.1%)	3.0 (1)	.083
EPDS≥13	13 (17.6%)	6 (15%)	7 (20.6%)	.40 (1)	.529
SCID-5, PND Dx	6 (8.1 %)	5 (12.5%)	1 (3%)	2.25 (1)	.209

Abbreviations: EPDS, Edinburgh postnatal depression scale; PASS, perinatal anxiety screening scale; PND Dx, diagnosis of postnatal depression; SCID-5, structured clinical interview for DSM disorders.

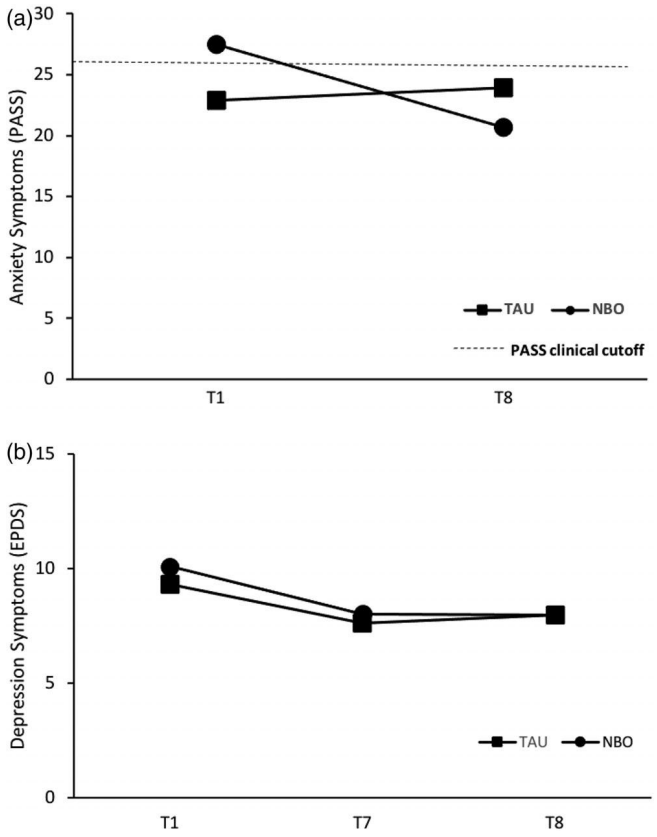

FIGURE 2 Change in (a) anxiety symptoms and (b) depression symptoms from baseline to post-treatment: intervention (NBO) versus TAU-only

revealed a significant decrease in depression symptoms in the intervention group from pre-intervention (M = 10.10, SD = 4.98) to post-intervention (M = 7.99, SD = 4.88), $t(39) = 2.91$, $p = .006$ (2-tailed); along with a non-significant decrease within the comparison group from pre-intervention ($M = 9.32$, $SD = 4.51$) to post-intervention (M = 7.98, SD = 4.75), t(33) = .1.72, $p = .096$. A significant decrease in anxiety symptoms occurred within the intervention group from pre-intervention ($M = 27.46$, $SD =$ 17.10) to post-intervention ($M = 20.72$, $SD = 12.73$), $t(39) =$ 3.11, $p = .004$; but not within the comparison group from pre-intervention (M = 22.89, SD = 14.57) to post-intervention ($M = 23.90$, $SD = 13.51$), $t(33) = .37$, $p = .710$.

3.6 | Differential susceptibility to NBO intervention effects

In exploratory analysis, intervention (G2) study completers with maternal sensory processing sensitivity (HSP) data ($n = 38$), were dichotomized into two subgroups: the top 70% HSP scorers ($n = 26$) and the bottom 30% HSP scorers ($n = 12$). There was an interaction effect of G2 subgroup and time on depression scores, the top 70% HSP mothers showing a significant reduction in depression symptoms over time ($n = 38$), $F(1,36) = 4.18$, $p = .048$, Cohen's $d = .56$. There was no significant interaction effect of G2 subgroup and time on anxiety symptoms $F(1, 36) = 3.50$, $p = .069$, Cohen's $d = .51$. There were main effects of G2 subgroup; the top 70% HSP mothers showing significantly higher depression symptoms at baseline $F(1,36) = 5.72$, $p = .022$, Cohen's $d = .70$ and anxiety symptoms at both time points $F(1, 36) = 8.16$, $p = .007$, Cohen's $d = .86$, compared to the bottom 30% HSP mothers. Effect sizes were medium or large. See Figure 3. There were no effects of G2 subgroup on emotional availability $F(1, 31) = .402$, $p = .872$, Cohen's $d = 0$. Missing HSP data in the comparison group precluded exploration of study outcomes according to HSP status and group (13/34 questionnaires incomplete).

3.7 | Intervention acceptability and fidelity

Of 51 eligible families in the intervention group, 48 (94%) received all three NBO sessions; and had two or more with the same clinician. Of 50 NBO sessions conducted in the first week of life/T4, 21 (42%) occurred in hospital before discharge. A total of 150 sessions were completed, lasting an average 60 min (range = 15–90 with no significant variation between the first, second and final sessions $F(2,147) =$ 1.9, $p = .15$). Most sessions (144/150 or 96%) were provided by an NBO-trained nurse. Due to nurse unavailability, four sessions were provided by a general practitioner (author SN) and two by a child and adolescent psychiatrist (author CWP).

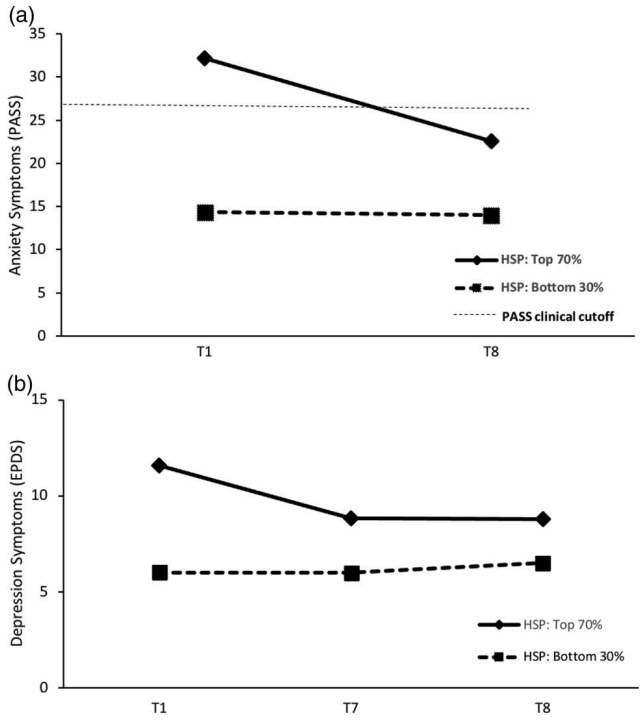

FIGURE 3 Change in (a) anxiety symptoms and (b) depression symptoms over time for medium-high versus low sensory processing sensitivity mothers receiving the intervention ($n = 38$). HSP = Highly sensitive person

Mothers rated 86%–88.5% of sessions ($n = 147$) as having helped them "quite a bit" or "a lot" to feel closer to baby, feel more confident parenting and get to know their baby more; 94.5% of sessions as helping them relate to the clinician "quite a bit" or "a lot"; and mothers rated the overall learning experience as excellent (85%), good (12%), fair (3%), and poor (0%).

Clinician-rated NBO fidelity was as follows ($n = 150$): 93%–97% sessions rated 4 or 5 (mostly or optimal) for collaboratively observing baby's behavior, interpreting meaning of baby's behavior, summarizing baby's preferences and difficulties, and reinforcing parental meaning-making; 4% sessions rated 4 or 5 (mostly or a lot) for involving gentle reinterpretation of mothers' meaning-making about their infant's behavior; 89% of sessions rated 4 or 5 (mostly or optimal) for including caregiving guidance based on observations of newborn capacities, preferences and difficulties; 98% sessions ($n = 148$), rated mothers' levels of engagement as 4 or 5 (mostly or completely), increasing from 96% for the first session ($n = 48$) to 100% for the third session.

3.8 | Predictors of depression diagnosis and mother-infant interaction

Exploratory multiple regression analysis examined baseline factors likely to influence PND diagnosis on the SCID and EA relationship quality at endpoint in the study comparison group ($n = 34$). Significant predictors for PND were low perceived partner support during pregnancy ($n = 3$) and meeting the randomization criteria of an EPDS score of ≥10 during pregnancy ($n = 15$). See Supporting Information, Appendix 10. Significant predictors for EAS-coded relationship quality included prenatal anxiety symptoms measured on the PASS, which predicted lower maternal sensitivity ($\beta = -.66$, $t(27) = -2.33$, $p = .04$) and greater maternal hostility ($\beta = -.62$, $t(27) = -3.64$, $p = .005$). Younger maternal age ($\beta = -.46$, $t(27) = -2.93$, $p = .015$) predicted greater maternal hostility. No significant predictors of overall EA quality or other EA scales were identified. See Supporting Information, Appendix 11. See also Limitations.

4 | DISCUSSION

Extensive, high-quality research has documented adverse effects of perinatal distress (particularly PND) on mothers, the mother-infant relationship and early child development, although the level of impact varies across studies (Erickson et al., 2019; Kingston et al., 2015; Netsi et al., 2018). There has been less research on very early relationship-based interventions that may alter the trajectory of families with parental distress, despite the first 3 months being a unique phase for infant development and the establishment of parental executive functioning (Nagy, 2011). This study examined the effects of the NBO intervention in a clinically at-risk population of first-time mothers identified in pregnancy with distress and risk of PND. Results revealed that the NBO improved the mother-infant relationship and reduced maternal distress, but had no observable effect on depression diagnosis. The NBO was associated with better maternal knowledge of infant development; there were no adverse effects. The study has illustrated that three NBO sessions in the first month of life can improve the infants interactive experience of the mother and maternal emotional adjustment, when antenatal risk and distress is present. It is the first Australian study examining the impact of the NBO intervention, and the first international study reporting NBO effects in this clinical population.

4.1 | NBO effects on the mother-infant relationship

A key impact of the NBO sessions was the enhanced quality of the infant's experience of the mother vis-à-vis higher maternal sensitivity and non-intrusiveness. Intervention effect sizes were medium. Determining whether the NBO stand-alone intervention in a real-life setting influences

mother infant interaction was a primary aim of the study. The finding is important given that even normal variation in early maternal sensitivity predicts infant structural brain development, early maternal intrusiveness predicts infant neural responses at 7 months, and both exert influence on infant attachment and later development (Huffmeijer et al., 2020; Kok et al., 2015). The clinical implication is that the NBO intervention may have the capacity to positively steer the infant's very early developmental trajectory in the presence of maternal distress via shifts in interaction quality.

4.2 | NBO effects on maternal postnatal depression and distress

Low prevalence of PND at infant age 4 months/T8 (8%) precluded detection of intervention benefit or otherwise in preventing PND. This prevalence was unexpected given the population was specifically screened for PND risk, and was comparable to the 7%–9% community prevalence in Australian first-time mothers at 3–6 months (Woolhouse et al., 2014). Notably, 17% of study completers scored ≥13 on EPDS at infant age 4 months/T8, in keeping with an at-risk population, but just 8% met diagnostic criteria for current major depressive episode on interview (SCID-5). This disparity between depression symptom scores and clinical diagnoses at the study endpoint was surprising and the reason is unclear. A recent meta-analysis found that the SCID is the most reliable of the available structured diagnostic interviews for diagnosing major depression in response to EPDS scores recorded up to 2 weeks prior, suggesting it was a good choice (Levis et al., 2019). A systematic review of the diagnostic accuracy of the EPDS confirmed the stringency of the cut-off score of 13, reporting specificity of .95 (.92–.96) and sensitivity of .66 (95% confidence interval .58–.74) for a cut-off of 13 and above, using data from 58 studies (Levis et al., 2020). It is hypothesized that in the current study the proportion of diagnoses was possibly affected by conducting the SCID-5 both concurrently and blinded to EPDS score.

Although the study did not detect intervention effects on depression diagnosis, it did detect NBO effects on maternal distress. The intervention recorded significant between-group reduction in anxiety symptoms, and within-group reductions in anxiety and depression symptoms, from above, to below, clinical cut-off levels. In exploratory analysis, anxiety in pregnancy predicted mother-infant interactional difficulties, namely less sensitive and more hostile interaction with the 4-month-old infant, as hypothesized from previous research (Riva-Crugnola et al., 2016). Detecting these effects was assisted by adding the PASS to the study protocol. The study adds to growing evidence the PASS is a useful screening tool for perinatal anxiety, which is commonly present and may otherwise go undetected (Chandra & Nanjundaswamy, 2020). The implication of the combined findings in this study and recent perinatal research is that antenatal screening for maternal distress symptoms identifies infants and their mothers who may or may not be diagnosed with PND in early infancy, but who nevertheless suffer and risk interactional relationship difficulties that impact infant development, and for whom very early intervention may be beneficial (Chandra & Nanjundaswamy, 2020; Glover, 2020).

4.3 | NBO intervention acceptability

Study retention was high and 94% of eligible participants received all three NBO sessions. Mothers valued the sessions and clinicians reported high engagement. This suggests the NBO is acceptable to distressed families; an important finding given the challenges converting distress to healthcare uptake (Holt et al., 2017). The NBO therapeutic approach of focusing on and supporting the infant with the parent while being attuned and responsive to parental distress in real-time, may be less confronting to mothers and bring the infant into the sphere of timely infant mental health support. If these preliminary findings of acceptability and effectiveness were replicated in a larger sample, the NBO could become the standard of front-line care for distressed families in the newborn period. It appears to be an acceptable, time-efficient intervention and may be an effective adjunct to antenatal and further postnatal support as warranted. In the UK, the government has endorsed the NBO for perinatal and infant mental health specialist health visitors (Rance, 2016). In Australia, the NBO is well-suited for targeted use, embedded within universal healthcare. In this study, NBO sessions were provided by a midwife or MCH nurse, professionals who already engage with mothers and infants in pregnancy, after birth and at MCH appointments at infant age 1, 2, 4, and 8 weeks. This relationship intervention could also contribute to broader efforts addressing the global burden of maternal distress on infants and families. Internationally, NBO training is brief and standardized with post-training accreditation; and in low-income settings, locally adapted training with supervision can protect fidelity while promoting affordability and cultural safety (Dawson & Frost, 2018).

4.4 | Preliminary assessment of NBO impacts on early infancy

Supporting successful breastfeeding and infant development are each stated aims of the NBO intervention

(Nugent et al., 2007). Intervention group infants were more likely to be breastfed both upon leaving hospital and at endpoint, however only 42% of dyads received their first intervention session while in hospital, and the difference at endpoint did not reach significance. At endpoint, intervention group mothers recorded significantly greater knowledge of newborn development. Missing data precluded repeated measures analysis of intervention effects, and these preliminary findings warrant further investigation. No significant effect of the NBO on infant development was observed using the Bayley-III, but this assessment was unfortunately probably hindered by the presence of floor effects, as described in previous studies of 4-month-old Australian infants (Anderson & Burnett 2017). Developmental assessment in future studies at age 6 months, or using the new Bayley-IV, which has Australian reference infants, may yield different findings (Bayley & Aylward, 2019).

4.5 | Exploration of differential susceptibility to intervention effects

The study results supported the NBO as an effective, integrated approach to infant and perinatal mental health, but exploratory analysis challenged the notion of a "one size fits all" intervention (Norbury, 2018). Mothers experienced variable benefits according to sensory processing sensitivity. The top 70% of HSP scorers, so-called orchids and tulips, had high distress in pregnancy that fell below clinical cut-offs over time, whilst the bottom 30%, or dandelions had lower distress in pregnancy and little change over time, despite intervention exposure. These exploratory findings align with an increasing body of evidence that "what works for whom" may be partly discerned via differential genetic susceptibility to environmental stress and support that is expressed and measurable as temperament (Greven et al., 2019). Whilst these findings in a very small sample must be interpreted cautiously, the effect sizes suggest further research may be warranted; to better direct resource-intensive intervention to infants and adults most likely to suffer and to benefit (Norbury, 2018).

4.6 | Strengths

The study population was screened for vulnerability, in response to findings that the NBO had no adverse effects but low evidence of benefit in low-risk populations (Barlow et al., 2018). This study provides additional evidence that the NBO has no adverse effects and has benefits in at-risk populations. The study used robust measures in a real-world clinical setting. Particular attention was given to NBO fidelity, partly in response to conflicting findings from similar interventions within home visiting programs overseas (P. Cooper et al., 2015; P. J. Cooper et al., 2009); and strong intervention adherence was recorded. The study applied a dose of three sessions, in response to Barlow's report of low-level effects of one to two sessions in low-risk populations, and found that 3–4 h of intervention provided as three NBO sessions in the first month mitigated distress and interaction difficulties at infant age 4 months/T8. The optimum dose remains the subject of future research; whilst fewer sessions are unlikely to be as effective, a higher dose might increase effect, or reduce engagement. The study promoted therapeutic alliance via high clinician continuity. Putative mechanisms of change in the NBO approach- beyond fidelity, dose and therapeutic alliance- include parental shifts in affect, reflectiveness, openness and responsiveness towards the infant's experience, and dyadic shifts towards reciprocity (McManus et al., 2020). The study findings support shifts in maternal affect and responsiveness. Future research should address whether quantitative change in parental reflective functioning occurs after such brief intervention, or is a reasonable expectation, given its developmental value to the infant (Barlow et al., 2021).

4.7 | Limitations

The sample was diverse (37.5% born overseas, and 13.5% speaking another language at home compared to 21% nationwide), however, eligibility criteria and lack of ethics approval to examine differences between refusers and participants mean the results cannot be generalized. Comparison of the percentage of pregnant women who screened positive for distress with general population data was not possible because the PASS is a relatively new measure. Although validated against an ICD-10 diagnostic assessment interview for anxiety disorder, and against gold standard diagnostic tools in other languages, the English language PASS requires further validation against a tool such as the SCID. The study focusses on the mother-infant dyad using the widely-researched EAS. Consistency between caregiver sensitivity measured on the EAS and on other interaction measures cannot be assumed. Further, despite common practice, and their use in this study, recent higher-order factor analysis raises unresolved questions about the validity of reporting individual EAS scales. This study's findings should be interpreted in light of these limitations and future intervention studies will benefit from further psychometric refinement of interaction measures (Aran et al., 2021; Bohr et al., 2018; Gridley et al., 2019). It was beyond scope to test for intervention effects on family, or beyond infant age 4 months/T8. Analyses were limited

by missing data and insufficient power to adjust for multiple comparisons. Larger trials are required with diverse populations. As NBO training is well-regulated, international research collaboration using pooled data is possible. Finally, the study was completed pre-COVID-19, thus does not assess the NBO in an era of facemasks, reduced face-to-face contact and other challenges to direct clinician-infant engagement.

4.8 | Conclusion

This trial provides evidence that three NBO sessions provided in the first month of life measurably improves mother-infant interaction and maternal distress, for infants and their first-time mothers identified in pregnancy with high maternal distress and a risk of PND. No intervention effect on PND diagnosis was observed.

4.9 | Implications

- Maternity care should identify and address distress beyond psychiatric diagnosis.
- Brief infant-parent mental health support for maternal distress, embedded in universal care, has potential to shift the early family developmental trajectory.
- Targeting maternal distress indirectly while directly engaging the infant may reduce barriers to mothers and infants accessing effective support.
- Sensory processing sensitivity might allow for targeting treatment to those most likely to benefit, but more research is needed.
- Future research should test the NBO as part of comprehensive, tailored support for families with parental distress.

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CONFLICT OF INTEREST

All authors have completed the Unified Competing interest form at www.icmj.org/coi_disclosure.pdf (available on request from the corresponding author) and declare that SN, SP-C and CP have no relationships with companies that might have an interest in the submitted work in the previous 3 years; their spouses partners or children have no financial relationships that may be relevant to the submitted work and have no non-financial interests that may be relevant to the submitted work.

IRB STATEMENT

Human Research Ethics Committee approval was received from both hospital sites involved in this research.

DATA AVAILABILITY STATEMENT

The authors have full control of the primary data and agree to allow the journal to review the statistical code and dataset upon request.

PATIENT CONSENT

Informed consent for participation in the study was obtained. Participant consent for data publication was not obtained as the data presented were anonymised and the risk of identification was considered negligible.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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