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A pilot study demonstrating the impact of the supporting and enhancing NICU sensory experiences (SENSE) program on the mother and infant

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ABSTRACT

Aim: To explore differences in maternal mental health and infant neurobehavioral outcome among infants who received and did not receive the Supporting and Enhancing NICU Sensory Experiences (SENSE) program.

Study design: Eighty preterm infants (50 receiving standard-of-care and 30 receiving the SENSE program) born ≤32 weeks gestation were enrolled within the first week of life in a prospective quasi-experimental design, using a historical control group for comparison. Standard-of-care consisted of tactile (skin-to-skin, touch, holding) and olfactory (scent cloth, close maternal contact) interventions as determined to be appropriate by health care professionals and parents. The SENSE group received specific doses of tactile (skin-to-skin care, holding, massage, touch), auditory (human speech, music), olfactory (scent cloth, close maternal contact), kinesthetic/vestibular (movement, rocking/transfers), and visual (dim or cycled light) exposures, based on the infant's post-menstrual age and tailored to medical status and infant cues according to the SENSE program. The SENSE program includes the intentional delivery of positive, age-appropriate sensory exposures by parents (or a sensory support team, when parents are unavailable) each day of NICU hospitalization. Infant neurobehavioral outcome, as well as maternal mental health and confidence, were assessed prior to NICU discharge, using standardized measures.

Results: Seventy-three infants were included in the final analysis. Mothers whose infants received the SENSE program demonstrated higher scores on the Maternal Confidence Questionnaire ($p = 0.01$). Infants who received the SENSE program demonstrated less asymmetry on the NICU Network Neurobehavioral Scale ($p = 0.02$; mean difference 0.9) and higher scores on the Hammersmith Neonatal Neurological Evaluation ($p < 0.001$; mean difference 4.8).

Discussion: Preliminary evidence demonstrates improvements in maternal confidence and infant neurobehavioral performance following SENSE implementation.

1. Introduction

Historically, the neonatal intensive care unit (NICU) environment has high sound levels [1], and infants are exposed to painful medical interventions [2] with lack of adequate positive sensory exposures [3]. Developmental care has been instituted to improve care for high-risk infants in the NICU and often includes strategies to eliminate excessive noise and light to the vulnerable infant [4]. While previous research has identified the negative impact of invasive and painful exposures [5], positive sensory experiences drive appropriate neuronal activity and are important for learning, memory, and the foundations of development [6]. Therefore, careful attention to ensuring positive sensory experiences, especially in NICU private rooms in which parents are not engaged in care, is important.

Preterm infants often spend months in the NICU during a critical period of brain development [7,8]. During this time in the NICU, optimal neural network development relies on appropriately timed and positive sensory exposures [9,10]. There is literature that has been well-

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understood for a long time, as well as new or emerging research, on the positive impact of sensory stimulation for the preterm infant in the NICU [11]. However, differences in the use and interpretation of available evidence, as well as differences in parent education and empowerment in the NICU, are prevalent [12]. Properly timed and age-appropriate positive sensory experiences can decrease stress and optimize positive learning experiences during this critical period of brain development. While many hospitals promote positive sensory experiences, such as skin-to-skin care, they are often done inconsistently or for short durations of time in comparison to the total length of hospital stay. The Supporting and Enhancing NICU Sensory Experiences (SENSE) program was developed to engage parents in consistently providing positive, developmentally appropriate sensory exposures to their high-risk infants in the NICU every day of hospitalization [13]. Specifically, infants who are hospitalized in private NICU rooms and who do not have significant parent engagement are at risk of inadequate positive sensory exposures [7], and the SENSE programs ensures an understanding of appropriate, intentional exposures that are aimed at fostering a positive developmental trajectory.

The SENSE program includes specific doses and targeted timing (based on postmenstrual age, PMA) of evidence-based interventions such as skin-to-skin care, infant massage, auditory exposure, holding, and rocking. The use of sensory interventions is tailored to the level of immaturity of the infant coupled with the development of the different senses. The guideline was developed using a rigorous scientific process [13] with the intention of optimizing parent engagement, while maximizing daily positive sensory exposures to improve infant development and parent-infant interaction. The SENSE program consists of parent educational materials aimed at informing parents on sensory development, parenting in the NICU, and reading infant cues in addition to the tailored evidence-based doses of sensory exposures to conduct with their infant each day of NICU hospitalization. Key personnel educate parents using the SENSE materials and ensure the infant can tolerate the doses of sensory exposures as defined for the infant's PMA. The sensory experiences in the SENSE program are designed for parents to complete with their infants, but a sensory support team can fill in gaps when parents are unable to be present to ensure regularly timed, positive sensory experiences.

There are similarities and differences of the SENSE program compared to other programs for NICU staff and parents. One of the most widely recognized programs, the Newborn Individualized Developmental Care and Assessment Program (NIDCAP) was pioneered by Heidelese Als three decades ago [15]. NIDCAP focuses on NICU staff education aimed at helping health care professionals understand and interpret infant behavior, so care can be individualized and provided in a way that is conducive with the behavioral signs of the infant. The Creating Opportunities for Parent Empowerment (COPE) program includes parent education materials aimed at improving the parent's ability to understand their infant's behavior, gain confidence, and build a relationship with the infant with four focused time points of education: shortly after birth, approximately one week after discharge, a few days after NICU discharge, and approximately 1–2 weeks after NICU discharge [16]. The COPE materials also include information on developmental milestones up to 9 months following NICU discharge. While parent education materials are provided, COPE training is aimed at staff, who then use the materials to educate parents. The Family Nurture intervention (FNI) uses a specialist to aid the emotional connection between parent and infant interactions in the NICU, with tasks including communication, eye contact, scent cloth exchange, and physical closeness [17]. The Collaborations with Parents program aims to target doctors and nurses with a focus on observing infant cues, recognizing how each family is unique and fostering sensitivity to each family unit [18]. Family Integrated Care (FiCare) aims to have health care professionals partner with families with the goal of training and having parents assume care of the infant to build confidence and engagement [19]. The Empower program consists of parent education materials given shortly after NICU admission, 2–4 days later, and then 4 weeks later. The Empower program targets parents with infants < 30 weeks gestation and includes activities to enhance parental recognition and response to infant behavioral cues, provision of human milk, kangaroo care, nuzzling, breastfeeding, oral feeding readiness/progression, and massage [20]. The H-Hope intervention includes maternal participatory guidance during activities that are part of the Auditory, Tactile, Visual, and Vestibular (ATVV) intervention [21]. The ATVV intervention includes 15-min long activities such as tactile, auditory, visual, and vestibular interventions conducted twice per day starting at 32 weeks PMA [22–24]. While these programs aim at care in the NICU environment, there are other programs that focus on the discharge process or the home environment following discharge. There is evidence supporting positive outcomes of high-risk infants and families related to the use of NIDCAP, COPE, FNI, and H-Hope/ATVV in the NICU [21,25–30].

The SENSE program is similar and different from these other NICU-based programs in that it includes parent education materials aimed at fostering an understanding of individualizing care related to infant behavioral signs as well as education on parenting within the NICU setting. SENSE educational materials also include the important components of sensory development that are unfolding within the NICU setting and then provide direction and intention to what parents can do to support their infant's development within the NICU. This includes specific, daily amounts of tactile, auditory, visual, kinesthetic/vestibular, and olfactory activities to conduct with the infant each day of hospitalization [31]. The SENSE program is unique in that it has a changing landscape of the type, timing, and dose of sensory exposures, based on the different developmental needs of infants at different PMAs. The license for the SENSE program is available through the Office of Technology Management [32], and > 140 hospitals worldwide are currently implementing the SENSE program. While the SENSE program was developed by synthesizing available evidence with expert and stakeholder input [11–13], it is important to evaluate its efficacy. Yet, no studies have yet reported the impact of the SENSE program.

2. Methods

The aim of this study was to explore the impact of the SENSE program, administered to preterm infants throughout NICU hospitalization, on maternal mental health and infant neurobehavioral outcome. This was a quasi-experimental design with a historical control group. This study was approved by the institutional review board at the study site, and parents signed informed consent.

2.1. Participants

Eighty infants (50 who received standard-of-care and 30 who received the SENSE program) were used for this study. Thirty preterm infants, who were born ≤32 weeks gestation, were enrolled within the first week of life in 2018 and received the SENSE program. Consecutive admissions from June to August of 2018 were recruited. Those with a congenital anomaly or who were not expected to survive, per the attending physician, were excluded. These infants were compared to a group of 50 historical controls (standard-of-care) of preterm infants born ≤32 weeks gestation in 2014, who were part of an overarching study on the progression of early feeding [33]. Consecutive admissions from January to June of 2014 were recruited, and infants were enrolled within the first week of life. The control group was enrolled prior to the development of the SENSE program, and they received standard-of-care. The number of infants in the control group was predetermined due to use of a sample from an overarching study. This cohort was chosen for comparison, as it was a sample that met the same inclusion criteria enrolled closest to the timeframe of the SENSE group enrollment. The SENSE cohort enrolled 30 infants to enable initial comparisons to a control group, but also to allow a large enough sample to ensure

implementation issues had been resolved prior to conducting a randomized controlled trial on the SENSE program.

2.2. Setting

Participants were hospitalized in the 85-bed level IV NICU at St. Louis Children's Hospital (which expanded to 125 beds in 2018). The control group also included infants hospitalized in the 20-bed special care nursery (Level III) at Barnes-Jewish Hospital, and 6 (23%) infants in the control group were from this additional, affiliated, and connected site. The special care nursery was an affiliated site of the Level IV NICU, accessible by bridge, staffed by same house staff, and had similar policies. The special care nursery closed/merged with the main level IV NICU at St. Louis Children's at the time of the SENSE cohort, with infants who normally would have gone to the special care nursery instead going to the Level IV NICU.

2.3. The SENSE program

The SENSE program includes parent education materials along with the specific amounts of auditory, tactile, vestibular, /kinesthetic, olfactory, and visual exposures to be conducted daily through hospitalization [32]. Depending on the infant's PMA and readiness/tolerance, tactile interventions can include gentle human touch, skin-to-skin care, or massage with a targeted minimum of 3 h by term equivalent age; auditory interventions can include language or music with a targeted minimum of 3 h by term equivalent age; visual interventions include dim and cycled light environments with human interaction provided at term equivalent age; vestibular interventions include rocking for a minimum of 7 min by term equivalent age; kinesthetic interventions include opportunities for free movement for 2 min prior to diaper changes. Olfactory interventions include use of a scent cloth and close maternal contact. The types and doses of each positive sensory exposure change based on the infant's level of immaturity, or PMA. The positive sensory exposures in the SENSE program are intended to be implemented by parents, when available, and the education materials stress the important role of the parents at the center of care delivery. However, when parents were not able to be present, a sensory support team member completed the sensory exposure doses defined in the program. The sensory support team was made up of occupational therapy graduate students who underwent a minimum of 20 h of education and training prior to administering sensory interventions (that included reading to the infant and/or providing gentle human touch) to the infants in the study. The SENSE program was designed to enable its implementation in settings without significant resources and includes activities that can be incorporated with ease into the daily flow of the NICU, with someone on the NICU team (such as a neonatal therapist) providing oversight of the program.

Parents, members of the health care team, and the sensory support team tracked the sensory exposures that were delivered using bedside logs, and these logs were used to ensure infants received the doses of sensory exposures defined in the SENSE program. During the time of the pilot study, the doses of sensory exposures had been defined, and the parent education materials had been developed. However, during the process of the pilot study, modifications to the education materials were made based on implementation challenges and feedback from families and health care professionals. Implementation materials were important for ensuring that the infants received the described sensory exposures in a safe, consistent manner.

2.4. Standard of care in the control group

The historical controls received standard-of-care, which consisted of promotion of skin-to-skin holding and other developmental care interventions per the discretion and availability of parents, nurses, and therapists in the NICU. While standard-of-care included many of the interventions described in the SENSE program, it is different from the SENSE group in that administration of the sensory exposures did not include a daily intention to implement specific doses of sensory exposures related to the infant's PMA, as described in the SENSE program.

2.5. Measures

Several measures of infant neurobehavior and maternal mental health and confidence were used to explore differences between the control and treatment groups. At term equivalent age (between 37 and 41 weeks PMA), mothers in both cohorts completed a comprehensive questionnaire, which contained standardized measures of parent mental health and confidence, and infants in both cohorts received comprehensive neurobehavioral assessment at the bedside prior to NICU discharge.

2.5.1. Factors collected from the medical record

Infant factors that were collected included estimated gestational age (EGA), birthweight, APGAR scores at 1 and 5 min, mode of delivery (vaginal or Caesarean section), sex, Clinical Risk Index for Babies (CRIB score) to measure initial medical severity, days of endotracheal intubation, days of continuous positive airway pressure (CPAP), whether the infant received breast milk feedings, retinopathy of prematurity (ROP), necrotizing enterocolitis (NEC), days of total parenteral nutrition (TPN), cerebral injury, patent ductus arteriosus (PDA), PMA at discharge, and length of stay. Cerebral injury was defined, from MRI or cranial ultrasound, by having either a grade III-IV intraventricular hemorrhage or cystic periventricular leukomalacia. Family factors were collected and included maternal age, number of other siblings, whether part of a multiple birth, race (African American or not African American), insurance type (public or private), marital status (single or married), whether the mother had a college degree, whether the mother was employed (part time or full time), and annual household income ($< \$25{,}000$ or $\geq \$25{,}000$). The room type (private or open ward) that the infant was in during the NICU hospitalization was also documented, as the study site NICU consists of approximately half open ward beds and half private room beds.

2.5.2. Maternal outcome prior to NICU discharge

Prior to discharge from the NICU (when the infant was between 37 and 41 weeks PMA), the infant's mother completed a questionnaire that has been used in our longitudinal studies of preterm infants since 2000 and contains standardized assessments, including the Parental Stress Scale (PSS) [34], State Trait Anxiety Inventory (STAI) [35], Edinburgh Post Natal Depression Scale (EPDS) [36], Modified Perinatal PTSD Questionnaire (PPQ) [37], and the Parental Role Alterations subscale from the Parental Stressor Scale: NICU [37]. Parenting confidence was assessed using the Maternal Confidence Questionnaire (MCQ) [38] and the Infant Care Questionnaire (ICC) [39]. The PSS consists of 18 questions and aims to measure levels of stress, taking into account negative and positive aspects of parenting. The STAI is the most widely used self-report assessment of anxiety in adults. It consists of two 20-item scales that differentiate if the adult has anxiety as a personality trait, or if there is a temporary condition of state anxiety. The EPDS is a 10-question self-report measure, for which cut-offs for diagnosis of clinical depression have been established. The PPQ consists of 10 questions and aims to assess for post-traumatic stress signs [40]. The Parental Role Alterations subscale from the Parental Stressor Scale: NICU consists of 14 questions and aims to determine parental role alteration. The MCQ consists of 14 questions, and aims to assess maternal confidence, and the ICQ consists of 22 items and aims to assess maternal confidence in infant care and has three summary scores including Mom and Baby, Emotionality, and Responsiveness. The total scores for the PSS, EPDS, PPQ, Parental Stressor Scale: NICU, MCQ: the state score on the STAI; and the 3 summary scores of the ICQ were used as dependent variables, investigating the impact of the parent-delivered

sensory-based intervention, SENSE, on maternal health factors. When infants were part of a multiple birth, each mother was represented in the data only once when investigating maternal outcomes.

2.5.3. Infant outcome prior to discharge from the NICU

2.5.3.1. NICU Network Neurobehavioral Scale (NNNS). At term equivalent age (between 37 and 41 weeks PMA), prior to NICU discharge, infants had a comprehensive neurobehavioral assessment using the NICU Network Neurobehavioral Scale (NNNS) [41] by an examiner who was certified in its use. The NNNS was conducted at the infant's bedside in the NICU and takes approximately 20 min to administer. It has 13 summary scales including: habituation, orientation, self-regulation, hypertonia, hypotonia, asymmetry, non-optimal reflexes, excitability, lethargy, arousal, quality of movements, stress, and tolerance of handling. The NNNS is a standardized assessment, and the examiner requires specialized training. The NNNS is appropriate for infants prior to term age once the infant can tolerate multiple position changes and is off invasive respiratory support. It can be used until 46–48 weeks PMA. The NNNS has been used extensively with preterm infants in the NICU and has good reliability and validity [42]. The habituation items on the NNNS were not administered for this investigation, due to the need for a quiet environment that was contrary to many of the bedspaces where infants were hospitalized in the NICU. All analyses with NNNS summary scores as an outcome controlled for age at the time of evaluation (PMA) due to the known impact of PMA on neurobehavioral function [8].

2.5.3.2. Hammersmith Neonatal Neurological Evaluation (HNNE). At term equivalent age, the infant was also assessed with the Hammersmith Neonatal Neurological Assessment (HNNE) [43]. This is a 34-item assessment that takes approximately 10–15 min to complete. The HNNE has good reliability [44]. It has good sensitivity for identifying children with brain alterations on MRI, but poor specificity [45]. The total score for the HNNE was used as an outcome variable.

2.6. Statistical analysis

Group homogeneity was defined by exploring differences in infant and family factors across groups using independent samples *t*-tests, nonparametrics, and chi-square analyses. This enabled controlling for factors that were different between groups (when $p < 0.05$). Differences in maternal health variables at term equivalent age were investigated using analysis of covariance, while controlling for EGA, insurance type, room type, race, marital status, and maternal age, in addition to factors that differed across groups. EGA was included in the model, as it has been well documented to be related to outcome [46]. Insurance type was included as a proxy for socioeconomic status, due to its potential impact on maternal mental health [47]. Room type was included due to its potential impact on parenting, stress, and maternal and infant behavior [7,48]. Race was included in the model due to its potential impact on parenting behaviors and maternal health [3]. Marital status was included due to its potential relationship with perceived social support, and maternal age was included due to its potential influence on maternal health [3,49]. Analyses that investigated neurobehavior as an outcome used analysis of covariance and additionally controlled for the PMA at the time of testing, as neurobehavioral performance is known to change across time from preterm birth until term equivalent age [8]. Based on the exploratory nature of this study, statistical tests were not corrected for experiment-wise error.

3. Results

Eighty infants were enrolled (50 historical controls receiving standard-of-care and 30 who received the SENSE program).

Seventy-seven families were approached in the historical control group with 50 enrolled (65%). Of the 50 historical controls who were enrolled, one expired and one transferred to another hospital prior to discharge with no available outcome data. Forty-eight infants remained in the cohort at NICU discharge. Of the 48 infants, four had missing maternal mental health measures due to the mother not filling out the questionnaire, and seven were part of a multiple birth, leaving 37 for analysis of maternal factors. Of the 48 infants discharged from the NICU, seven infants were missing neurobehavioral scores due to an early discharge or due to their medical status. Forty-one infants were used to investigate differences in neurobehavior.

Thirty-nine families were approached for the treatment group, with 30 enrolled (77%). Of the 30 infants who were enrolled and received the SENSE program, one expired and one withdrew. Twenty-eight remained in the cohort at NICU discharge. Of the 28 infants remaining, one had missing maternal mental health measures due to the mother not filling out the questionnaire, and five were part of a multiple birth, leaving 22 for analysis of maternal factors. Of the 28 infants who remained in the cohort at discharge, two infants were missing neurobehavioral scores due to early discharge. Twenty-six infants had neurobehavioral testing available for analysis.

This resulted in a total sample of 73 infants (46 control/standard-of-care and 27 treatment/SENSE) who had either maternal mental health measures or neurobehavioral assessment scores or both to analyze. These 73 infants were used to report sample descriptives.

See Table 1 for sample descriptives along with investigations into group homogeneity. There were significant differences between groups in the following factors: mode of delivery, days of CPAP, and presence of ROP. Therefore, these factors were controlled for in the statistical model.

See Table 2 for relationships between group assignment and maternal factors. Mothers who received the SENSE program had more confidence, measured by the MCQ ($p = 0.01$), after controlling for infant and maternal factors. On average, mothers who received the SENSE program scored 8.2 points higher on the MCQ. There were no other relationships between group assignment and any of the other maternal factors.

See Table 3 for relationships between group assignment and infant neurobehavior. Infants who received the SENSE program had less asymmetry on the NNNS ($p = 0.02$; mean difference 0.9) and had higher scores on the HNNE ($p < 0.001$; mean difference 4.8). There were no other significant relationships between group assignment and other summary scores on the NNNS.

4. Discussion

The key findings of this pilot study are that the SENSE program was related to more maternal confidence, in addition to better infant neurobehavior with less asymmetry on the NNNS and better HNNE scores. This is the first study to report outcomes related to the SENSE program, which is being implemented in NICUs throughout the United States and abroad.

Mothers who had infants receive the SENSE program demonstrated more parent confidence. Mothers of preterm infants hospitalized in the NICU can feel disempowered, lack understanding about their role, feel overwhelmed, and withdrawal from being present to aid their coping [50]. Psychological distress is common among parents of preterm infants in the NICU [7] and has been related to decreased parenting confidence [51]. There is evidence that communication provides attention to the emotions related to being a NICU parent and can make parents feel included as an essential person in the infant's life [52]. Facilitating participation in the infant's care can also aid a parent in coping [53]. Parent participation in the NICU has been related to improved parent confidence [3,51]. The SENSE program aims to identify the parent as the most important person in the infant's life, educate the parent on infant development and exposures in the NICU, and establish a guideline for interaction that is tailored to the infant's PMA and

Table 1
Sample descriptives and group homogeneity.

	Mean ± SD; or N (%); or median (IQR) Total sample (n = 73)	Mean ± SD; or N (%); or median (IQR) Historical cohort (n = 46)	Mean ± SD; or N (%); or median (IQR) SENSE cohort (n = 27)	*p-Value
Infant factors				
EGA	28.0 ± 2.6	27.6 ± 2.6 (range 23–32)	28.6 ± 2.4 (range 24–32)	0.09
Birth weight	1125.0 ± 385.8	1084.7 ± 396.1	1193.7 ± 364.6	0.25
Apgars, 1 min	3.9 ± 2.4	3.8 ± 2.5	4.19 ± 0.4	0.49
Apgars, 5 min	6.0 ± 2.1	5.8 ± 2.2	6.3 ± 2.0	0.27
Sex, female	41 (56%)	23 (50%)	18 (67%)	0.17
Mode of delivery, Caesarean section (n = 69)	31 (45%)	10 (24%) (n = 42)	21(78%) (n = 27)	< **0.001**
Clinical Risk Index for Babies score	7.3 ± 4.0	7.9 ± 4.0	6.2 ± 3.9	0.06
Days of endotracheal intubation	3.0 (1.0–15.5)	1.5 (0.8–16.3)	6.0 (1.0–15.0)	0.16
Days of CPAP	1.0 (0–6.0)	0 (0–1.0)	6.0 (1.8–10.0)	< **0.001**
Breast milk feedings (yes)	64 (88%)	39 (85%)	25 (93%)	0.33
ROP	31 (42%)	12 (26%)	19 (70%)	< **0.001**
NEC	6 (8%)	5 (11%)	1 (4%)	0.28
Days of TPN	9.0 (6.0–16.0)	11.0 (6.8–11.0)	7.0 (6.0–12.0)	0.04
Cerebral injury	12 (16%)	7 (15%)	5 (19%)	0.71
Periventricular leukomalacia	6 (8%)	3 (7%)	3 (11%)	0.49
IVH grade III–IV (n = 72)	9 (13%)	5 (11%) (n = 45)	4 (15%) (n = 27)	0.65
PDA	21 (29%)	13 (28%)	8 (30%)	0.90
PMA at NICU discharge	38.3 ± 4.2	39.2 ± 4.6	39.3 ± 3.6	0.94
Length of stay	78.0 (47.5–105.0)	82.0 (40.0–116.5)	73.0 (51.0–73.0)	0.73
Family factors				
Maternal age	28.3 ± 6.3	28.9 ± 6.3	27.4 ± 5.8	0.33
Number of siblings	1.0 (0–2.3)	1.0 (0–2.8)	1.0 (0.8–2.3)	0.65
Multiple birth	22 (30%)	12 (26%)	10 (37%)	0.33
Race (African-American)	30 (41%)	18 (39%)	12 (44%)	0.66
Insurance type (public)	49 (67%)	29 (63%)	20 (74%)	0.33
Marital status (married) (n = 60)	27 (45%)	(n = 37) 18 (50%)	(n = 23) 9 (39%)	0.68
College degree (n = 59)	21 (36%)	15 (41%) (n = 37)	6 (27%) (n = 22)	0.30
Mother employed (n = 60)	32 (53%)	17 (46%) (n = 37)	15 (65%) (n = 23)	0.21
Income (< $25,000) ($n$ = 58)	27 (45%)	17 (47%) (n = 36)	9 (41%) (n = 22)	0.54
Room type (private room)	30 (41%)	17 (37%)	13 (48%)	0.35

Bolded p values represent those that reached significance (p < .05).

* p-Value is from investigating differences in infant and maternal factors across groups using independent samples t-tests, nonparametrics, and chi-square analyses. Abbreviations: EGA: estimated gestational age, CPAP: continuous positive airway pressure, ROP: retinopathy of prematurity, NEC: necrotizing enterocolitis, TPN: total parenteral nutrition, IVH: intraventricular hemorrhage, PMA: postmenstrual age, PDA: patent ductus arteriosus. Cerebral injury includes the presence of either cystic periventricular leukomalacia or a grade III-IV intraventricular hemorrhage. Mother employed includes part time or full time employment.

medical status, while giving parents choices in different ways to engage. While this is the first study to report on maternal outcomes related to the SENSE program, other programs aimed at connecting mother and baby, such as the ATVV intervention and H-Hope have also demonstrated a positive impact on parent-infant interaction [21].

Although confidence is an important outcome, the SENSE program was not related to improvements in maternal mental health, such as stress, anxiety, and depression. There has been heightened awareness of the significant mental health challenges that parents of preterm infants face, in addition to the interventions to support NICU staff to address them [54]. While parent engagement in the NICU has been related to improved maternal mental health outcomes [55], factors that contribute to maternal mental health are multifactorial, including previous history of mental health challenges, complex social factors, and/or situational factors [56–58] that could not be appropriately accounted for in this small pilot study. It is also possible that interventions that address mental health challenges require a more comprehensive approach than what the education and participation of the mother in the SENSE program provides. However, future investigations could aid in better understanding the impact of the SENSE program on mothers with and without mental health challenges.

The SENSE program was related to better early infant neurobehavior. The risk of developmental challenges among preterm infants is high, yet the brain is undergoing rapid development during the period from preterm birth to term equivalent providing an opportunity for improving the developmental trajectory through positive sensory exposures known to improve outcomes. However, prior to the development of the SENSE program, interventions such as skin-to-skin care and auditory exposures were often done inconsistently (not systematically over time during the entire hospitalization) without modification based on the level of immaturity, PMA. The SENSE program was developed to ensure positive sensory experiences every day of hospitalization to foster appropriate neuronal activity and improve the early developmental trajectory [11]. Asymmetry is common in preterm infants as they often demonstrate head turn preference and head deformities [59,60]. Symmetry is important for opportunities for balanced exposures across both sides of the environment and through all 4 extremities in addition to preventing deformation of the skull due to prolonged pressure to one area of the head [61]. Others have reported relationships with parent holding, skin-to-skin care, and occupational therapy with early neurobehavior in addition to long term outcomes [3,62,63]. The SENSE program further builds on these findings by combining available evidence into a cohesive program. It will be important to follow these infants into early childhood, as development rapidly changes during the first several months of life, and early neurobehavior can be impacted by resolving medical complications [64]. However, early neurobehavior is related to long term outcome [65,66], showing promise that the SENSE program could be beneficial not only

Table 2
Relationships between group assignment (SENSE versus standard-of-care) and maternal measures.

	Mean ± SD Total sample (n = 59)	Mean ± SD Historical cohort (n = 37)	Mean ± SD SENSE cohort (*n* = 22)	*p-Value	**p-Value
Stress (PSS) (n = 59)	26.5 ± 5.7	26.7 ± 5.4	26.3 ± 6.2	0.73	
Depression (EPDS) (n = 59)	7.32 ± 4.6	7.08 ± 4.2	8.5 ± 5.9	0.27	
Anxiety (STAI-State) (n = 59)	29.4 ± 8.5	30.4 ± 7.9	29.5 ± 8.7	0.67	
Anxiety (STAI-Trait) (n = 58)	30.2 ± 8.1	30.1 ± 8.5	28.0 ± 8.6	0.36	
Parental role alteration (PSS-NICU)	2.9 ± 1.0	2.8 ± 0.8	2.8 ± 1.13	0.80	
Maternal confidence (MCQ)	44.4 ± 8.1	41.4 ± 7.6	49.5 ± 6.1	< **0.001**	**0.01**
Confidence in infant care (ICQ)-mom and baby	4.4 ± 0.4	4.3 ± 0.4	4.5 ± 0.4	**0.03**	0.24
Confidence in infant care (ICQ)-emotionality	4.4 ± 0.8	1.3 ± 0.9	4.6 ± 0.5	0.18	
Confidence in infant care (ICQ)-responsiveness	4.0 ± 0.5	4.0 ± 0.5	4.0 ± 0.5	0.84	
Post-traumatic stress (PPQ)	7.48 ± 7.6	8.25 ± 7.6	6.23 ± 7.6	0.33	

*p-Value is from investigating differences across groups using independent samples t-tests. **p-Value is from investigating differences across groups (among those with $p < 0.05$) using analysis of covariance while controlling for estimated gestational age, insurance type, room type, infant race, mother's marital status, maternal age, as well as factors that were different across groups including retinopathy of prematurity, mode of delivery, days of total parenteral nutrition, and days of continuous positive airway pressure. The n for these analyses differ from the n for the neurobehavioral analyses, as each mother-infant dyad is represented once, so there is a smaller n accounting for multiple births (in addition to some infants not receiving neurobehavioral testing and some mothers not completing the questionnaire as described in the Results section).

on neurobehavior identified in the neonatal period, but with the potential to improve long term outcomes. Future, properly-powered studies, can also better elucidate why SENSE programming may impact some areas of neurobehavior and not others.

The SENSE program was developed using a rigorous scientific process that included evidence related to positive sensory exposures during NICU hospitalization and parent and health care professional input, while integrating this with an understanding of normal fetal and neonatal development and exposures [13]. This enabled defining a daily plan of sensory exposures to be carried out by parents every day of NICU hospitalization to foster the early parent-child relationship, improve parent participation in the NICU, and improve infant neurodevelopmental outcomes. This is the first study to demonstrate outcomes related to the SENSE program, which demonstrates promise for optimizing the environment for high-risk infants in the NICU.

This study has limitations, most notably being that it was a small pilot study that used a historical control. The two groups were enrolled several years apart, which further increases the risk for confounding factors. In addition, it is a challenge to fully untangle confounding variables related to the medical course of high-risk infants in the NICU. Infants can have a wide range of medical complications and social factors that can impact their experiences and developmental course. Many studies aim to overcome these challenges related to confounding variables by enrolling low-risk samples. However, this is not representative of high-risk infants who are hospitalized in Level III and IV NICUs. Therefore, we have included a sample of high-risk infants in a Level IV NICU, but collected and controlled for infant and maternal factors that can impact outcome within the statistical model. The addition of multiple covariates decreases power in detecting differences across groups. This study was a pilot study that was not powered for hypothesis testing. This study also explored multiple different outcomes, increasing the risk for a Type I error. This study evaluates the impact of the SENSE program among a group of infants at a single site, where the SENSE program was being implemented for the first time.

Table 3
Relationships between group (SENSE versus standard-of-care) and infant neurobehavior.

	Mean ± SD; Total sample (*n* = 67)	Mean ± SD; Historical cohort (*n* = 41)	Mean ± SD; or N SENSE cohort (*n* = 26)	*p-Value	**p-Value
NICU Network Neurobehavioral Scale (NNNS) summary scores					
Orientation	3.7 ± 1.4	3.8 ± 1.3	3.5 ± 1.5	0.41	
Tolerance of handling	0.7 ± 0.5	0.7 ± 0.4	0.6 ± 0.5	0.15	
Quality of movement	3.9 ± 0.8	4.0 ± 0.7	3.7 ± 0.9	0.14	
Self-regulation	4.6 ± 0.7	4.8 ± 0.7	4.4 ± 0.7	0.09	
Suboptimal reflexes	6.9 ± 2.3	7.0 ± 2.4	6.7 ± 2.1	0.63	
Stress	0.3 ± 0.1	0.3 ± 0.1	0.3 ± 0.1	0.67	
Arousal	3.8 ± 0.8	3.9 ± 0.8	3.6 ± 0.7	0.14	
Hypertonia	0.9 ± 1.2	1.1 ± 1.4	0.7 ± 0.7	0.19	
Hypotonia	0.8 ± 0.8	0.6 ± 0.8	1.0 ± 0.9	0.08	
Asymmetry	2.5 ± 1.7	2.9 ± 1.8	2.0 ± 1.3	**0.03**	**0.02**
Excitability	3.9 ± 2.4	3.7 ± 2.3	4.1 ± 2.6	0.58	
Lethargy	6.5 ± 2.6	6.0 ± 2.5	7.3 ± 2.6	**0.04**	0.07
Hammersmith Neonatal Neurological Evaluation (HNNE) total score	17.2 ± 4.9	15.3 ± 4.2	20.1 ± 4.6	< **0.001**	< **0.001**

*p-Value is from investigating differences in neurobehavior across groups while controlling for the PMA at the time of testing using analysis of covariance. **p-Value is from investigating differences in neurobehavior (among those with $p < 0.05$) across groups while controlling for estimated gestational age at birth, insurance type, room type, infant race, mother's marital status, maternal age, and postmentrual age at the time of testing in addition to factors that differed across groups, which included retinopathy of prematurity, mode of delivery, days of total parenteral nutrition, and days of continuous positive airway pressure.

Due to its pilot nature, no treatment fidelity or measures of parent involvement were studied making this an important area for future exploration. Further, while there was intentional delivery of sensory interventions for the SENSE cohort, standard-of-care in the control group is not well-understood in terms of daily sensory exposures that were delivered. Further studies of the SENSE program could also better identify treatment fidelity in addition to whether stimuli were provided by parents or staff, with investigation into whether one is more important compared to the other. Parent report measures were used for the maternal outcomes, and this is susceptible to bias and problems with potential for failure to report. Neurobehavioral testing was done at term equivalent age, prior to NICU discharge, but outcomes did not extend beyond hospitalization. Finally, this study was conducted in a setting with a population with many socioeconomic challenges that may not generalize to other settings with different populations. In addition, the study site produced previous findings related to the private NICU room and auditory exposures. This may have resulted in historic change in practices related to the environment, which could have impacted study findings as well.

Despite the limitations of this pilot study, it is the first to investigate the impact of the SENSE program and sets the stage for further inquiry. A properly-powered randomized clinical trial investigating the effect of the SENSE program on maternal outcomes, mother-infant interaction, and early neurobehavior is nearing completion by the study team. Infants enrolled in this randomized clinical trial will be followed until at least one year of age to enable reporting of outcomes beyond NICU discharge.

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The copyright for the SENSE program is held by the Washington University Office of Technology Management. SENSE materials are currently available to other hospitals and individuals for research and clinical applications 'at-cost'.

CRediT authorship contribution statement

Roberta Pineda:Conceptualization, Methodology, Investigation, Project administration, Formal analysis, Writing - original draft, Writing - review & editing.**Michael Wallendorf**:Formal analysis, Writing - review & editing.**Joan Smith**:Conceptualization, Methodology, Investigation, Project administration, Formal analysis, Writing - original draft, Writing - review & editing.

Declaration of competing interest

Two of the authors received grant funding to develop the SENSE program. The SENSE program is currently available 'at cost' through the Washington University Office of Technology Management, but they currently do not receive royalties from sales.

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