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RESEARCH ARTICLE

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

Susan Nicolson[1,2,3] | **Sarah-Pia Carron**[4] | **Campbell Paul**[1,3,5]

[1]Department of Psychiatry, University of Melbourne, Parkville, Victoria, Australia

[2]Department of General Practice, University of Melbourne, Parkville, Victoria, Australia

[3]Women's Mental Health Service, Royal Women's Hospital, Melbourne, Victoria, Australia

[4]Monash Health Adult Mental Health, Melbourne, Victoria, Australia

[5]Royal Children's Hospital, Melbourne, Victoria, Australia

Correspondence
Susan Nicolson, Women's Mental Health Service, Royal Women's Hospital, Flemington Road, Melbourne, Victoria 3052, Australia.
Email: s.nicolson@unimelb.edu.au

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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. S*econdary 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

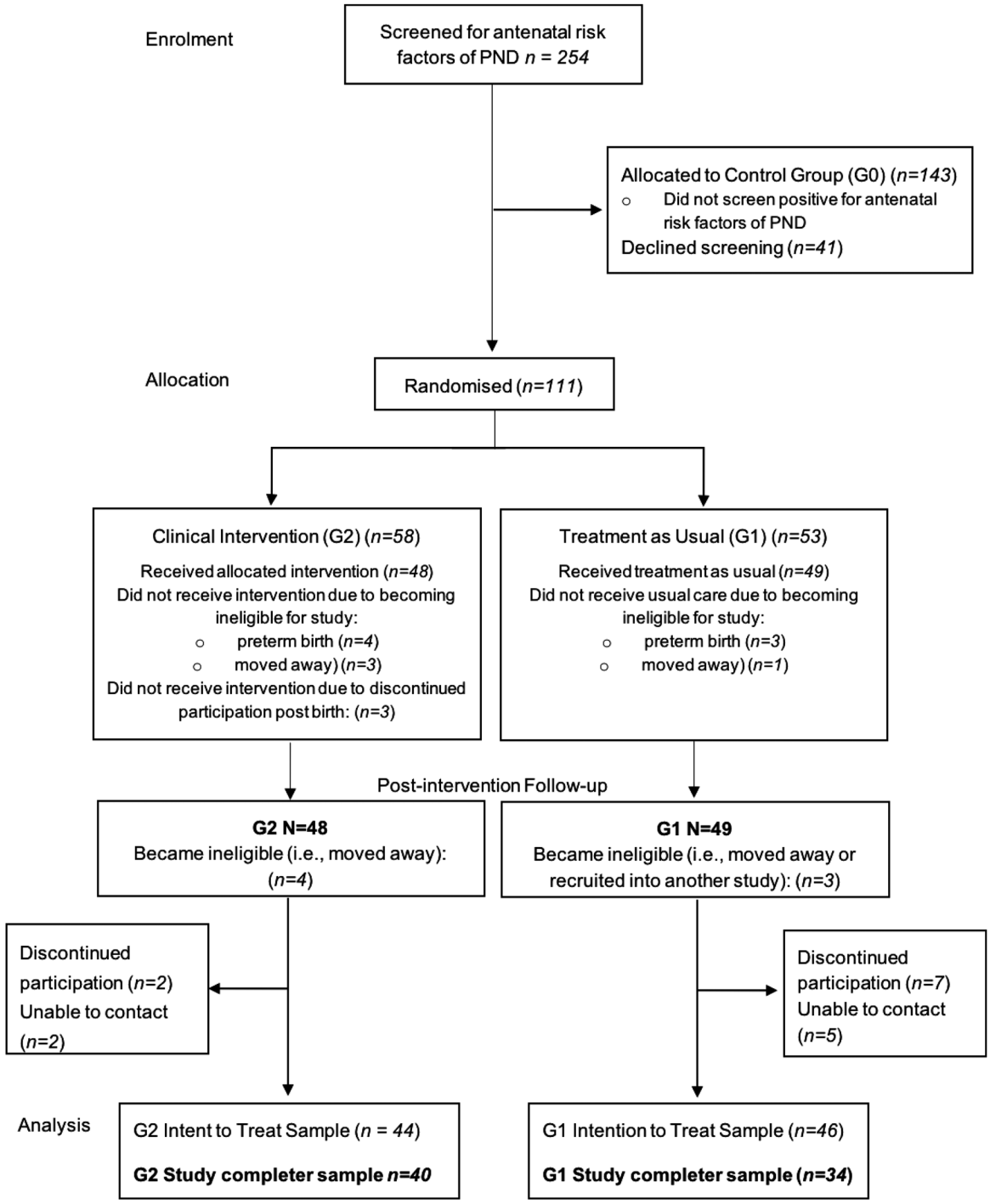

FIGURE 1 CONSORT diagram of participant flow and attrition. PND = post-natal depression

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.

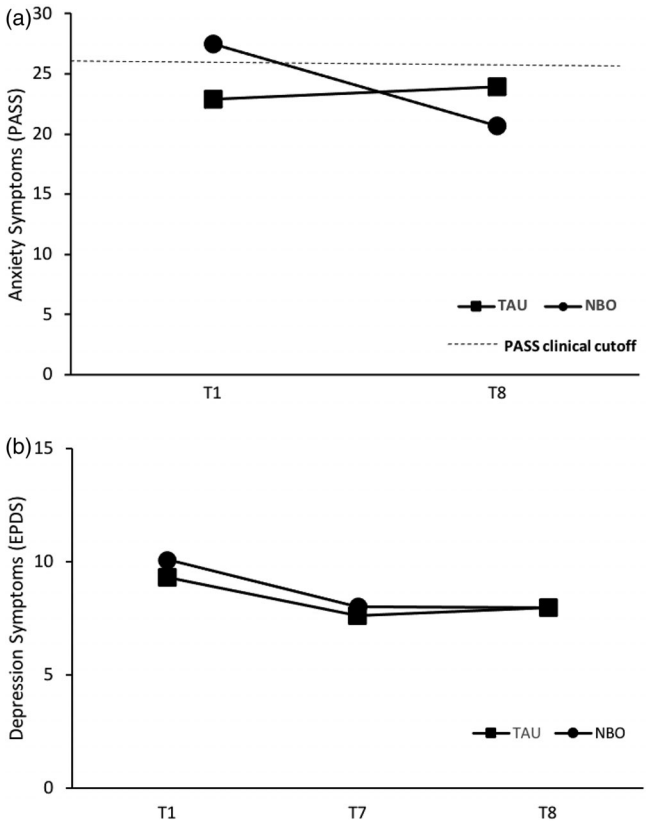

FIGURE 2 Change in (a) anxiety symptoms and (b) depression symptoms from baseline to post-treatment: intervention (NBO) versus TAU-only

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).

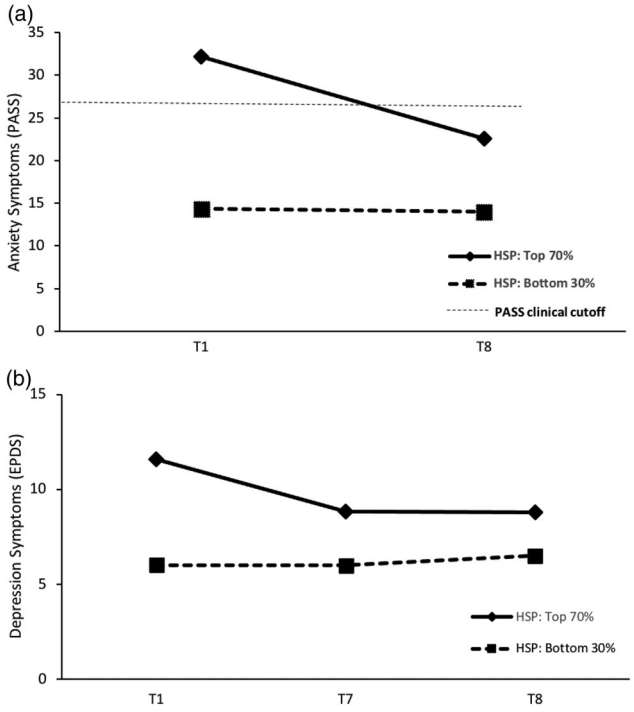

FIGURE 3 Change in (a) anxiety symptoms and (b) depression symptoms over time for medium-high versus low sensory processing sensitivity mothers receiving the intervention ($n = 38$). HSP = Highly sensitive person

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.

ORCID

Susan Nicolson https://orcid.org/0000-0003-0395-6406

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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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