Research Square

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Effects of a multicomponent five-element music-based nursing intervention during kangaroo mother care on preterm infant neurobehavior and maternal outcomes: a randomized controlled trial

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Abstract

Background

Kangaroo mother care supports preterm infants and maternal participation, but evidence on culturally informed multicomponent music-based nursing packages integrated with KMC remains limited. This study evaluated the effects of such a package on infant neurobehavior and maternal outcomes.

Methods

In this single-center, parallel-group randomized trial, 110 dyads were allocated to routine neonatal intensive care unit care plus kangaroo mother care (KMC) or the same care plus the structured multicomponent intervention. The protocol used outcome-specific follow-up schedules: NBNA follow-up was scheduled for 40 weeks' postmenstrual age (PMA), whereas CMAI and PSOC were assessed after the 4-week intervention. Intention-to-treat analyses included all randomized dyads; missing values were multiply imputed, and follow-up scores were analysed by baseline-adjusted ANCOVA with HC3 robust standard errors. The NBNA total score was primary and the CMAI total score key secondary; Holm correction was applied across these total-score tests, and complete-case ANCOVA served as a sensitivity analysis.

Results

All 110 randomized dyads were included in the intention-to-treat analyses. The baseline-adjusted intervention effect was 6.83 points for NBNA (95% CI, 5.98–7.68) and 3.07 points for CMAI (95% CI, 2.51–3.64); both Holm-adjusted P values were < 0.001. Complete-case estimates were closely concordant at 6.81 points (95% CI, 5.95–7.67; n = 103) and 3.07 points (95% CI, 2.49–3.65; n = 103), respectively. Exploratory NBNA domain and CMAI dimension findings remained significant after false-discovery-rate control; PSOC remained exploratory.

Conclusions

Baseline-adjusted intention-to-treat analyses showed higher NBNA scores at follow-up scheduled for 40 weeks' PMA and higher 4-week maternal attachment scores with the structured multicomponent intervention. Concordant imputed and complete-case estimates support the randomized comparison; findings apply to the complete package rather than five-element music alone.

Trial registration:

Chinese Clinical Trial Registry, ChiCTR2600119036; retrospectively registered on 14 February 2026.

BACKGROUND

Advances in perinatal medicine have improved the survival of infants born prematurely, making the quality of early development and the experience of families increasingly important considerations in neonatal care [1, 2]. Preterm infants, defined as infants born before 37 completed weeks of gestation, may require hospitalization during a period of continuing neurological and behavioral maturation. In the NICU, necessary medical procedures occur alongside environmental noise, illumination, and restrictions on parent–infant contact. The resulting care environment presents challenges not only for the infant's regulation of sensory input but also for the mother's opportunities to establish an early relationship with her infant [3, 4]. Interventions addressing these two aspects together are therefore relevant to developmental and family-centered nursing care.

Kangaroo mother care is an established approach that places skin-to-skin contact at the center of care for preterm and low-birth-weight infants. Within the clinical framework used in this study, KMC provides opportunities for thermal support, breastfeeding guidance, close observation, and maternal participation in everyday care [11, 12]. Its relational value is important: the mother is not simply a visitor but an active participant in caring for her infant. Nevertheless, the sensory experience accompanying a KMC session depends on how the session is organized. Adding a structured auditory component represents a modification of that experience, rather than a remedy for an assumed absence of auditory input during KMC itself.

Music-based interventions have been investigated as one way to organize auditory stimulation for preterm infants [6, 7]. The relevant distinction is between carefully controlled auditory exposure and adding more sound to an already complex environment. Research on sound reduction in the NICU underscores the importance of the acoustic setting [5]. Thus, an adjunctive music protocol needs to specify playback characteristics, timing, duration, supervision, and responses to infant discomfort. The clinical question is whether a reproducible intervention integrated into existing care offers an advantage over that care alone, not whether sound exposure is beneficial regardless of its delivery conditions.

Previous research has examined KMC combined with music, including a randomized trial focused on attachment between mothers and their premature infants [8]. Five-element music combined with KMC has also been studied in relation to growth and neurobehavioral outcomes [10]. The present investigation therefore builds on an existing combined-intervention approach. A remaining question concerns how a standardized, culturally informed protocol relates simultaneously to infant neurobehavior, maternal attachment, and the mother's sense of competence. These outcomes are related but not interchangeable: infant neurobehavior reflects observed performance, attachment concerns the maternal emotional bond, and parenting competence addresses the mother's perceived capability and satisfaction in her parenting role.

TCM five-element music provides the cultural and theoretical framework for the protocol examined here. It relates musical modes to the five zang organs and uses these associations to guide music selection within a broader understanding of physical and emotional well-being [9]. In the present study, this

framework informed a common selection of three musical pieces rather than individualized treatment based on separately assessed syndromes. Distinguishing the rationale for selecting the music from evidence about how it works is essential. A comparison with KMC alone can evaluate the combined care package, but cannot establish that its effects depend on the five-element classification rather than the auditory and interpersonal components of the intervention.

Accordingly, this single-center randomized trial compared routine NICU care plus KMC with the same care supplemented by a structured, multicomponent five-element music-based nursing intervention. The study evaluated early neurobehavioral performance using the NBNA and maternal outcomes using the CMAI and PSOC. By retaining both infant and maternal outcomes, the investigation aimed to contribute to the evaluation of an integrative nursing approach for preterm infant–mother dyads, while keeping its conclusions specific to the intervention delivered, the outcomes measured, and the short-term follow-up available.

METHODS

Study design and setting

This was a single-center, two-arm, parallel-group randomized controlled trial conducted in the NICU of a tertiary hospital in Yancheng, Jiangsu Province, China. Recruitment was completed in December 2025; 110 dyads (110 infants, 110 mothers, and 110 independent families) were enrolled after 6 August 2025. Eligible dyads were assigned in a 1:1 ratio to routine NICU care plus KMC or to the same care supplemented by the structured, multicomponent five-element music-based nursing intervention. The protocol used outcome-specific follow-up schedules: maternal outcomes were evaluated after the 4-week intervention, whereas NBNA follow-up was scheduled separately for 40 weeks' postmenstrual age (PMA) to provide a common developmental-stage target. These schedules were designed for the respective outcome domains and were not assumed to coincide.

Sample selection criteria

Infants were eligible if they were born before 37 weeks of gestation [2], were admitted within 3 days after birth, had completed and passed bilateral hearing screening within 72 hours of admission, and had no identified hearing impairment. They were required to have stable vital signs, including heart rate, respiratory rate, and peripheral oxygen saturation, and to be clinically suitable for KMC. Participating mothers were required to have no severe postpartum complications, psychiatric history, or hearing dysfunction and to participate voluntarily after providing written informed consent.

Infants were excluded if they had complex congenital malformations, severe inborn errors of metabolism, marked abnormalities on cranial ultrasonography, or severe perinatal asphyxia. Infants whose disease or treatment required a special position incompatible with standard KMC were also

excluded. Mothers requiring mandatory bed rest after delivery, or otherwise unable to perform KMC, were not eligible.

Sample size calculation

Sample size planning was based on a comparison of two independent means, drawing on NBNA results from a previous study [10]. The reported planning assumptions were a two-sided α of 0.05, 90% power, a standard deviation of 1.80, and a between-group difference of 1.11. The calculation was:

n per group = $2[(1.96 + 1.28) \times 1.80 / 1.11]^2 = 55.21$.

These assumptions correspond to approximately 56 evaluable dyads per group before accounting for attrition. The recruitment target and achieved enrollment were 110 dyads, with 55 assigned to each group. Thus, the enrolled sample was slightly below the calculated evaluable sample and did not provide the full additional allowance for the anticipated 10% loss to follow-up. The precision of the outcome estimates was evaluated using confidence intervals.

Randomization, allocation concealment, and blinding

Sequence generation and randomization unit. The one-dyad-per-family design was used; when both co-twins were eligible, one was selected by a random-number method before treatment allocation. Before recruitment, a 1:1 allocation sequence was generated in Microsoft Excel by randomly ordering the integers 1–110; even-numbered values were assigned to the control group and odd-numbered values to the intervention group, yielding 55 assignments per group. The sequence was completed before recruitment, with no stratification or block randomization. The sequence-generation procedure was documented, although the identity of the individual who generated the sequence was not recorded.

Allocation concealment and implementation. To keep upcoming assignments unavailable during eligibility assessment and consent, each allocation was placed in a separate, sequentially numbered, opaque, sealed envelope corresponding to enrollment order. The envelopes were held by a designated custodian. A recruiting investigator first confirmed eligibility, obtained written informed consent, and assigned the next sequential study number; only then did the custodian open the corresponding envelope in order and communicate the assignment for implementation. This separation of recruitment from envelope custody delayed disclosure of group assignment until enrollment was complete.

Blinding and role separation. Blinding of mothers and intervention providers was not feasible because the auditory and associated nursing procedures were readily identifiable. Intervention delivery and outcome measurement were assigned to different personnel: the certified neonatal specialist nurse who performed the NBNA did not deliver the intervention. Assessor masking was not assured because access to allocation and intervention information was not formally restricted. The CMAI and PSOC were self-reported by mothers who were aware of the care received. Data management and statistical

analysis were undertaken by nursing postgraduate team members who were not involved in intervention delivery. Neutral recoding of group labels and delayed release of an allocation key were not used; formal analyst blinding was therefore not assumed.

Ethical considerations and trial registration

The study was approved by the Institutional Clinical Research Ethics Committee (Approval No. 2025-J-105). Written informed consent was obtained from participating mothers before enrollment. All 110 dyads were enrolled after 6 August 2025. The trial was retrospectively registered with the Chinese Clinical Trial Registry on 14 February 2026 (ChiCTR2600119036).

Establishment of the intervention team

The nine-member team comprised one chief physician in neonatology, one head nurse, one deputy chief superintendent nurse, three certified neonatal specialist nurses, and three nursing postgraduate students. The neonatologist assessed infant clinical condition and provided guidance on medical decisions. The head nurse coordinated protocol development and supervised implementation. Two neonatal specialist nurses and the deputy chief superintendent nurse delivered the intervention and undertook designated data-collection tasks. The postgraduate students supported literature retrieval, data management, and statistical analysis.

The team members had clinical experience and communication skills relevant to working with mothers of hospitalized preterm infants. Staff delivering the intervention were not responsible for outcome assessment. This separation distinguished intervention delivery from measurement, while not implying that assessors were unaware of allocation.

Protocol development and standardized training

The combined protocol was developed through a review of relevant domestic and international guidelines and studies, followed by consultation with clinical nursing experts. The KMC component drew on the Clinical Practice Guidelines for Kangaroo Mother Care in Preterm and Low Birth Weight Infants and the related nursing group standard [11, 12]. The five-element music component drew on the TCM framework and published nursing descriptions of its application [9, 13].

Before formal implementation, team members received standardized training. Implementing nurses were trained in the KMC procedure, preparation of the mother and infant, clinical precautions, and the theoretical rationale and practical delivery of the structured, multicomponent five-element music-based nursing intervention. Training was intended to support consistent positioning, scheduling, playback, monitoring, and responses to discomfort across the intervention sessions.

Kangaroo mother care in both groups

Before each KMC session, the nurse verified the mother's identity, explained the procedure, and obtained her cooperation. The mother was guided to wear an isolation gown and mask and to perform hand hygiene using the seven-step handwashing technique. She was assisted into a semi-reclined position at an angle of approximately 30–45 degrees, with a soft pillow supporting her lower back. A screen was used to protect privacy.

The infant, wearing only a diaper, was placed skin-to-skin against the mother's chest. The head was turned to one side, and the limbs were maintained in a naturally flexed position. The upper limbs rested beside the trunk or on the mother's chest, and the lower limbs were placed in a flexed, frog-leg position. The mother supported the infant's buttocks, and the nurse covered the infant's back with a blanket. Vital signs were monitored continuously. The mother was instructed to notify staff promptly of any discomfort affecting either herself or the infant and received guidance on breastfeeding techniques.

KMC commenced approximately 72 hours after enrollment once the infant was clinically stable and had no contraindication. Both groups were managed under the same standardized schedule: sessions were arranged on Mondays, Wednesdays, and Fridays, each lasting 30–45 minutes, with 12 sessions scheduled over 4 weeks.

Structured multicomponent five-element music-based nursing intervention

In addition to KMC, intervention-group dyads received a structured package comprising recorded five-element music, guided maternal relaxation and music-synchronized gentle back stroking, close nursing observation, and minimization of strong light and environmental interruptions. The components were co-delivered within a standardized nursing protocol; accordingly, the trial evaluated assignment to the complete package under the standardized protocol rather than the separate effect of each component. Following discussion among the research team and clinical nursing experts, three pieces were selected using the TCM associations of musical modes with the zang organs [9, 13]. The protocol classified "Chun Jiang Hua Yue Ye" (Moonlight on the Spring River) as the Zhi selection, "Yang Chun Bai Xue" (White Snow in Early Spring) as the Shang selection, and "Yun Shui Chan Xin" (Zen Mind of Clouds and Water) as the Gong selection. These pieces were played in rotation.

Within the theoretical framework used to develop the protocol, Zhi was associated with the Heart and calming the spirit, Shang with the Lung and harmonization of qi, and Gong with the Spleen and support of digestive function. The protocol rationale related these associations to the vulnerability and immaturity of preterm infants. These descriptions explain the cultural basis of the music selection; they are not outcomes or mechanisms measured in the trial. All intervention dyads received the standardized selection rather than an individually assessed, syndrome-specific music prescription.

Intervention delivery and safety monitoring

Trained nurses operated a dedicated player positioned on the bedside pendant column, approximately 15–25 cm from the mother's and infant's ears. The implemented protocol used a sound level of 40–45 dB, with instantaneous peaks not exceeding 60 dB, and real-time monitoring with a sound-level meter. Strong light and other environmental interruptions were minimized during playback. The multicomponent package was implemented during the scheduled KMC sessions three times per week within the 16:00–17:00 period, after the main daytime ward procedures, for 30–45 minutes per session over 4 weeks.

During playback, nurses closely observed the infant's facial color, breathing, and limb responses. The intervention was paused if irritability, crying, or fluctuations in vital signs occurred, and the cause was assessed. Mothers were guided to relax while listening and to stroke the infant's back gently in time with the music. This guided maternal touch formed part of the intervention package and was not a separate randomized component.

After KMC, two staff members checked the infant's identity, returned the infant to the incubator, and ensured a comfortable position.

Intervention fidelity and dose documentation

Participant- and session-level fidelity records were available for all 110 randomized dyads. The planned KMC dose was 12 sessions over 4 weeks in both groups (three sessions per week, 30–45 minutes per session), and completion of at least 10 sessions was defined as receipt of ≥ 80% of the planned dose. The actual KMC session count represented total exposure across the complete 4-week programme, including hospital and home sessions; home sessions were therefore reported as a component of, rather than in addition to, the total dose. In the intervention group, completion of the multicomponent package was recorded concurrently with the corresponding KMC sessions.

The fidelity records documented session number and duration, home implementation, temporary pauses, sessions terminated without resumption, protocol deviations, and potential cross-group contamination. Pause monitoring used predefined infant, maternal, and procedural or environmental safety categories; more than one contributing reason could be recorded for a paused session. The number and cumulative duration of home sessions were recorded among dyads who entered the home phase.

Control condition and care after discharge

The control group received the same KMC component in addition to routine NICU nursing care, without the structured multicomponent intervention package. Routine care included environmental comfort, thermal protection, vital-sign monitoring, airway management, nutritional support, positioning, skin protection, infection prevention and control, and reduction of adverse stimuli such as excessive noise and light. No ordinary or sham music or conditions matched for maternal touch, additional nurse attention, or session-specific environmental management were used. The comparison therefore estimated the added effect of the complete package over routine care plus KMC rather than the effect of five-element music in isolation. The same KMC schedule applied to both groups, and actual KMC exposure was compared quantitatively.

For infants discharged before week 4, mothers continued the assigned care at home after discharge-day training. A KMC guidance booklet and WeChat or telephone support were provided, and intervention-group mothers additionally used the selected MP3 recordings during KMC. Home-session counts and cumulative minutes were incorporated into the participant-level fidelity records. Maternal questionnaires were collected after the 4-week intervention, and NBNA follow-up was scheduled separately for 40 weeks' PMA. Potential cross-group contamination was monitored through the fidelity records.

Outcome measures

Neonatal neurobehavior.

The NBNA described by Bao was used to assess early neurobehavioral performance [14]. It contains 20 items across five domains: behavioral competence, passive muscle tone, active muscle tone, primitive reflexes, and general response. Each item is scored from 0 to 2, yielding a total score from 0 to 40; higher scores represent better performance on the assessment. The total score and all five domain scores were analysed.

Baseline NBNA was performed before the intervention. Follow-up NBNA was scheduled for 40 weeks' PMA in the preterm infant follow-up clinic rather than at a fixed 4-week interval after baseline. Scheduling NBNA for this PMA provided a common term-equivalent developmental reference and avoided equating the 4-week intervention period with infant developmental age. The same certified neonatal specialist nurse performed the NBNA assessments.

Maternal–infant attachment.

The CMAI, developed and psychometrically evaluated in Chinese by Chen and colleagues, was used to assess maternal attachment [15]. The instrument contains 26 items covering pleasure in the infant, identification with the infant, love for the infant, and understanding of the infant. Items are scored on a four-point scale, giving a total score from 26 to 104; higher scores indicate stronger maternal attachment. A Cronbach's α of 0.94 has been reported for the Chinese version [15]; this coefficient refers to previous validation rather than the present sample.

The CMAI was administered before the intervention and after the 4-week intervention period. Both the total score and the four dimension scores are presented, so that the overall comparison can be interpreted alongside the pattern across aspects of the maternal attachment construct.

Parenting sense of competence.

The Chinese PSOC evaluated by Yang and colleagues was used to assess mothers' perceived parenting competence [16]. The 17-item measure comprises efficacy and satisfaction dimensions and uses six response categories. According to the scoring protocol used in this study, efficacy comprises items 1, 6, 7, 10, 11, 13, 15, and 17; satisfaction comprises items 2, 3, 4, 5, 8, 9, 12, 14, and 16. The nine satisfaction

items are reverse-scored. The theoretical total range is 17–102, with higher scores indicating a higher sense of competence.

A Cronbach's α of 0.82 has been reported for the Chinese version [16]; this coefficient refers to previous validation rather than a new estimate in this study. Maternal PSOC questionnaires were administered at baseline and after 4 weeks. Total and dimension summaries are presented in Table 4. The recorded aggregate total scores were not internally concordant with the two dimension scores, and item-level responses were unavailable for verification; PSOC findings were therefore interpreted as exploratory.

Data collection and quality control

A general information questionnaire and baseline NBNA, CMAI, and PSOC assessments were completed within 24 hours of enrollment. Infant clinical information was obtained from the electronic medical record. Each mother completed one CMAI and one PSOC per time point through Wenjuanxing (Questionnaire Star), with team guidance. Follow-up maternal questionnaires were completed after the 4-week intervention, whereas NBNA follow-up followed the protocol-specified 40-week PMA target. This outcome-specific collection plan preserved the distinction between intervention completion and infant developmental-stage assessment. The analytic dataset did not include participant-level postnatal age or PMA at baseline, actual intervention start or completion dates, the actual NBNA assessment date, PMA at assessment, or elapsed days from randomization or intervention completion to NBNA.

Quality-control procedures included standardized training, use of a fixed neonatal specialist nurse for NBNA assessment, individual review of returned questionnaires for validity and patterned responding, and cross-checking of data entry by two nursing postgraduate students. The analysis distinguished infant clinical assessments from maternal self-reported outcomes. Assessment by personnel separate from the intervention team and cross-checking of entered data were used to reduce avoidable measurement and transcription variation.

STATISTICS

Descriptive analyses were performed in IBM SPSS Statistics version 27.0. Inferential analyses were conducted in Python version 3.13.5 using statsmodels version 0.14.6 and SciPy version 1.17.0. The NBNA total score at follow-up scheduled for 40 weeks' PMA was treated as the primary outcome, consistent with the NBNA-based sample-size calculation, and the CMAI total score after 4 weeks was treated as a key secondary outcome. NBNA domains, CMAI dimensions, and PSOC results were exploratory. The primary and key secondary total-score analyses followed the intention-to-treat principle and included all 110 randomized dyads.

Seven dyads (four intervention and three control) did not provide follow-up outcomes. To retain all randomized assignments, incomplete values required for the intention-to-treat models were handled using multiple imputation by chained equations with predictive mean matching (100 imputations). The imputation model included randomized group, gestational age, birth weight, maternal age, 1- and 5-min Apgar scores, and available baseline and follow-up NBNA and CMAI total scores. Estimates were

combined using Rubin's rules. Each family contributed one dyad, so no adjustment for within-family clustering was required.

For the primary NBNA and key secondary CMAI analyses, the follow-up score was regressed on randomized group and the corresponding baseline score. Intervention-minus-control adjusted mean differences and 95% confidence intervals were estimated using HC3 robust standard errors; Holm adjustment conservatively controlled family-wise error across the two principal total-score tests. Complete-case ANCOVA (n = 103) was the principal sensitivity analysis. NBNA follow-up was scheduled for 40 weeks' PMA in both randomized groups, providing a common intended developmental-stage reference, whereas maternal outcomes were assessed after 4 weeks. Because actual assessment dates, PMA at assessment, and elapsed days were unavailable, direct comparison or adjustment for actual NBNA timing was not possible. A supportive sensitivity model additionally adjusted for gestational age at birth as an indirect proxy for the planned interval to 40 weeks' PMA; it was not considered a substitute for direct timing adjustment. Exploratory domain and dimension ANCOVAs adjusted for the corresponding baseline score and used the Benjamini–Hochberg false discovery rate across nine tests. Diagnostic checks assessed regression-slope homogeneity, linearity, variance stability, multicollinearity, and influential observations.

Fidelity analyses included all 110 randomized dyads. Continuous dose measures were summarized as mean ± standard deviation and compared between groups using independent-samples t tests, with mean differences and 95% confidence intervals. Completion of ≥ 80% of the planned dose was summarized as n (%) and compared using a risk ratio with a 95% confidence interval. Home-session summaries were calculated among dyads who entered the home phase; temporary pauses, sessions terminated without resumption, protocol deviations, and contamination were summarized descriptively.

RESULTS

Participant flow and general characteristics

A total of 110 preterm infant–mother dyads were randomized, with 55 allocated to each group. Four intervention dyads did not provide follow-up outcomes: three were transferred to other hospitals and one discontinued treatment. Three control dyads did not provide follow-up outcomes: two were transferred to other hospitals and one withdrew from the study. All 110 randomized dyads were retained in the intention-to-treat analyses through multiple imputation. Observed follow-up data were available for 51 intervention and 52 control dyads (n = 103), who formed the complete-case sensitivity population. Figure 1 shows the participant flow and analysis populations.

Baseline characteristics are presented in Table 1 for the 103-dyad complete-case sensitivity population. Mean gestational age was 33.80 ± 2.20 weeks in the intervention group and 33.99 ± 1.91 weeks in the control group; mean birth weight was 2111.76 ± 577.14 g and 2151.73 ± 533.49 g, respectively. The

corresponding maternal ages were 31.37 ± 5.82 and 30.45 ± 6.53 years. These descriptive comparisons were not used to determine covariate inclusion in the randomized-group models.

The same protocol-specified 40-week PMA target applied to both randomized groups, providing a common intended developmental reference for the NBNA comparison. Participant-level actual assessment dates, PMA at assessment, and elapsed days were unavailable; consequently, timing distributions and between-group timing comparisons are not presented.

Intervention fidelity and actual dose

Participant-level fidelity data were available for all 110 randomized dyads. Across the complete 4-week programme, including hospital and home sessions, the intervention and control groups completed 10.71 ± 1.84 and 10.80 ± 1.70 KMC sessions, respectively (mean difference, − 0.09; 95% CI, − 0.76 to 0.58; P = 0.789). Mean participant-level session duration was 37.38 ± 4.09 and 37.80 ± 3.85 minutes (mean difference, − 0.42; 95% CI, − 1.92 to 1.08; P = 0.580). Completion of ≥ 80% of the planned dose (≥ 10 of 12 sessions) was achieved by 45 of 55 dyads (81.8%) in each group (risk ratio, 1.00; 95% CI, 0.84 to 1.19; P = 1.000). Intervention-group dyads completed 10.71 ± 1.84 multicomponent package sessions.

Before week 4, 50 intervention dyads (90.9%) and 49 control dyads (89.1%) were discharged and entered the home phase. Among these dyads, mean home KMC sessions were 7.74 ± 1.87 and 7.80 ± 1.76, and cumulative home KMC doses were 288.87 ± 77.36 and 294.78 ± 73.93 minutes, respectively. Temporary pauses occurred in 6 intervention dyads (10.9%) and 5 control dyads (9.1%), involving 8 and 6 sessions; the pauses were managed under the predefined infant, maternal, and procedural or environmental safety criteria. All paused sessions resumed, and no session was terminated without resumption. No protocol deviations or cross-group contamination were documented (Table 5).

Neonatal neurobehavioral assessment

Observed NBNA total scores among the 103 completers were 18.98 ± 2.54 versus 18.52 ± 2.56 at baseline and 31.27 ± 2.06 versus 24.33 ± 2.32 at follow-up scheduled for 40 weeks' PMA in the intervention and control groups, respectively. In the primary baseline-adjusted intention-to-treat ANCOVA (n = 110), the adjusted mean difference was 6.83 points (95% CI, 5.98–7.68; Holm-adjusted P < 0.001). The complete-case estimate was nearly identical at 6.81 points (95% CI, 5.95–7.67; n = 103). A supporting sensitivity model additionally adjusted for gestational age at birth and yielded 6.82 points (95% CI, 5.96–7.68; n = 110). Exploratory baseline-adjusted domain effects ranged from 0.51 to 1.93 points and all remained significant after false-discovery-rate control (adjusted P ≤ 0.004; Table 2).

Maternal–infant attachment

Observed CMAI total scores among the 103 completers were 73.59 ± 4.38 versus 72.88 ± 4.39 at baseline and 81.06 ± 1.63 versus 77.88 ± 1.52 after 4 weeks in the intervention and control groups, respectively. In the key secondary baseline-adjusted intention-to-treat ANCOVA (n = 110), the adjusted mean difference was 3.07 points (95% CI, 2.51–3.64; Holm-adjusted P < 0.001). The complete-case estimate was closely concordant at 3.07 points (95% CI, 2.49–3.65; n = 103). Exploratory baseline-

adjusted dimension effects ranged from 0.48 to 1.26 points and all remained significant after false-discovery-rate control (adjusted $P \leq 0.009$; Table 3).

Model diagnostics

Diagnostic checks supported the ANCOVA specifications. No material departures from regression-slope homogeneity, linearity, variance stability, multicollinearity, or influence assumptions were identified, and HC3 robust standard errors were retained for inference. The fractions of missing information were low (5.7% for NBNA and 6.0% for CMAI).

Parenting sense of competence

PSOC was treated as an exploratory outcome outside the two principal total-score analyses. The recorded total-score data yielded baseline values of 74.53 ± 2.88 and 74.54 ± 2.87 and follow-up values of 88.06 ± 2.57 and 76.52 ± 2.29 in the intervention and control groups, respectively. Because the aggregate total scores were not internally concordant with the two dimension scores, these complete-case summaries were not used for confirmatory inference (Table 4).

Table 1
Baseline characteristics of the complete-case sensitivity population

Characteristic	Intervention (n = 51)	Control (n = 52)	t / χ^2	P
Infant sex, n (%)			1.730	0.188
Male	33 (64.7)	27 (51.9)		
Female	18 (35.3)	25 (48.1)		
Gestational age (weeks)	33.80 ± 2.20	33.99 ± 1.91	-0.450	0.654
Birth weight (g)	2111.76 ± 577.14	2151.73 ± 533.49	-0.365	0.716
Birth head circumference (cm)	30.47 ± 2.57	30.38 ± 2.33	0.198	0.843
Birth length (cm)	43.62 ± 3.60	44.16 ± 3.27	-0.807	0.422
Apgar score				
1 min	6.90 ± 1.29	7.19 ± 1.03	-1.267	0.208
5 min	8.00 ± 1.27	8.27 ± 0.89	-1.252	0.213
Maternal age (years)	31.37 ± 5.82	30.45 ± 6.53	0.672	0.503
Maternal education level			1.342	0.511
Primary school or below	3 (5.9)	3 (5.8)		
Junior high school	18 (35.3)	13 (25.0)		
Senior high school or above	30 (58.8)	36 (69.2)		
Pregnancy complications			1.414	0.234
Yes	42 (82.4)	47 (90.4)		
No	9 (17.6)	5 (9.6)		
Infant plurality at birth			1.839	0.175
Singleton	46 (90.2)	42 (80.8)		
Twin	5 (9.8)	10 (19.2)		
Delivery mode			0.647	0.421
Vaginal delivery	13 (25.5)	17 (32.7)		
Cesarean section	38 (74.5)	35 (67.3)		

Values are observed mean ± standard deviation or n (%) for the 103-dyad complete-case sensitivity population, not the full intention-to-treat population. The t statistic is reported for continuous variables

and χ^2 for categorical variables.

Table 2
NBNA scores and adjusted effects at follow-up scheduled for 40 weeks' PMA

Outcome / time	Intervention observed (n = 51)	Control observed (n = 52)	Model n	Adj. P	Adjusted mean difference (95% CI)
Behavioral competence Baseline	6.00 ± 1.34	5.60 ± 1.21	—	—	—
Behavioral competence Scheduled follow-up	10.02 ± 0.81	9.40 ± 1.07	103	0.004	0.51 (0.17, 0.84)
Active muscle tone Baseline	4.00 ± 1.10	4.06 ± 1.45	—	—	—
Active muscle tone Scheduled follow-up	6.12 ± 0.77	4.19 ± 1.07	103	< 0.001	1.93 (1.57, 2.30)
Passive muscle tone Baseline	3.16 ± 0.73	3.17 ± 0.76	—	—	—
Passive muscle tone Scheduled follow-up	6.08 ± 0.72	4.17 ± 0.79	103	< 0.001	1.92 (1.71, 2.12)
Primitive reflexes Baseline	2.69 ± 0.76	2.63 ± 0.77	—	—	—
Primitive reflexes Scheduled follow-up	4.51 ± 0.58	3.08 ± 1.06	103	< 0.001	1.41 (1.10, 1.71)
General response Baseline	3.14 ± 0.35	3.06 ± 0.42	—	—	—
General response Scheduled follow-up	4.55 ± 0.73	3.48 ± 0.94	103	< 0.001	1.02 (0.69, 1.34)
Total score	18.98 ± 2.54	18.52 ± 2.56	—	—	—

Outcome / time	Intervention observed (n = 51)	Control observed (n = 52)	Model n	Adj. P	Adjusted mean difference (95% CI)
Baseline					
Total score Scheduled follow-up	31.27 ± 2.06	24.33 ± 2.32	110	< 0.001	6.83 (5.98, 7.68)

Observed values are mean ± standard deviation among 103 dyads with NBNA data. Follow-up was scheduled for 40 weeks' PMA in both groups, providing a common intended developmental-stage target and remaining distinct from the 4-week maternal outcome assessment; participant-level actual assessment dates and PMA were unavailable. The total-score effect is the primary intention-to-treat ANCOVA estimate from 100 multiply imputed datasets (n = 110), adjusted for baseline NBNA and using HC3 robust standard errors; its P value is Holm-adjusted across the primary NBNA and key secondary CMAI total-score tests. Domain effects are exploratory complete-case ANCOVA estimates (n = 103), adjusted for the corresponding baseline domain; P values are Benjamini–Hochberg false-discovery-rate adjusted across the five NBNA domains and four CMAI dimensions. CI, confidence interval; NBNA, Neonatal Behavioral Neurological Assessment; PMA, postmenstrual age.

Table 3
Observed CMAI scores and adjusted intervention effects

Outcome / time	Intervention observed (n = 51)	Control observed (n = 52)	Model n	Adj. P	Adjusted mean difference (95% CI)
Pleasure in the infant Baseline	17.00 ± 1.20	16.92 ± 1.20	—	—	—
Pleasure in the infant 4 weeks	19.02 ± 0.81	18.48 ± 1.11	103	0.006	0.52 (0.16, 0.87)
Identification with the infant Baseline	32.29 ± 1.54	32.02 ± 1.63	—	—	—
Identification with the infant 4 weeks	34.98 ± 0.81	34.54 ± 1.04	103	0.009	0.48 (0.12, 0.84)
Love for the infant Baseline	13.51 ± 1.53	13.25 ± 1.17	—	—	—
Love for the infant 4 weeks	15.02 ± 0.81	14.12 ± 0.78	103	< 0.001	0.86 (0.55, 1.16)
Understanding of the infant Baseline	10.78 ± 1.72	10.69 ± 1.20	—	—	—
Understanding of the infant 4 weeks	12.04 ± 0.82	10.75 ± 0.90	103	< 0.001	1.26 (0.95, 1.58)
Total score Baseline	73.59 ± 4.38	72.88 ± 4.39	—	—	—
Total score 4 weeks	81.06 ± 1.63	77.88 ± 1.52	110	< 0.001	3.07 (2.51, 3.64)

Observed values are mean ± standard deviation among 103 dyads with follow-up data. The total-score effect is the key secondary intention-to-treat ANCOVA estimate from 100 multiply imputed datasets (n = 110), adjusted for baseline CMAI and using HC3 robust standard errors; its P value is Holm-adjusted across the primary NBNA and key secondary CMAI total-score tests. Dimension effects are exploratory

complete-case ANCOVA estimates (n = 103), adjusted for the corresponding baseline dimension; P values are Benjamini–Hochberg false-discovery-rate adjusted across nine domain and dimension tests. CMAI, Chinese Maternal Attachment Inventory; CI, confidence interval.

Table 4
Exploratory PSOC total and dimension scores

Outcome / time	Intervention (n = 51)	Control (n = 52)	t	P	Mean difference (95% CI)
Efficacy Baseline	37.82 ± 1.67	37.81 ± 1.66	0.048	0.962	0.02 (-0.63, 0.67)
Efficacy 4 weeks	44.80 ± 1.33	39.15 ± 1.36	21.310	< 0.001	5.65 (5.12, 6.18)
Satisfaction Baseline	34.92 ± 1.82	34.90 ± 1.81	0.050	0.961	0.02 (-0.69, 0.73)
Satisfaction 4 weeks	43.25 ± 1.76	37.15 ± 1.36	19.659	< 0.001	6.10 (5.49, 6.72)
Total score Baseline	74.53 ± 2.88	74.54 ± 2.87	-0.016	0.987	-0.01 (-1.13, 1.11)
Total score 4 weeks	88.06 ± 2.57	76.52 ± 2.29	24.068	< 0.001	11.54 (10.59, 12.49)

Note: Values are observed complete-case summaries (n = 103). PSOC, Parenting Sense of Competence Scale; CI, confidence interval. PSOC was outside the primary and key secondary total-score testing hierarchy and was treated as exploratory because the recorded aggregate total scores were not internally concordant with the two dimension scores and item-level responses were unavailable for verification.

Table 5
Intervention fidelity and actual dose by randomized group

Fidelity measure	Intervention group (n = 55)	Control group (n = 55)	Between-group comparison
Planned KMC sessions, n	12	12	—
Actual KMC sessions over 4 weeks, mean ± SD[1]	10.71 ± 1.84	10.80 ± 1.70	MD − 0.09 (− 0.76 to 0.58); P = 0.789
Mean session duration, min	37.38 ± 4.09	37.80 ± 3.85	MD − 0.42 (− 1.92 to 1.08); P = 0.580
Completed ≥ 80% of planned dose, n (%)	45 (81.8)	45 (81.8)	RR 1.00 (0.84 to 1.19); P = 1.000
Multicomponent package sessions, mean ± SD	10.71 ± 1.84	Not applicable	—
Discharged before week 4 and entered the home phase, n (%)	50 (90.9)	49 (89.1)	—
Home KMC sessions, mean ± SD[2]	7.74 ± 1.87	7.80 ± 1.76	MD − 0.06 (− 0.78 to 0.67)
Home cumulative KMC dose, min[2]	288.87 ± 77.36	294.78 ± 73.93	MD − 5.91 (− 36.09 to 24.27)
Dyads with ≥ 1 temporary pause, n (%)	6 (10.9)	5 (9.1)	—
Total temporarily paused sessions, n	8	6	—
Sessions terminated without resumption, n	0	0	—
Dyads with protocol deviations, n (%)	0 (0.0)	0 (0.0)	—
Documented cross-group contamination, n (%)	Not applicable	0 (0.0)	—

Note: Values are mean ± standard deviation or n (%). Completion of ≥ 80% of the planned dose was defined as completion of at least 10 of the 12 scheduled sessions. [1]Actual KMC sessions represent the total number completed during the full 4-week programme, including hospital and home sessions. [2]Home-session summaries were calculated among dyads who entered the home phase and form part of, rather than an addition to, the total 4-week dose. Between-group mean differences were calculated as intervention minus control. A paused session could have more than one recorded contributing reason. CI, confidence interval; KMC, kangaroo mother care; MD, mean difference; RR, risk ratio.

The number screened before randomization was not recorded; therefore, the flow diagram begins at randomization. All 110 randomized dyads were included in the primary intention-to-treat analyses;

missing outcomes were multiply imputed. Observed follow-up data from 51 intervention and 52 control dyads formed the complete-case sensitivity population. Maternal outcomes were assessed after the 4-week intervention, whereas NBNA follow-up was scheduled separately for 40 weeks' PMA to provide a common developmental-stage target; the figure does not imply that these assessments occurred at the same time. Routine NICU care was provided in both groups. KMC, kangaroo mother care; NICU, neonatal intensive care unit; PMA, postmenstrual age.

DISCUSSION

Principal findings and the contribution of the study

This trial evaluated a structured, culturally informed, nurse-delivered, multicomponent intervention integrated with KMC for preterm infants and their mothers. In the baseline-adjusted intention-to-treat analyses including all 110 randomized dyads, the intervention group had higher NBNA and CMAI total scores than the routine-care-plus-KMC group. The effects were closely reproduced in the complete-case analyses, and the NBNA estimate remained stable in the supporting gestational-age-at-birth sensitivity model. Retaining all randomized dyads, adjusting for baseline scores, using robust inference, controlling multiplicity, and obtaining concordant sensitivity estimates strengthen confidence that the findings were not driven by baseline imbalance or the selected missing-data approach. The findings characterize the randomized effect of assignment to the standardized intervention strategy, whose procedural arrangements were implemented as specified; exploratory domain and dimension results were directionally consistent, whereas PSOC remained exploratory.

Quantitative fidelity findings further support the implementation quality. In both groups, 81.8% of dyads completed at least 80% of the planned KMC dose, mean session duration remained within the prespecified 30–45-minute range, and actual KMC frequency and duration were closely comparable. This reduces concern that the outcome differences were explained by unequal KMC exposure and supports interpretation of the randomized comparison as the added effect of the multicomponent package.

Considering infant and maternal outcomes together is clinically meaningful because the intervention was delivered through a shared care encounter. NBNA scores concern the infant's performance during a structured assessment, whereas the CMAI captures the mother's reported emotional relationship with her infant. Their concurrent assessment broadens the evaluation beyond a single physiological or questionnaire outcome. At the same time, favourable results in both domains do not establish that improvement in one caused improvement in the other. The study did not evaluate reciprocal pathways or demonstrate a dyadic mechanism.

Interpretation of the infant neurobehavioral findings

The adjusted NBNA effect is consistent in direction with the earlier study of five-element music combined with KMC reported by Zheng [10]. That work provides a direct point of comparison because it

also considered neurobehavioral outcomes in preterm infants. Broader work on sensory stimulation and KMC provides additional context for evaluating combined developmental-care approaches [17, 19]. Nevertheless, correspondence in direction should not be equated with equivalence in clinical population, intervention exposure, assessment timing, or effect magnitude. The primary estimate applies to all 110 randomized dyads under the stated imputation model, and its close agreement with the complete-case estimate supports the stability of the observed randomized-group difference.

The domain-level findings provide additional information about the pattern of the neurobehavioral difference. Differences were observed not only in the NBNA total but also in behavioral competence, active and passive muscle tone, primitive reflexes, and general response. This pattern indicates that the observed total-score difference was not attributable to a single reported domain. However, domains contain different numbers of items and have different score ranges. Their raw mean differences should not be used to rank which neurobehavioral system benefited most. The dimension comparisons are exploratory, and the study does not establish clinically important change thresholds for either the individual domains or the total score.

A plausible explanation is that the combination of close skin-to-skin contact and a predictable auditory sequence provided a more structured sensory context during the intervention sessions. Previous work on music-related cerebral activity and sensory stimulation makes this an appropriate hypothesis for further investigation [17, 18]. It does not justify asserting that this trial demonstrated synapse formation, normalization of neural circuits, or changes in cortical development. No electrophysiological, neuroimaging, or neuroendocrine measures were collected. Similarly, proposed roles for cortisol reduction, hypothalamic–pituitary–adrenal regulation, or oxytocin cannot be tested from NBNA scores alone.

The protocol used two outcome-specific follow-up schedules, each aligned with the construct being assessed. Maternal outcomes were assessed after the 4-week intervention, linking their interpretation to completion of the nursing programme, whereas NBNA follow-up was scheduled for 40 weeks' PMA to provide a common term-equivalent developmental reference. Applying the same PMA target in both randomized groups supported comparability of the intended infant assessment stage and avoided equating intervention duration with developmental age. Actual assessment dates, PMA at assessment, and elapsed days were unavailable, so individual adherence to the target and between-group differences in actual timing could not be quantified or adjusted directly. The essentially unchanged estimate in the supportive gestational-age-at-birth model is consistent with the stability of the randomized-group comparison, while this model was not interpreted as a replacement for direct timing adjustment.

Maternal–infant attachment and the care encounter

The higher CMAI score in the intervention group is consistent with the attachment-focused randomized trial of KMC combined with music [8]. Related work has examined KMC combined with auditory stimulation in infants receiving non-invasive mechanical ventilation [22], although that clinical context should not be assumed to be identical to the clinically stable population enrolled here. The present study

adds a dimension-level description: pleasure, identification, love, and understanding all favoured the intervention at follow-up. Together, these dimensions suggest that the observed attachment difference extended across several aspects of the mother's reported relationship with her infant, rather than being confined to enjoyment of contact.

One possible interpretation is that the combined sessions offered mothers a recognizable and repeated opportunity to engage with their infants. Nurses prepared the mother for KMC, maintained a supervised environment, and guided relaxed listening and gentle touch. These elements may have made participation feel more active and coherent than an unstructured visit. Research on maternal attachment during NICU hospitalization provides context for the importance of contact and participation [23]. However, the study did not measure session-level interaction quality or demonstrate that music itself, rather than the additional guidance and structured attention, produced the attachment difference.

Attachment was measured through maternal self-report, and mothers knew which intervention they received. The CMAI results therefore reflect perceived attachment rather than an independently observed measure of attachment behavior. Expectation and the experience of extra professional support could have contributed to the reports. These considerations do not remove the value of mothers' perceptions, but they define the outcome more accurately. Future evaluations would be stronger if self-report were complemented by an independently assessed description of mother–infant interaction.

Parenting competence as a distinct maternal outcome

Parenting competence was included because confidence in caregiving and satisfaction with the parenting role are not adequately represented by an attachment measure alone. The Chinese PSOC distinguishes efficacy from satisfaction [16], allowing the care experience to be considered from both perspectives. Research on KMC and maternal parenting competence supports the relevance of this outcome to neonatal nursing [24]. In the present intervention, repeated participation, guidance on holding and breastfeeding, and opportunities to observe the infant could plausibly influence a mother's sense of capability. This is a proposed interpretation of the care process rather than a demonstrated mediator.

The distinction between efficacy and satisfaction is important when interpreting an intervention delivered during hospitalization. Guided practice may offer mothers opportunities to become familiar with handling their infant, whereas satisfaction also concerns their experience of the parenting role. These are plausible pathways for future investigation, not mechanisms demonstrated by the present comparisons. The exploratory PSOC summaries suggested higher efficacy and satisfaction in the intervention group, but the internal discordance between aggregate total and dimension scores prevents a definitive interpretation. Future studies should verify item-level scoring before examining whether changes in parenting confidence and attachment are related.

The role of the five-element framework

Within the integrated package, the TCM framework provided a culturally coherent and transparent rationale for music selection. The associations of Zhi, Shang, and Gong with the Heart, Lung, and Spleen, respectively, informed the selected repertoire [9, 20], while the related concept of unity between form and spirit provided conceptual context for bringing bodily closeness, emotional experience, and a shared sensory setting together [21]. The framework therefore made the cultural basis of the music component explicit, while not constituting a tested therapeutic or biological mechanism.

The use of the same three musical pieces across intervention dyads supported standardized delivery, although individualized syndrome differentiation was not examined. The repertoire was not compared with ordinary music, sham music, alternative modes, or another auditory condition. Consequently, the trial cannot establish that five-element music is superior to ordinary music or that the five-element classification is necessary for the observed outcomes. Work on five-element music has also addressed emotional symptoms outside neonatal care [25], but that indirect evidence cannot demonstrate reduced maternal anxiety in this population. Maternal anxiety, autonomic regulation, and neuroendocrine responses remain potential topics for future evaluation rather than mechanisms confirmed here.

Implications for neonatal nursing practice

The protocol's practical contribution lies in translating a culturally informed concept into a clearly specified, multicomponent nursing package integrated with an existing nurse-supervised KMC encounter. Its implemented procedures encompass staff responsibilities, preparation of the mother and infant, positioning, standardized scheduling, playback arrangements, monitoring, and criteria for pausing a session. These elements make the intervention a structured nursing activity in which music is accompanied by observation and support for maternal participation. Its potential value lies in organizing a shared care experience without separating auditory exposure from positioning, infant responses, or communication with the mother. The implemented protocol therefore provides a replicable delivery framework.

The findings favour continued evaluation of such structured approaches rather than unrestricted adoption of the exact protocol. Where such a multicomponent intervention is considered, it should remain subordinate to the infant's clinical condition and the existing KMC care process. The reported sound levels and equipment placement describe this study's implementation procedures and are not established by this trial as universally appropriate exposure limits. The high proportion of dyads continuing care at home supports the feasibility of extending nurse-guided KMC and the assigned package across hospital and home phases; future multicenter studies can examine longer-term implementation and formal dose–response relationships.

Strengths, limitations, and future research

Strengths include pre-recruitment generation of an individual-level 1:1 allocation sequence, sequentially numbered opaque sealed-envelope allocation concealment, separation of recruitment from envelope custody, a shared KMC comparator, explicit delivery procedures, assessment of both infant and maternal

outcomes, and one-dyad-per-family enrollment. Analytic strengths include retention of all 110 randomized dyads in the intention-to-treat models, adjustment for baseline scores, multiple imputation of incomplete outcomes, HC3 robust inference, conservative multiplicity control, explicit separation of principal and exploratory analyses, and close agreement across intention-to-treat, complete-case, and gestational-age-at-birth sensitivity estimates. The outcome-specific schedule further strengthened temporal interpretability by linking maternal outcomes to completion of the 4-week intervention and infant neurobehavior to a shared developmental-stage target, rather than treating intervention duration and developmental age as interchangeable. Together with the concordant sensitivity estimates, this supports the stability of the randomized-group comparison. The multiple-imputation analysis assumes that missing values were conditionally missing at random given the included variables; actual NBNA timing was unavailable for direct comparison or adjustment. Mothers and intervention providers were aware of assignment, and formal masking of the NBNA assessor and data analysts was not documented.

Fidelity-related strengths include participant-level monitoring across the complete 4-week programme, the same planned KMC schedule in both groups, standardized staff training, fixed playback procedures, real-time sound-level monitoring, predefined safety-pause criteria, and structured post-discharge support. More than 80% of dyads in each group completed at least 80% of the planned KMC dose, mean session duration remained within the prespecified range, actual KMC exposure was similar between groups, and all paused sessions were resumed without protocol deviations or documented contamination. These findings support stable implementation and feasibility across hospital and home phases. Because the intervention components were co-delivered, however, the fidelity data do not establish a formal dose–response relationship or isolate the contribution of any single component.

The trial was registered retrospectively, limiting prospective verification of outcome priorities, and the achieved sample did not meet the attrition-adjusted requirement implied by the specified sample-size assumptions. Follow-up was short, and adverse-event rates, maternal anxiety, and later developmental outcomes were not reported. Interpretation of parenting competence additionally depends on resolving the PSOC scoring inconsistency. Future trials should use prospective registration, retain baseline postnatal age and PMA, intervention start and completion dates, actual assessment dates and PMA, verify item-level scoring, and include an active auditory or attention comparator. Follow-up at later corrected ages would help determine whether an early neurobehavioral difference corresponds to sustained developmental or family benefit.

CONCLUSIONS

In this single-center randomized trial, baseline-adjusted intention-to-treat analyses of all 110 randomized preterm infant–mother dyads showed higher NBNA scores at follow-up scheduled for 40 weeks' PMA and higher maternal attachment scores after the 4-week intervention among dyads assigned to the standardized, implemented multicomponent five-element music-based nursing protocol plus routine care and KMC than among those assigned to routine care plus KMC. Quantitative fidelity monitoring showed

good dose completion (81.8% in both groups), comparable KMC exposure, and high coverage of home continuation. The close agreement between the imputed and complete-case estimates supports the robustness of the randomized comparison. The findings support further evaluation of the culturally informed, nurse-delivered package and apply to the package as a whole rather than establishing an independent effect of five-element music or a validated TCM-specific mechanism. PSOC findings remain exploratory.

Abbreviations

ANCOVA
Analysis of covariance
CI
Confidence interval
CMAI
Chinese Maternal Attachment Inventory
HC3
Heteroskedasticity-consistent standard error estimator type 3
KMC
Kangaroo mother care
MD
Mean difference
NBNA
Neonatal Behavioral Neurological Assessment
NICU
Neonatal intensive care unit
PMA
Postmenstrual age
PSOC
Parenting Sense of Competence Scale
RR
Risk ratio
SD
Standard deviation
TCM
Traditional Chinese medicine

Declarations

Ethics approval and consent to participate

All experiments were performed in accordance with relevant guidelines and regulations (such as the Declaration of Helsinki).The study was approved by the Institutional Clinical Research Ethics Committee of Yancheng First People's Hospital (Approval No. 2025-J-105). Written informed consent was obtained from the mothers of all participating infants before enrollment.

Consent for publication

Not applicable.

Availability of data and materials

The de-identified datasets used and/or analysed during the current study and the study protocol are available from the corresponding author on reasonable request, subject to applicable institutional and ethical requirements.

Competing interests

The authors declare that they have no competing interests.

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Authors' contributions

ZM and CM contributed equally to study conception and design, protocol development, data acquisition, data analysis and interpretation, and drafting of the manuscript. CWQ and SJ contributed to participant recruitment, intervention implementation, data collection, and data management. CWH and TXJ contributed to study conception, methodology, clinical supervision, project administration, and critical revision of the manuscript. All authors read and approved the final manuscript.

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References

1. Wang WP, Sun K, Chang LW, Pediatrics. Beijing: People's Medical Publishing House; 2020.
2. Shao XM, Ye HM, Qiu XS. Practical Neonatology. 5th ed. Beijing: People's Medical Publishing House; 2019.
3. Caporali C, Pisoni C, Gasparini L, et al. A global perspective on parental stress in the neonatal intensive care unit: a meta-analytic study. J Perinatol. 2020;40:1739–52.
4. Wang JY, Lin M, Xu DM, et al. Application of family-participatory multi-sensory support program based on enriched environment theory in preterm infants in neonatal intensive care unit. Chin J Pract Nurs. 2025;41:241–50.
5. Almadhoob A, Ohlsson A. Sound reduction management in the neonatal intensive care unit for preterm or very low birth weight infants. Cochrane Database Syst Rev. 2020;2020:CD006693.
6. Ma XL. Analysis of clinical effects of music therapy applied in preterm infants [dissertation]. Zhangjiakou: Hebei North University; 2025.
7. Lin XY, Tang X, Yang LX, et al. Research progress on music intervention in adjuvant therapy for preterm infants. Chin J Neonatol. 2025;40:761–4.
8. Vahdati M, Mohammadizadeh M, Talakoub S. Effect of kangaroo care combined with music on the mother-premature neonate attachment: a randomized controlled trial. Iran J Nurs Midwifery Res. 2017;22:403–7.
9. Cheng ZT, Jiang X, Huang JW, et al. Research progress on TCM five-tone therapy. China's Naturopathy. 2022;30:122–5.
10. Zheng QQ. Effects of five-element music therapy combined with kangaroo care on physical growth and neurodevelopment of preterm infants [dissertation]. Tangshan: North China University of Science and Technology; 2021.
11. Committee E-BP, Branch NP, Chinese Medical Doctor Association. Clinical practice guidelines for kangaroo mother care in preterm and low birth weight infants (2022). Chin J Evid Based Med. 2023;23:249–64.
12. Zhao LJ, Zhao MH, Qin A, et al. Interpretation of the group standard of kangaroo mother care method by Shanghai Nursing Association. Shanghai Nurs J. 2025;25:7–12.
13. Zhao N, Huang XY, Liu CM, et al. Interpretation of the group standard for application nursing standards of five-element music therapy. J Nurs Adm. 2025;25:253–6.
14. Bao XL. Neonatal behavioral competence and assessment methods. J Pract Diagn Ther. 2003;17:441–3.
15. Chen CJ, Sung HC, Chen YC, et al. The development and psychometric evaluation of the Chinese version of the maternal attachment inventory. J Clin Nurs. 2013;22:2687–95.
16. Yang X, Gao LL, Zhang ZX, et al. Reliability and validity of the Chinese version of the Parenting Sense of Competence Scale in postpartum women. Chin J Nurs. 2014;49:881–5.
17. Huang T, Zheng JH, Lin CY. Research progress on the effects of sensory stimulation on neurodevelopment of preterm infants. Chin J Nurs. 2023;58:1456–62.

18. Chen YJ. Effects of music therapy on electroencephalographic activity and behavioral neurodevelopment in preterm infants [dissertation]. Guangzhou: Guangzhou University of Chinese Medicine; 2017.
19. Zhang YM, Ge Y, Du RY, et al. Meta-analysis of the effects of kangaroo mother care on neurobehavioral development of preterm infants. J Women Child Health Guide. 2026;5:192–9.
20. Jiang X, Liu Y. Discussion on five-tone differentiation and five-tone therapy. Chin J Tradit Chin Med. 2024;39:3778–80.
21. Mo H, Wang T, He M et al. Exploring the pathogenesis and manifestations of form-spirit disharmony caused by five emotions in Huangdi Neijing from the perspective of spirit. Chin J Tradit Chin Med 2021;(4):1845–9.
22. Liang LQ. Application study of kangaroo mother care combined with auditory stimulation intervention in preterm infants receiving non-invasive mechanical ventilation. Chin Health Care Wellness. 2024;42:114–7.
23. Lei L, Yin HY, Tan JD, et al. Study on the current status and influencing factors of maternal-infant attachment during hospitalization of preterm infants in NICU. J Nurs Sci. 2020;35:77–80.
24. Dai L. Effects of kangaroo mother care on parenting sense of competence and parenting stress in mothers of preterm infants. Chin Clin Nurs. 2024;16:23–6.
25. Zhang JN. Clinical study on the effects of five-element music therapy on anxiety and depression in female triple syndrome [dissertation]. Beijing: Beijing University of Chinese Medicine; 2024.

Figures

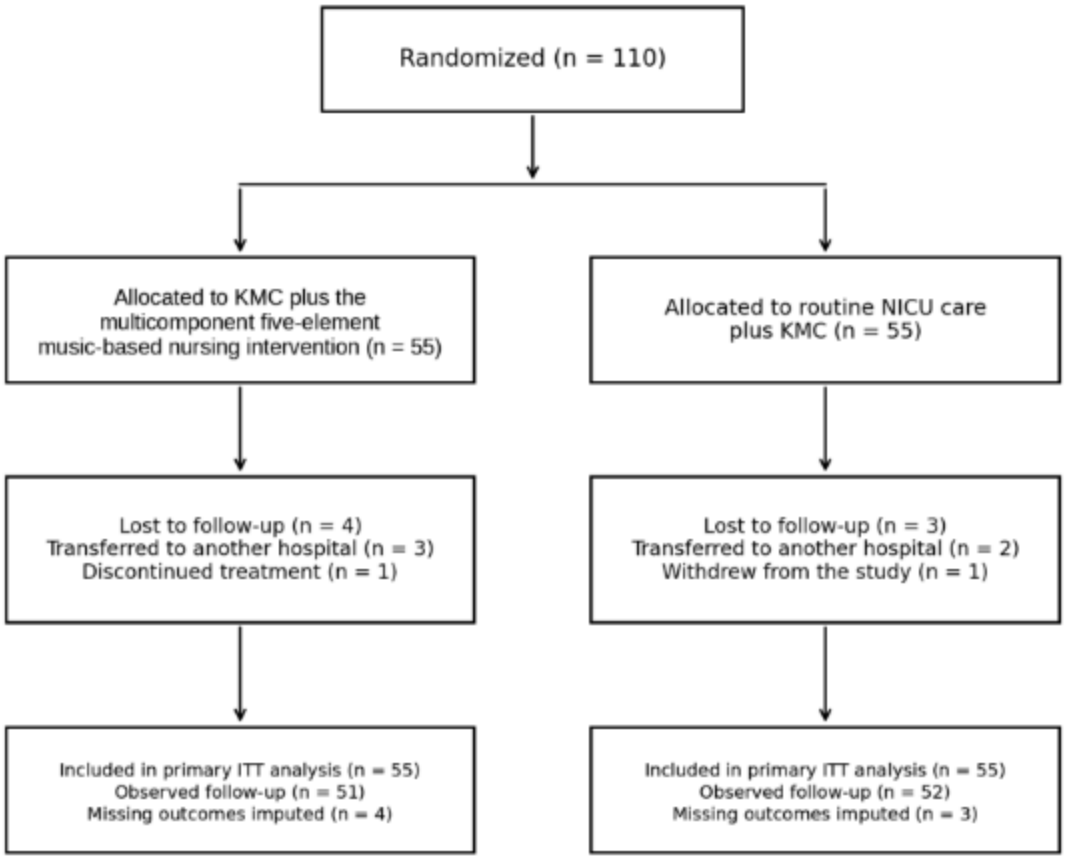


Figure 1

Participant flow and analysis populations

The number screened before randomization was not recorded; therefore, the flow diagram begins at randomization. All 110 randomized dyads were included in the primary intention-to-treat analyses; missing outcomes were multiply imputed. Observed follow-up data from 51 intervention and 52 control dyads formed the complete-case sensitivity population. Maternal outcomes were assessed after the 4-week intervention, whereas NBNA follow-up was scheduled separately for 40 weeks' PMA to provide a common developmental-stage target; the figure does not imply that these assessments occurred at the same time. Routine NICU care was provided in both groups. KMC, kangaroo mother care; NICU, neonatal intensive care unit; PMA, postmenstrual age.