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Impact of Structured Massage Therapy on Physiological Stability, Comfort, Sleep, and Stress in Late Preterm Infants: A Randomized Controlled Trial

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Abstract:

Objective: This randomized controlled trial aimed to evaluate the effects of structured massage therapy on sleep quality, stress, comfort, and physiological parameters in late preterm infants.

Methods: Forty late preterm infants (35–37 gestational weeks) were randomly allocated to a massage group (n=20) or a control group (n=20). The intervention group received a standardized 15-minute massage three times daily for three consecutive days. Data were collected using physiological monitoring, the Premature Infant Comfort Scale (PICS), the Neonatal Stress Scale (NSS), and actigraphy (SOMNOwatch™). This study was conducted in the neonatal intensive care units of Van Training and Research Hospital, University of Health Sciences, between September 2024 and September 2025, and was approved by the relevant institutional ethics committee in accordance with the Declaration of Helsinki.

Results: Massage therapy significantly improved physiological stability, demonstrated by lower heart rate and respiratory rate and higher oxygen saturation compared to controls ($P<0.05$). Post-intervention comfort scores were significantly higher in the massage group ($P=0.002$). Significant within-group improvements were observed in sleep and stress parameters ($P<0.001$); however, no statistically significant between-group differences were identified ($P>0.05$).

Conclusion: Massage therapy is an effective and clinically relevant non-pharmacological intervention for enhancing physiological stability and comfort in late preterm infants. Although improvements in sleep and stress were comparable to routine care, the significant improvement in comfort supports its integration into neonatal nursing protocols to optimize immediate clinical outcomes and neurobehavioral organization.

Clinical Trials Number: NCT07322731

Keywords: Massage Therapy, Preterm Infant, Health Care, Physiological Stability

Approximately 15 million infants are born preterm (gestational age <37 weeks) worldwide each year, a figure that continues to rise as a global public health concern [1]. Complications of preterm birth are responsible for 35% of neonatal deaths and carry significant long-term

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morbidity risks among survivors, including neurodevelopmental disorders, learning disabilities, and visual and auditory impairments [1, 2]. This vulnerable population requires prolonged monitoring in the Neonatal Intensive Care Unit (NICU) to sustain vital functions such as feeding and respiration [3].

The NICU environment constitutes an overstimulating and stressful setting for the immature nervous systems of preterm infants. These infants are continuously exposed to multiple painful and distressing stimuli, including elevated noise levels, persistent light exposure, and invasive medical procedures [4]. Such environmental factors not only destabilize vital signs — including heart rate, respiratory rate, and oxygen saturation — but may also inflict lasting damage on the autonomic nervous system [5, 6]. Furthermore, intensive care routines in the NICU significantly disrupt sleep cycles, which are critical for brain development and synaptic plasticity [7, 8]. Sleep disruption can adversely affect growth hormone secretion, thereby delaying clinical recovery and prolonging the time to hospital discharge [7].

In contemporary neonatal nursing practice, non-pharmacological approaches have come to the forefront as strategies for enhancing infant comfort, managing stress, and promoting stabilization. Alongside methods such as kangaroo care, environmental modifications, and olfactory stimulation, infant massage has attracted growing attention as a safe and cost-effective complementary intervention [9, 10]. The literature indicates that structured massage protocols augment vagal activity, thereby reducing cortisol levels and contributing to stress reduction and improved sleep quality [11, 12]. Meta-analyses and randomized controlled trials have further demonstrated that pediatric massage prolongs sleep duration [13], supports weight gain [14], and shortens the length of hospital stay [15].

Nevertheless, evidence-based studies that simultaneously examine the synergistic effects of infant massage on stress, comfort, and vital signs in preterm infants — particularly within the late preterm cohort (35–37 weeks) — remain limited. It is of paramount importance that NICU nurses integrate non-pharmacological approaches of this nature into clinical practice in accordance with the principles of atraumatic care, rather than focusing exclusively on medical management [16]. In this context, the present randomized controlled trial aimed to comprehensively evaluate the effects of massage therapy on sleep quality, comfort, stress indicators, and physiological parameters in infants born at 35–37 weeks of gestation. The following hypotheses were tested: massage therapy in preterm infants would (1) support physiological stabilization, (2) reduce stress and enhance comfort, and (3) improve sleep architecture (duration and efficiency).

H1: Post-intervention heart rate, respiratory rate, and oxygen saturation (SpO_2) values in massaged preterm infants will be statistically significantly more stable than those in the control group.

H2: Massage therapy will statistically significantly improve comfort levels (Premature Infant Comfort Scale [PICS] scores) in preterm infants compared to the control group.

H3: Stress scores (Neonatal Stress Scale [NSS]) in massaged preterm infants will be statistically significantly lower than those in the control group.

H4: Massage therapy will significantly increase sleep efficiency and total sleep duration while reducing the number of awakenings and wake after sleep onset (WASO) duration compared to the control group.

METHODS

Study Design and Aim

This study was conducted as a randomized controlled experimental trial to evaluate the effects of massage therapy on sleep quality, comfort, stress indicators, and physiological parameters in late preterm infants (35–37 gestational weeks) admitted to the NICU. The study was designed and reported in accordance with the CONSORT (Consolidated Standards of Reporting Trials) guidelines (Figure 1).

Sample and Power Analysis

The study population consisted of preterm infants admitted to the Level I and Level II NICU services of Van Training and Research Hospital, University of Health Sciences, between September 2024 and September 2025. Sample size was calculated using G*Power (v3.1.9.2), based on the reference study by Düken and Yayan [17] conducted with preterm infants. Using an effect size of d=1.192, α=0.05, and 95%

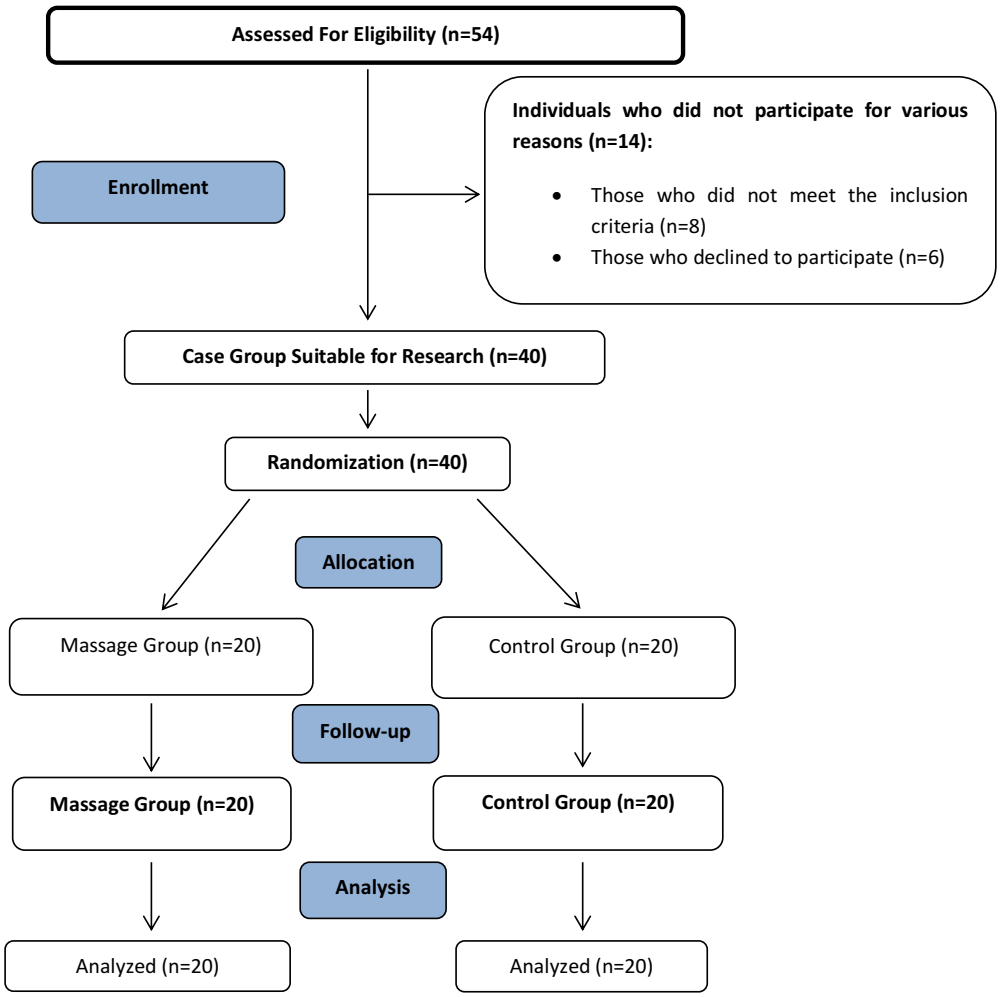


FIGURE 1. CONSORT flow diagram [36].

power (1-β), the analysis determined that a minimum of 20 infants per group were required. The study was completed with a total of 40 infants (20 in the massage group, 20 in the control group). Of the 54 infants assessed for eligibility, 14 were excluded (8 did not meet the inclusion criteria and 6 declined participation), resulting in 40 infants being randomized into the study groups (n=20 massage, n=20 control).

Randomization and Blinding

Simple randomization — a method equivalent to complete randomization in its balancing properties — was employed for group allocation. For each eligible infant, the researcher drew a ball from a sealed black pouch using a closed-selection method. White balls designated the massage group and red balls designated the control group, thereby minimizing selection bias and ensuring homogeneous distribution between groups. No dropouts occurred during the study, and all randomized participants were included in the analyses.

Given the nature of the intervention, blinding of the interventionist was not feasible. However, assessor blinding was implemented to reduce measurement bias. The researcher responsible for statistical analyses received data coded as "Group A" and "Group B," with group identities remaining concealed until all analyses were complete.

Inclusion and Exclusion Criteria

Inclusion Criteria

Parental written informed consent; gestational age of 35–37 weeks (up to 36 weeks + 6 days); birth weight >1,500 g; Apgar score ≥7; absence of known congenital or neurological disorders.

Exclusion Criteria

Requirement for mechanical ventilatory support; history of major surgery; active infection; or any dermatological condition compromising skin integrity that would preclude massage application.

Data Collection Instruments

Mother and Infant Demographic Information Form

A structured form capturing demographic, obstetric, and neonatal characteristics (gestational age, birth weight, sex, etc.).

Vital Signs Recording Form

This form was developed by the researcher based on the relevant literature to assess the physiological status of preterm infants [18,19]. It includes key vital parameters: heart rate, respiratory rate, body temperature, and oxygen saturation. Measurements were obtained using standard clinical monitoring equipment and recorded at predetermined time points.

Premature Infant Comfort Scale (PICS)

The PICS is an adapted form of the COMFORT scale developed to assess comfort levels in preterm infants [20, 21]. Its Turkish validity and reliability were established by Alemdar and Tüfekçi [22]. The scale comprises 7 parameters — alertness, agitation, respiration/crying, body movement, muscle tone, facial expression, and heart rate — each scored from 1 to 5. Total scores range from 7 to 35, with higher scores indicating lower comfort. The cutoff score is ≥17.

Neonatal Stress Scale (NSS)

The NSS was developed to evaluate stress levels in preterm infants through behavioral and physiological indicators [23]. The scale consists of eight subscales: facial expression, skin color, respiration, activity, comfort, muscle tone, extremities, and posture. Each item is scored on a 3-point scale ranging from 0 to 2, where higher scores indicate greater stress-related responses. The total score ranges from 0 to 16, with higher total scores reflecting higher levels of neonatal stress. During the assessment, infants are observed for stress-related behavioral and physiological signs, and scores are assigned according to the criteria defined for each subscale. The NSS has been used as a practical tool for evaluating stress responses in preterm infants in clinical settings.

Actigraphy (SOMNOwatch™)

An actigraphy device was used to assess the sleep process. Actigraphy is a non-invasive method that continuously records limb movement and quantitatively measures activity levels at defined time intervals. Data obtained from the device were analyzed in 1-minute epochs using the manufacturer-provided analysis software, with sleep and wakefulness states automatically classified. Sleep parameters were calculated as follows: sleep efficiency, total sleep duration, number of awakenings, and wake after sleep onset (WASO). Actigraphy has been reported to be a widely used and validated method for assessing sleep-wake patterns in infant and young child populations, with its validity supported in comparative studies with polysomnography [24].

Procedure and Data Collection

Prior to study commencement, parents were informed about the purpose of the study and written informed consent was obtained. Participants were assigned to the intervention and control groups via randomization. Data were collected at baseline and at the conclusion of the three-day intervention period using identical protocols.

Intervention Group: Massage Protocol

Massage was administered by a certified researcher with specialized training in infant massage over three consecutive days, three times daily (08:00–10:00, 14:00–16:00, and 19:00–21:00), either one hour before or one hour after feeding.

Each session lasted 15 minutes and was structured to incorporate both tactile (effleurage, petrissage) and kinesthetic (passive joint movements) stimulation (5 min tactile + 5 min kinesthetic + 5 min tactile). Infants were positioned in the supine and prone positions sequentially during the massage.

Prior to each session, hand hygiene was performed, hands were warmed, and the incubator temperature was maintained between 30°C and 36°C. Environmental stimuli (light and noise) were minimized throughout the session to preserve infant comfort.

Infants in the intervention group underwent 24-hour actigraphy recordings before the intervention and after the third day, with sleep duration, sleep efficiency, number of awakenings, and WASO parameters assessed. Vital signs were recorded and scales administered at the same time points.

Control Group: Standard Care

Infants in the control group received the standard nursing care protocol of the NICU. This care encompassed feeding, positioning, vital sign monitoring, hygiene maintenance, and required medical treatments; no additional tactile stimulation or massage was provided during the study period. Parallel to the intervention group, 24-hour actigraphy recordings were conducted for the control group at baseline and at the end of the third day; vital signs were recorded and scale assessments were performed at the same time points.

Ethical Considerations

Before initiation of the study, approval was obtained from the Non-Interventional Clinical Research Ethics Committee of Yüzüncü Yıl University (Approval No: 2024/10-14, Date: 20.09.2024) and institutional authorization was secured from the hospital administration. Parents of the infants were provided with a written informed consent form and both written and verbal consent were obtained. The study was conducted in adherence to the principles of the Declaration of Helsinki throughout its entire duration.

Statistical Analysis

Data were analyzed using SPSS v27.0. Descriptive statistics included counts, percentages, means, and standard deviations. Normality of the data distribution was assessed via Skewness-Kurtosis values and the Shapiro-Wilk test. Between-group homogeneity was evaluated using the Chi-square and Fisher's exact tests; within-group changes were examined with the Paired Samples t-test, and between-group differences with the Independent Samples t-test. A significance level of $P<0.05$ was applied to all analyses.

RESULTS

The baseline characteristics of the enrolled mothers and neonates are presented in Table 1. Statistical analyses revealed no significant differences between

TABLE 1. Baseline Characteristics of Mothers and Neonates

		Study group			
		Massage	Control	Test statistics	P-value
Maternal age (years)		30±6.87	28.15±6.15	0.898	0.375*
History of preterm birth (yes)	Yes	3 (15)	4 (20)	0.173	0.677**
	No	17 (85)	16 (80)		
Gestational age (weeks)	35.	9 (45)	10 (50)	0.497	0.780**
	36.	7 (35)	5 (25)		
	37.	4 (20)	5 (25)		
Birth weight (g)		2390.25±449.10	2390.25±449.10	1.171	0.249*
Infant sex	Girl	7 (35)	12 (60)	2.506	0.113**
	Boy	13 (65)	8 (40)		
Mode of delivery	Normal	3 (15)	3 (15)	0.000	1.000**
	C/S	17 (85)	17 (85)		
Feeding method	Breastfeeding	14 (70)	8 (40)	3.636	0.057**
	OG	6 (30)	12 (60)		

Data are shown as mean±standard deviation or n (%) where appropriate. C/S, caesarean section; OG, Orogastric tube.
*Independent Samples t-test, **Chi-square test.

the massage group (n=20) and the control group (n=20) with respect to maternal age, history of preterm birth, gestational age, birth weight, infant sex, mode of delivery, or feeding method (P>0.05). These findings confirm that the groups were homogeneously distributed across key clinical and demographic variables, thereby establishing an appropriate baseline for a randomized controlled trial.

No statistically significant difference in heart rate was detected between the massage and control groups at baseline (P=0.480). Following the intervention, a highly significant reduction in heart rate was observed in the massage group (from 143.20±10.55 to 128.15±7.91 bpm; P<0.001), whereas the reduction in the control group was comparatively modest (P=0.037). Post-intervention between-group comparisons demonstrated that the massage group had significantly lower heart rate values than the control group (t=3.463; P=0.001), with a large effect size (Cohen's d >0.8) (Table 2).

At baseline, SpO_2 values were significantly higher in the control group than in the massage group (P=0.033). Following the intervention, a highly significant increase in oxygen saturation was recorded in the massage group (from 94.60±1.76% to 96.95±0.83%; P<0.001), whereas no significant change was observed in the control group (P=0.154). In the post-intervention period, SpO_2 levels in the massage group were statistically significantly higher than those in the control group (P<0.001, Table 2).

A significant reduction in respiratory rate was observed in the massage group post-intervention (P<0.001), whereas no significant change was detected in the control group (P=0.428). Between-group comparisons confirmed that the post-intervention respiratory rate was significantly lower in the massage group than in the control group (P=0.001). No statistically significant differences were found in body temperature, either between groups (P=0.567) or within groups over time (P>0.05) (Table 2).

Comparative analysis of PICS total scores before and after the intervention is presented in Table 3. At baseline, no significant difference in comfort scores was found between the massage and control groups

TABLE 2. Comparison of Physiological Parameters by Group

	Massage	Control	Test statistic	P-value*
Pre-procedure peak heart rate	143.20±10.55	140.80±10.75	0.713	0.480
Post-procedure peak heart rate	128.15±7.91	137.65±9.38	3.463	**0.001**
Test statistic	8.965	2.244		
P-value**	**<0.001**	**0.037**		
Pre-procedure oxygen saturation	94.60±1.76	95.85±1.81	2.212	**0.033**
Post-procedure oxygen saturation	96.95±0.83	95.35±1.63	3.914	**<0.001**
Test statistic	7.378	1.486		
P-value**	**<0.001**	0.154		
Pre-procedure respiratory rate	53.90±1.21	53.00±1.38	2.196	**0.034**
Post-procedure respiratory rate	52.00±0.65	53.20±1.36	3.559	**0.001**
Test statistic	7.025	0.809		
P-value**	**<0.001**	0.428		
Pre-procedure fever	36.89±0.13	36.95±0.08	1.696	0.098
Post-procedure temperature	36.87±0.15	36.90±0.13	0.578	0.567
Test statistic	0.476	1.278		
P-value**	0.640	0.217		

Data are shown as mean±standard deviation.

*Independent Samples t-Test; **Paired Samples t-Test. Statistically significant P-values are shown in bold.

TABLE 3. Comparison of the Premature Infant Comfort Scale by Group

	Study status			
	Massage	**Control**	**Test statistics**	**P-value***
Pre-procedure comfort total score	14.75±1.52	14.4±1.47	0.742	0.460
Post-procedure comfort total score	10.65±2.52	13.15±2.28	3.292	**0.002**
Test statistic	9.853	2.544		
P-value**	**<0.001**	**0.020**		

Data are shown as mean±standard deviation.

*Independent Samples t-test; **Paired Samples t-test. Statistically significant P-values are shown in bold.

(14.75±1.5 and 14.4±1.47, respectively, P=0.460), confirming group homogeneity at study onset. Following the intervention, comfort scores in the massage group were significantly lower (indicating higher comfort) than in the control group (10.65±2.52 vs. 13.15±2.28; t=3.292; P=0.002). A highly significant within-group reduction (improvement) in comfort scores was recorded in the massage group post-intervention (P<0.001). Although the control group also demonstrated a statistically significant reduction in scores over time (P=0.020), the clinical depth and statistical power of this improvement were considerably less pronounced than in the massage group.

Neonatal Stress Scale scores were analyzed both between and within groups (Table 4). At baseline, no significant difference was found between the massage group (4.15±2.01) and the control group (4.35±2.08) (P=0.759), indicating comparable stress levels prior to the intervention period. Following the study period, the mean NSS score decreased to 2.00±1.62 in the massage group and to 2.95±2.04 in the control group. Although the massage group demonstrated lower post-procedure stress scores, the between-group difference was not statistically significant (t=1.631, P=0.111). Within-group analyses showed a significant reduction in NSS scores from pre-procedure to post-procedure measurements in both groups (massage group: P<0.001; control group: P=0.005).

Findings pertaining to sleep efficiency, total sleep duration, number of awakenings, and WASO are presented in Table 5. Within-group analyses revealed statistically significant improvements in all sleep parameters post-intervention relative to baseline in both the massage and control groups (P<0.001 for most parameters). Sleep efficiency in the massage group increased from 83.25% to 88.5%, while a comparable improvement was observed in the control group (from 84.6% to 87.9%).

Between-group comparisons in the post-intervention period revealed no statistically significant differences in sleep efficiency (P=0.776), sleep duration (P=0.308), number of awakenings (P=0.656), or WASO (P=0.585). These findings indicate that both interventions produced positive effects on sleep parameters; however, massage did not demonstrate superior efficacy compared to the control condition.

TABLE 4. Comparison of Neonatal Stress Scale Scores by Group

	Study group			
	Massage	**Control**	**Test statistics**	**P-value***
Pre-procedure NSS total	4.15±2.01	4.35±2.08	0.309	0.759
Post-procedure NSS total	2.00±1.62	2.95±2.04	1.631	0.111
Test statistic	4.454	3.200		
P-value**	**0.001**	**0.005**		

Data are shown as mean±standard deviation. NSS, neonatal stress scale.

*Independent Samples t-test; **Paired Samples t-test. Statistically significant P-values are shown in bold.

TABLE 5. Comparison of Sleep Parameters in Infants by Group

	Study group			
	Massage	**Control**	**Test statistics**	**P-value***
Pre-procedure sleep efficiency	83.25±10.42	84.6±9.07	0.437	0.665
Post-procedure sleep efficiency	88.5±7.02	87.9±6.17	0.287	0.776
Test statistic	4.794	3.334		
P-value**	**<0.001**	**0.003**		
Pre-procedure sleep duration	837.8±179.87	856.85±203.49	0.314	0.755
Post-procedure sleep duration	968.8±145.94	918.35±162.2	1.034	0.308
Test statistic	6.550	2.707		
P-value**	**<0.001**	**0.014**		
Number of awakenings before surgery	97.75±58.45	95.2±66.18	0.129	0.898
Post-procedure awakening count	72.8±48.69	80.7±61.8	0.449	0.656
Test statistic	6.814	5.139		
P-value**	**<0.001**	**<0.001**		
Pre-procedure WASO value	121.45±71.96	118.8±83.03	0.108	0.915
Post-procedure WASO value	84.95±58.82	96.6±74.1	0.551	0.585
Test statistic	7.541	5.910		
P-value**	**<0.001**	**<0.001**		

Data are shown as mean±standard deviation. WASO, wake after sleep onset.

*Independent Samples t-test; **Paired Samples t-test. Statistically significant P-values are shown in bold.

DISCUSSION

This randomized controlled trial comprehensively assessed the effects of structured massage therapy on physiological stabilization, comfort, stress, and sleep parameters in late preterm infants (35–37 gestational weeks). The findings demonstrate that massage therapy produced statistically and clinically significant improvements in heart rate, oxygen saturation, and respiratory rate. Comfort levels were significantly higher in the massage group than in the control group; within-group improvements were observed in stress and sleep parameters in both groups, although no statistically significant between-group differences were identified. This pattern is largely consistent with the existing literature and yields important insights into the distinctive clinical characteristics of the late preterm population.

In the present study, massaged infants demonstrated a significant reduction in heart rate from 143.20±10.55 to 128.15±7.91 bpm (P<0.001), a significant increase in oxygen saturation from 94.60% to 96.95% (P<0.001), and a marked decrease in respiratory rate (P<0.001). Changes in these parameters were considerably more limited in the control group, with post-intervention between-group differences reaching statistical significance (P=0.001 for heart rate; P<0.001 for SpO_2). These findings directly corroborate those of the randomized controlled trial by Düken *et al*. [19], which applied the same three-day protocol and reported significant reductions in heart rate and respiratory rate, along with significant increases in oxygen saturation, in the massage group compared to controls. Concurrently, our physiological findings align with the randomized controlled trial by Alinejad-Naeini *et al*. [25], which demonstrated that the 'M' Technique® significantly improved physiological stabilization in preterm neonates — an effect the authors attributed to enhanced vagal activation within the polyvagal theory framework. A meta-analysis by Zhang *et al*. [26] encompassing 15 randomized controlled trials

confirmed that massage therapy significantly increased oxygen saturation (SMD=2.00; 95% CI: 1.17–2.83; P<0.0001). Furthermore, Weerakul *et al*. [27] highlighted that moderate-pressure massage suppresses sympathetic nervous system activity, activates vagal pathways, and thereby reduces heart rate while augmenting gastrointestinal motility in preterm infants.

The primary mechanism underlying these effects of massage on physiological stabilization is explained by parasympathetic system activation triggered by stimulation of cutaneous mechanoreceptors. Tactile stimulation activates the posterior insular cortex via C-tactile afferents, suppressing autonomic arousal and producing reductions in heart rate and respiratory rate [19]. The fact that our intervention protocol encompassed both tactile (effleurage, petrissage) and kinesthetic (passive joint movement) components supports the synergistic effect of this multimodal stimulation. In this regard, the systematic review and meta-analysis by Mollà-Casanova *et al*. [28] demonstrated that massage therapy combined with passive mobilizations significantly improved weight gain and length of hospitalization, further substantiating the clinical value of the kinesthetic component in our protocol. The stable body temperatures observed in both groups indicate that massage did not exert any adverse effect on thermoregulation, which is consistent with the safety profiles reported by Alinejad-Naeini *et al*. [25] and Zhang *et al*. [26].

The significant reduction in PICS total scores in the massage group (from 14.75±1.52 to 10.65±2.52; P<0.001) and the statistically significant post-intervention between-group difference (P=0.002) supported Hypothesis H2 and demonstrated that massage exerts a clinically important effect on comfort in late preterm infants. This finding is consistent with the randomized controlled trial by Zhang and Wang [29], which showed that mother-administered massage significantly improved growth parameters in infants born at 32–34 weeks and in which mothers also qualitatively reported that their infants appeared relaxed and displayed a tendency toward sleep during the massage. The concurrent occurrence of comfort improvement alongside physiological stabilization is clinically significant, as the heart rate and respiration/crying subscales of the PICS are directly related to the physiological parameters that improved in parallel. Massage is known to trigger the release of oxytocin and endorphins through tactile stimulation; these neuropeptides attenuate pain perception and suppress autonomic arousal, thereby enhancing comfort [27]. The statistically significant improvement in comfort observed over time in the control group as well (P=0.020) suggests that routine NICU care provides a baseline level of comfort, although the improvement in the massage group was markedly superior in both effect size and clinical depth. This finding is further corroborated by the comprehensive umbrella review by Chen *et al*. [30] evaluating the effects of pediatric massage in infants and children under 5 years of age, which demonstrated significant effects of massage on pain management and oxygen saturation with high-quality evidence.

NSS assessments revealed significant reductions in stress scores post-intervention relative to baseline in both groups (massage group: P<0.001; control group: P=0.005); however, the between-group difference did not reach statistical significance post-intervention (P=0.111). While this finding does not support Hypothesis H3, the substantially greater statistical power of the stress reduction in the massage group (P<0.001) compared to the control group (P=0.005) suggests that a between-group difference may reach significance in a study with a larger sample size. This pattern is consistent with the discussion presented in the PREMM protocol study by Lai *et al*. [31], which highlighted the prevailing environmental stress burden in preterm infants and the spontaneous improvement afforded by routine NICU care.

Biochemical evidence regarding the effect of massage on stress further supports these findings. In the first systematic review and meta-analysis to evaluate the effect of massage on cortisol levels in infants, Jabraeili *et al*. [32] reported mixed cortisol responses, yet noted that some studies demonstrated significant reductions in cortisol levels following massage. This meta-analysis highlighted methodological inconsistencies with respect to biochemical markers and underscored the need for studies incorporating standardized cortisol measurement. McCarty *et al*. [33] measured salivary cortisol levels in extremely preterm infants and their mothers before and after massage, reporting a significant cortisol reduction of 20.1% in responsive

mothers — a proportion that exceeded the 15.5% threshold used to define a clinically meaningful stress response. The authors noted that parent-administered massage may reduce the physiological stress biomarker in mothers in the short term, highlighting important implications for its integration into NICU clinical practice. A key methodological limitation of the present study is that stress assessment relied solely on observational NSS scores, without the inclusion of biochemical biomarkers such as cortisol or salivary alpha-amylase, which constrains more objective interpretation of the stress response. Future studies incorporating such biomarkers alongside the NSS may more definitively elucidate the specific effects of massage on stress mechanisms.

Significant improvements were recorded in all sleep parameters — sleep efficiency, total sleep duration, number of awakenings, and WASO — relative to baseline in both groups ($P<0.001$); however, post-intervention between-group comparisons did not yield statistical significance ($P>0.05$). This finding does not support Hypothesis H4; nonetheless, the increase in total sleep duration in the massage group from 837.8±179.87 to 968.8±145.94 minutes and the improvement in sleep efficiency from 83.25% to 88.5% should be regarded as clinically meaningful changes. The study by Düken and Yayan [17] provides clear context for these findings: in preterm infants aged 28–37 weeks, sleep duration in the massage group increased by approximately five hours compared to the pre-intervention period, whereas sleep duration decreased in the control group ($P<0.001$). In that study, although the between-group difference in sleep duration was significant, no significant differences were found in sleep efficiency, number of awakenings, or WASO, suggesting that individual sleep parameters are sensitive to distinct NICU environmental factors and intervention duration.

Multiple explanations exist for the failure to achieve between-group significance for sleep in the present study. First, the more mature nervous systems of late preterm infants (35–37 weeks) facilitate spontaneous sleep improvement in response to standard NICU care, which accounts for the strong within-group improvements also observed in the control group. Additionally, the three-day intervention period may have been insufficient to achieve between-group statistical significance for sleep parameters; notably, Lai *et al*. [31] demonstrated that long-term massage sustained until term-equivalent age positively influenced cerebral electrical activity in very preterm infants. Moreover, the sample size of n=20 per group in the present study may not have provided adequate statistical power for sleep variables, despite the objective measurement afforded by SOMNOwatch™ actigraphy. The partial validation of actigraphy against polysomnography in the preterm infant population must also be considered when interpreting results [24]. Recent literature supports these findings: Belpınar *et al*. [34] evaluated the effects of massage and foot reflexology on sleep parameters in preterm infants aged 30–37 weeks using actigraphy and demonstrated that sleep efficiency and total sleep duration improved significantly in the massage group compared to the control group. Similarly, the meta-analysis by Bilgiç *et al*. [35] examining the effects of non-pharmacological interventions on sleep parameters in preterm infants emphasized that intervention duration and sample size play critical roles in determining between-group significance.

Strengths and Limitations

This study offers several methodological strengths that support the validity and clinical relevance of its findings. The randomized controlled trial design, implemented in strict accordance with CONSORT guidelines, minimized selection bias and ensured homogeneous group distribution across all key demographic and clinical variables. A distinguishing feature of this study is its simultaneous assessment of four distinct outcome domains — physiological stability, comfort, stress, and sleep — within a single protocol, enabling a comprehensive evaluation of massage therapy's multidimensional effects, an approach rarely adopted in the existing literature. The use of SOMNOwatch™ actigraphy for sleep measurement provided continuous, objective, and quantitative data across 24-hour periods, substantially reducing observer bias compared to conventional observational methods. Intervention fidelity was ensured through a standardized massage protocol administered by a certified researcher, enhancing reproducibility and translational applicability. Importantly, by specifically targeting the late preterm

cohort (35–37 gestational weeks) — a clinically underrepresented yet high-risk population in neonatal massage research — this study contributes population-specific evidence to the field. Finally, assessor blinding during statistical analysis mitigated measurement bias, preserving analytical integrity within the inherent constraints of this intervention type.

The single-center design limits the generalizability of findings to different clinical and cultural settings. Additionally, the relatively small sample size further limits the statistical power and generalizability of the findings. Blinding of the interventionist was not achievable given the nature of the intervention. The restriction of stress assessment to a behavioral observation scale — without biomarkers such as cortisol, which could not be utilized due to limitations in hospital infrastructure — represents an additional limitation. Furthermore, the sensitivity of biomarker levels in preterm infants to physiological and environmental factors may complicate standardization of measurements. These findings are generalizable to clinically stable, late preterm infants at 35–37 gestational weeks cared for in settings comparable to the study institution. Generalizability is limited for infants at lower gestational ages, clinically unstable cases, and centers employing different care protocols.

CONCLUSION

The findings of this study provide clinically relevant evidence for NICU protocols that prioritize physiological stabilization and comfort optimization. Structured massage therapy resulted in significant improvements in key physiological parameters and infant comfort, supporting its role as an effective, evidence-based, non-pharmacological intervention in late preterm infants. While improvements in sleep and stress parameters were observed within groups, the absence of significant between-group differences suggests that these outcomes may be influenced by routine NICU care and the relatively short intervention duration. Therefore, the primary clinical value of massage therapy in this population appears to lie in its capacity to enhance physiological stability and comfort rather than to produce additional benefits in sleep and stress beyond standard care.

Integration of massage therapy into routine neonatal nursing care is important for improving physiological parameters. The inclusion of parents in the massage process may not only contribute to improvements in the infant's clinical trajectory but may also strengthen mother-infant bonding and parental self-efficacy. In future studies, larger sample sizes, longer intervention durations (at least 7–14 days), multicenter designs, and the addition of cortisol measurements and EEG-based sleep assessments could more definitively elucidate the mechanisms of action and stress-sleep outcomes of massage therapy. Gestational age-specific designs comparing late preterm infants with those born at earlier gestational ages are also expected to contribute to identifying the developmental threshold below which the biological and clinical effects of the intervention become most pronounced.

Ethics Approval and Consent to Participate

This study was approved by the Van Yüzüncü Yıl University Non-interventional Clinical Research Ethics Committee (Decision No: 2024/10-4; date: 20.09.2024). All procedures were conducted in accordance with the ethical standards of the institutional and national research committees and with the 1964 Helsinki Declaration and its later amendments. Written informed consent was obtained from all participants' parents for the publication of this study.

Clinical Trial Registration

This randomized controlled trial was registered in clinicaltrials.gov, and the registration number NCT07322731 was received.

Data Availability Statement

The data that support the findings of this study are available from the corresponding author upon reasonable request.

Authors' Contribution

Study Conception: RA, YG, MED; Study Design: RA, YG, MED; Supervision: RA; Funding: YYU BAP (Project No: 11429); Materials: RA, YG, MED; Data Collection and/or Processing: RA, YG; Statistical Analysis and/or Data Interpretation: RA, MED; Literature Review: RA, YG, MED; Manuscript Preparation: RA, YG, MED; Critical Review: RA.

Conflict of Interest Statement

All authors have completed the ICMJE uniform disclosure form and declare that no potential conflicts of interest, financial or otherwise, exist regarding the research, authorship, or publication of this manuscript.

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Generative Artificial Intelligence Statement

The authors used DeepL for initial translation and ChatGPT for language editing and proofreading to improve the clarity and readability of the manuscript. These generative AI tools were used solely for linguistic enhancement. All scientific content, including study design, data analysis, interpretation, and conclusions, was developed entirely by the authors. The authors take full responsibility for the integrity and accuracy of the work.

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