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# The effects of maternally administered neonate massage on feeding tolerance and physiological indicators in neonates admitted to the neonatal intensive care unit: A Randomized Controlled Trial

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## Abstract

**Background:** Feeding intolerance, defined as the inability to maintain enteral feeding, is frequently observed in neonates with immature gastrointestinal tracts in neonatal intensive care units (NICUs). This study aimed to examine the effects of maternally administered infant massage on feeding tolerance and physiological indicators in NICU-admitted neonates.

**Methods:** This single-blind, parallel-group randomized controlled trial was conducted among neonates admitted to the NICU of a university-affiliated tertiary neonatal and pediatric center in Isfahan, Iran. Using simple random allocation via card shuffling, 62 neonates meeting the inclusion criteria were divided into two groups: intervention and control. The intervention group received maternally administered massage for five days, three times daily for 20 minutes after feeding with breast or formula milk. The control group received routine care. Assessed outcomes were gastric residual volume, abdominal circumference, frequency of vomiting and stools, and physiological indicators checklist, which measured respiratory rate, heart rate, and oxygen saturation ($SaO_2$) levels two hours after each feeding every day for five days. Data were analyzed using the Mann–Whitney U test, Wilcoxon signed-rank test, and ANCOVA in SPSS v.26, with a significance level of $p < 0.05$.

**Results:** Neonates in the intervention group showed a greater reduction in gastric residual volume % ($r^2$ = 0.82, 95% CI [0.75, 0.88]), abdominal circumference (r = 0.82, 95% CI [0.68, 0.97]), and vomiting frequency (r = 0.83, 95% CI [0.69, 0.97]) compared to the control group. Additionally, stool frequency increased significantly in the intervention group (r = 0.85, 95% CI [0.73, 0.99]). In this group, $SaO_2$ levels increased (r = 0.82, 95% CI [0.68, 0.97]), while heart rate (r = 0.83, 95% CI [0.69, 0.97]) and respiratory rate (r = 0.85, 95% CI [0.73, 0.99]) decreased significantly, indicating improved physiological stability.

**Conclusion**: Maternally administered infant massage appeared effective in improving feeding tolerance and physiological indicators in this study. Healthcare teams may also consider training mothers to provide neonate massage as a complementary intervention to support feeding tolerance in newborns admitted to the NICU.

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## Highlights

**What is current knowledge?**

Feeding intolerance is common in preterm neonates due to gut immaturity. Massage therapy is known to potentially improve gastrointestinal function and physiological stability, but most evidence relies on therapist-provided massage, not maternal involvement.

**What is new here?**

This study demonstrates that maternally administered massage significantly improves feeding tolerance (reduced vomiting, gastric residue, and abdominal distention; increased stools) and stabilizes physiological indicators (improved oxygen saturation, reduced HR and RR). It highlights the feasibility and benefits of integrating mothers into NICU care as active participants in their neonate's well-being.

## Introduction

Over the past decade, global preterm birth rates have remained unchanged, with approximately 13.4 million preterm infants born in 2020 (9.9% of all births). Complications from preterm birth are the leading cause of under-five mortality, contributing to around one million neonatal deaths annually. The majority of these deaths occur in low- and middle-income countries (1). The prevalence of this issue is exemplified by countries such as Iran, which has an estimated preterm or low birth weight rate of 9.2% (2).

The major causes of death in preterm infants are low birth weight, infections, and birth asphyxia. One of the most common challenges facing such infants is weakness in breastfeeding skills, which are vital for their physiological stability and weight gain for discharge (3). As the coordination of swallowing and sucking abilities develops around 32-34 weeks after birth, feeding difficulties arise due to inadequate gastrointestinal tract development and gastric (gavage) residual volume (GRV). If such problems threatening preterm neonates are not addressed, multiple growth disorders are likely to develop later (4).

One of the immature gastrointestinal tract disruptions commonly observed in neonatal intensive care units (NICUs) is feeding intolerance, or the inability to maintain enteral feedings, characterized by symptoms such as high GRV, abdominal distention or increased abdominal circumference, and vomiting. Most immediate interventions to address research-based feeding intolerance still focus largely on the prevention and monitoring of symptoms that develop under this condition (5). With regard to the relationship between feeding intolerance and necrotizing enterocolitis, as an inadequate gastrointestinal emergency and one of the leading causes of neonate mortality, healthcare teams in NICUs dedicate much attention to all feeding intolerance symptoms. In this regard, nurses, as key members of healthcare teams, know how to manage nutritional disorders in such cases (6). Considering the limited abilities of neonates in terms of food intake and absorption to obtain enough calories for proper growth, an integral part of nursing activities in NICUs is the use and management of gastric tubes (7).

Neonates admitted to NICUs are typically exposed to many stressful stimuli, such as noise and light, and even some invasive procedures that can alter their sensory and cognitive functions (8,9). In view of this, the majority of researchers and specialists have turned to non-invasive interventions over the last few decades (10). For example, NICUs worldwide now utilize care strategies based on the stimulation of the neonate's central nervous system and senses, including touch, smell, and vision, along with the development of kinetic movements (11).

Research on neonate massage to improve feeding intolerance commenced for the first time with Tekginduz et al. (12). Touch has been described as one of the useful sensory stimulations in such situations. As silent speech or non-verbal communication, it generates physiological responses through touch receptors in the skin and their analysis in the brain (8). If touch is practiced in a gentle, soothing manner, therapeutic effects and satisfaction are achieved. Hence, massage has been suggested as complementary and alternative medicine (6). Supporting this, a recent systematic review and meta-analysis of randomized controlled trials found that neonate massage significantly reduces gastric residual volume (GRV) and vomiting frequency in preterm neonates, indicating its effectiveness in enhancing feeding tolerance (13).

Notably, touch increases the rates of digestion and absorption in neonates (14). In this way, the parasympathetic nerves of the intestine are stimulated, food intake is enhanced, and insulin secretion occurs. In addition, massage is one of the effective strategies to establish warm and intimate physical-emotional connections between mothers and neonates in NICUs (15).

As evidenced in Field's model (16), touching neonates contributes to expanding chest circumference, physical growth, bowel movements, and reducing GRV (17). Some studies have similarly reported that massage has no negative impacts on neonates. Ghasemi et al. (2019) also found that massage was not stressful (18), as it could improve the sleep-wake cycle and mother-neonate interactions (19). Previous research has further shown that hypoxia may occur during medical and nursing procedures in neonates, so touch is sometimes avoided due to fear of physiological distress (i.e., hypoxia and heart rate (HR) changes) caused by excessive stimulation and insufficient studies on touch safety (20).

Preterm neonates are often deprived of the skin stimulation that occurs during intrauterine growth. After birth, these neonates lack constant contact with their parents because of hospitalization in NICUs, which affects their psychological and biological development. Greater knowledge of these factors has encouraged NICUs to make the best use of interventional massage procedures and protocols to support central nervous system and emotional development in such neonates (21).

Given the critical role of healthcare teams in empowering mothers to improve neonate outcomes, alongside the potential benefits of neonate massage and persistent concerns regarding its physiological safety, this study aims to investigate the effects of maternally administered neonate massage on feeding tolerance and physiological indicators in neonates admitted to the NICU. By exploring this non-invasive, mother-led intervention, we seek to contribute to the growing body of evidence supporting practical strategies for enhancing care and improving outcomes in this vulnerable population.

## Methods

### Study design

This single-blind, parallel-group randomized controlled trial was conducted among neonates admitted to the NICU who met the eligibility criteria.

### Participants

Participants were recruited using a convenience sampling approach. They were 62 neonates aged 1 to 28 days who were admitted to the NICU at Imam Hossein University-affiliated tertiary neonatal and pediatric center in Isfahan, Iran, between January and August 2023.

The flow of participants through each stage of the randomized controlled trial-including enrollment, randomization and group allocation, follow-up, and analysis-is shown in Figure 1.

Eligible neonates were required to have their mothers physically and mentally present at the NICU bedside to perform neonate massage. Inclusion criteria consisted of gestational age between 28-37 weeks, birth weight ≥ 1500 g, and Apgar scores ≥ 7 at both 1 and 5 minutes. Neonates needed to demonstrate hemodynamic stability, evidenced by a pinkish hue, body temperature of 36-37°C, and oxygen saturation levels > 84%.

Exclusion criteria included the presence of congenital anomalies, infections, central nervous system damage (e.g., cerebral hemorrhage or seizures), inherited metabolic disorders, shock, severe birth asphyxia, or conditions requiring specialized medical interventions such as mechanical ventilation (Unless approved by the attending physician). Neonates were also excluded if they presented with hyperbilirubinemia requiring phototherapy, dermatological conditions (e.g., rashes, soft tissue injuries, fractures), or had received vaccinations within 72 hours prior to the initiation of neonate massage.

Additional exclusion criteria during the intervention period included the need for emergent medical interventions during massage sessions, occurrence of arrhythmias, changes in the clinical stability of the neonate or mother, maternal withdrawal of consent, or early discharge prior to completion of the intervention protocol.

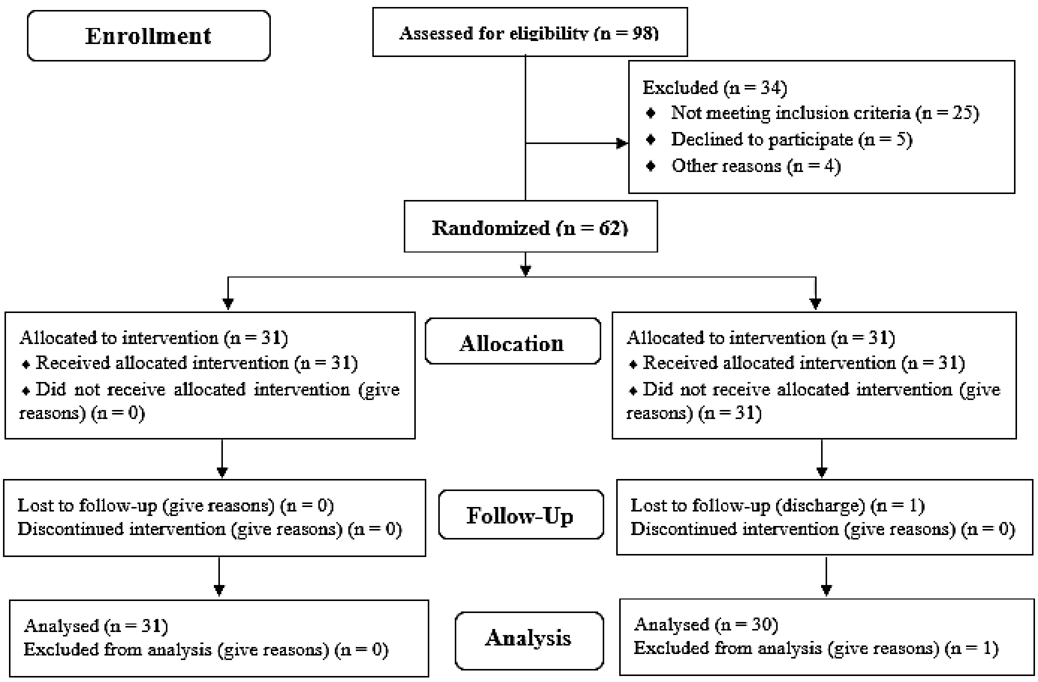


**Figure 1.** Study flow diagram

### Sample size

The required sample size was calculated based on a two-tailed test with allocation ratio = 1:1, 5% significance level (α = 0.05), 80% power (β = 0.2), and a detectable difference of 0.75 SD (δ=0.75σ), using the following formula: $n = \frac{2\sigma^2(z_{1-\alpha/2}+z_{1-\beta})^2}{\delta^2}$.

This calculation yielded a required sample of 28 neonates per group. To compensate for a potential 10% dropout rate, the final sample size was increased to 31 neonates in each group. The assumed effect size was informed by prior research on the impact of abdominal massage on feeding tolerance among preterm neonates (7,22). During the study, one participant from the control group was lost to follow-up (1.6%) due to early discharge, resulting in a final sample of 61 neonates (intervention = 31, control = 30).

### Randomization-and allocation concealment

A simple randomization method with a 1:1 allocation ratio was used to allocate participants into intervention and control groups. A total of 62 identical cards were prepared and numbered sequentially from 1 to 62. These cards were thoroughly shuffled and placed in an envelope. Two independent research assistants, who were not involved in participant recruitment or data collection, each drew one card at a time from the envelope and announced the number aloud. This process was performed in the presence of the neonate's mother.

Neonates whose card numbers were even were assigned to the intervention group, while those with odd numbers were allocated to the control group. The card drawing was performed only after participant eligibility had been confirmed. Each card was used only once and was not returned to the envelope after being drawn. The randomization sequence was generated concurrently with allocation concealment, and group allocation was not predictable in advance.

### Blinding

Due to the nature of the study, blinding of mothers, neonates, and researchers was not feasible. All outcome assessments were conducted by trained NICU nurses who were blinded to group allocation.

### Intervention Protocol

In the intervention group, neonate massage was administered by trained mothers over a 5-day period. Each day, the massage was performed three times (Morning, noon, and evening), with each session lasting approximately 20 minutes. The massage sessions were conducted after feeding with either breast milk or formula and after diaper change to ensure comfort and consistency.

The massage protocol in this study was adapted from the widely recognized method developed by Field et al. at the Touch Research Institute, which has demonstrated efficacy in numerous studies (23,24).

The massage protocol consisted of three stages: two tactile (Stages 1 and 3) and one kinesthetic stimulation (Stage 2), performed as follows:

**Stage 1 - Tactile stimulation (8 minutes):** The neonate was placed in the right lateral position. Six moderate-pressure strokes (10 seconds each) were applied to the head, left shoulder and arm, back (Excluding the spine), and left leg. The neonate was then repositioned to the left lateral side, and the same strokes were applied to the head, right shoulder and arm, back, and right leg.

**Stage 2 - Kinesthetic stimulation (4 minutes):** With the neonate in the supine position, six flexion and extension movements (10 seconds each) were performed on the right arm, left arm, right leg, and left leg.

**Stage 3 - Tactile stimulation (8 minutes):** The procedure from Stage 1 was repeated: strokes were applied first on the right side (Head, left arm) and then on the left side (Head, right arm, back, and right leg).

All massages were performed according to a standardized protocol taught to mothers during the training phase and supervised periodically by the research team to ensure consistency.

For the control group, no massage intervention was administered during the study period.

### Outcomes measures

The primary outcome of the study was feeding tolerance, assessed using the Tube Feeding Intolerance Checklist, which included measures of GRV, abdominal circumference, and the frequency of vomiting and stools.

The secondary outcomes included physiological indicators, specifically HR, respiratory rate (RR), and oxygen saturation ($SaO_2$). These were measured immediately before and 1 hour after each massage session.

### Data collection tools and validity

Data collection tools included a demographic form, the Tube Feeding Intolerance Checklist, and a physiological indicators checklist. The demographic form gathered information on neonate gender, maternal age and education, paternal education, family economic status, gestational age, chronological age, weight, height, and length of stay (LoS).

The Tube Feeding Intolerance Checklist was used to assess GRV, abdominal circumference (In centimeters), and the frequency of vomiting and stools two hours after each feeding every day for five days, with no additional feedings during this washout period. The physiological indicators checklist measured RR, HR, and oxygen saturation levels two hours after each feeding every day for five days.

To assess HR and $SaO_2$, a cardio-respiratory monitor (Vectra model, manufactured by Sazgan Gostar Company, Iran, in 2016) was used. The device was calibrated at the beginning of the study by a biomedical engineer to ensure reliability and accuracy. Throughout the study period, the stability of the monitor's performance was regularly checked and confirmed by the biomedical team at predefined intervals. All measurements were taken using this validated device under standardized conditions.

### Statistical analysis

All analyses were performed using SPSS software (Version 26.0, IBM Corp., Armonk, NY, USA). Descriptive statistics were used to summarize demographic and baseline characteristics. Descriptive statistics (Mean, standard deviation, median, interquartile range) were used to summarize the data.

The Kolmogorov-Smirnov test was applied to assess the normality of continuous variables. Between-group comparisons of demographic variables were conducted using the independent-samples t-test, Mann-Whitney U test, and Chi-square test, as appropriate. Since no statistically significant differences were observed between groups in demographic and baseline variables, they were considered homogeneous and thus were not included as covariates in further analyses.

For outcome variables, within-group comparisons were conducted using the paired t-test (For normally distributed data) and the Wilcoxon signed-rank test (For non-normally distributed data). Between-group comparisons were performed using ANCOVA (Adjusted for baseline values) for normally distributed outcomes, and the Mann-Whitney U test on change scores (Post–pre) for non-normally distributed variables. To assess clinical significance, effect sizes (Cohen's d, r, and partial $\eta^2$) and their 95% confidence intervals were reported alongside p-values. A p-value of less than 0.05 was considered statistically significant.

To address potential confounding, group homogeneity on demographic and baseline variables was confirmed ($p > 0.05$), minimizing confounding concerns. Between-group outcome analyses utilized ANCOVA, adjusted for baseline values, to further control for any potential confounding.

## Results

The study analyzed data from 61 neonates: intervention group (n = 31) and control group (n = 30). One neonate in the control group was discharged early, resulting in missing data for that participant. No statistically significant differences were observed between the groups in baseline demographic or clinical characteristics ($p > 0.05$; Table 1). These findings indicate that the groups were homogeneous at baseline.

Following the intervention, the intervention group demonstrated statistically and clinically significant improvements across all primary outcomes (All $p > 0.05$; Table 2).

GRV decreased significantly in the intervention group (From 11.98 ± 3.17% to 6.26 ± 1.78%; $p < 0.001$, d = 1.98, 95% CI [1.41, 2.55]). In contrast, GRV increased in the control group ($p = 0.001$, d = 0.59, 95% CI [0.14, 1.04]; moderate effect). ANCOVA (Adjusted for baseline values) confirmed a significant between-group difference ($p < 0.001$, $\eta^2 = 0.82$, 95% CI [0.75, 0.88]; very large effect).

Abdominal circumference showed a median reduction of 0.55 cm in the intervention group ($p < 0.001$, r = 0.87, 95% CI [0.76, 0.98]; very large effect), while a small increase was observed in the control group ($p < 0.001$, r = 0.72, 95% CI [0.56, 0.88]; large effect). The between-group comparison also indicated a significant and very large effect ($p < 0.001$, r = 0.82, 95% CI [0.68, 0.97]).

Vomiting frequency decreased in the intervention group (Median from 4 to 2 episodes; $p < 0.001$, $r = 0.89$, 95% CI [0.79, 0.99]; very large effect), while the control group showed no meaningful change ($p = 0.663$, $r = 0.08$, 95% CI [–0.18, 0.34]; negligible effect). The between-group difference was significant ($p < 0.001$, $r = 0.83$, 95% CI [0.69, 0.97]; very large effect).

Stool frequency increased substantially in the intervention group (Median from 4 to 8 episodes; $p < 0.001$, $r = 0.88$, 95% CI [0.77, 0.99]; very large effect), while a small decrease was observed in the control group ($p = 0.047$, $r = 0.36$, 95% CI [0.09, 0.63]; small-to-moderate effect). The between-group difference was also very large ($p < 0.001$, $r = 0.85$, 95% CI [0.73, 0.99]).

The massage group showed significant improvements in oxygen saturation, HR, and RR ($p < 0.001$), with large effect sizes ($r > 0.87$). In contrast, the control group exhibited no significant changes. Between-group comparisons confirmed substantially greater improvements in the intervention group ($p < 0.001$, $r > 0.82$).

**Table 1.** Comparison of individual characteristics between groups

| Variable | Control group (n=30) | Intervention group (n=31) | Test statistic | P-value |
|---|---|---|---|---|
| **Mother's age (Years)** | 29.37 ± 3.64 (22-36) | 32.29 ± 6.60 (18-42) | t = –0.674 | 0.503 |
| **Gestational age (Weeks)** | 34.87 ± 2.26 (28-37) | 34.65 ± 2.21 (29-37) | Z = –0.523 | 0.601 |
| **Infant's height (cm)** | 46.37 ± 5.61 (33-56) | 46.98 ± 5.44 (33-56) | t = –0.436 | 0.664 |
| **Infant's weight (g)** | 2559.83 ± 623.74 (1600-3800) | 2546.13 ± 587.83 (1600-3580) | t = 0.088 | 0.930 |
| **Infant's age (Days)** | 10.40 ± 2.97 (7-20) | 9.97 ± 5.33 (4-30) | Z = –1.159 | 0.247 |
| **Mother's occupation** | Housewife: 24 (80%)<br>Employee: 6 (20%) | Housewife: 24 (77.4%)<br>Employee: 7 (22.6%) | $\chi^2 = 0.061$ | 0.806 |
| **Type of delivery** | Vaginal: 10 (33.3%)<br>Cesarean: 20 (66.7%) | Vaginal: 12 (38.7%)<br>Cesarean: 19 (61.3%) | $\chi^2 = 0.191$ | 0.662 |
| **Infant's gender** | Male: 14 (46.7%)<br>Female: 16 (53.3%) | Male: 16 (51.6%)<br>Female: 15 (48.4%) | $\chi^2 = 0.149$ | 0.699 |
| **Feeding type** | Breastfeeding: 21 (70%)<br>Formula: 9 (30%) | Breastfeeding: 20 (64.5%)<br>Formula: 11 (35.5%) | $\chi^2 = 0.208$ | 0.648 |

Note: Continuous variables are presented as Mean ± SD with range in parentheses. Categorical variables are shown as frequency (Percentage).
Test statistics: t = Independent-samples t-test; U = Mann–Whitney U test; $\chi^2$ = Chi-square test.

**Table 2**. Comparison of outcomes before and after the intervention in the intervention (n = 31) and control (n = 30) groups

| Outcome variable | Group | Pre-Intervention | Post-Intervention | Within-Group p / Effect size/95% CI | Between-Group test / p / Effect size/95% CI |
|---|---|---|---|---|---|
| **Gastric residual volume (%)** | Intervention | 11.98 ± 3.17 | 6.26 ± 1.78 | p<0.001 / d=1.98<br>95% CI [1.41, 2.55] | ANCOVA (Adjusted) / p < 0.001 / $\eta^2 = 0.82$<br>95% CI [0.75–0.88] |
| | Control | 13.56 ± 4.48 | 15.92 ± 3.90 | p=0.001 / d=0.59<br>95% CI [0.14, 1.04] | |
| **Abdominal circumference (cm)** | Intervention | 27.07 (8.67) | 26.63 (8.93) | p<0.001 / r=0.87<br>95% CI [0.76, 0.98] | Mann–Whitney (Δ score)/ p < 0.001 / r = 0.82<br>95% CI [0.68, 0.97] |
| | Control | 31.91 (5.56) | 32.02 (5.70) | p<0.001 / r=0.72<br>95% CI [0.56, 0.88] | |
| **Vomiting frequency (Episodes)** | Intervention | 4.0 (2.0) | 2.0 (0.0) | p<0.001 / r=0.89<br>95% CI [0.79, 0.99] | Mann–Whitney (Δ score)/ p < 0.001 / r = 0.83<br>95% CI [0.69, 0.97] |
| | Control | 5.0 (1.0) | 5.0 (1.0) | p=0.663 / r=0.08<br>95% CI [-0.18, 0.34] | |
| **Stool frequency (Episodes)** | Intervention | 4.0 (2.0) | 8.0 (2.0) | p<0.001 / r=0.88<br>95% CI [0.77, 0.99] | Mann–Whitney (Δ score)/ p < 0.001 / r = 0.85<br>95%CI [0.73, 0.99] |
| | Control | 5.0 (2.0) | 4.0 (1.0) | p=0.047 / r=0.36<br>95% CI [0.09, 0.63] | |
| **SaO2 (%)** | Intervention | 94.6 (1.0) | 96.2 (0.8) | p < 0.001 / r = 0.87<br>95% CI [0.76, 0.98] | Mann–Whitney (Δ score) / p<0.001 / r=0.82<br>95% CI [0.68, 0.97] |
| | Control | 93.8 (1.4) | 93.1 (0.8) | p < 0.001 / r = 0.72<br>95% CI [0.56, 0.88] | |
| **HR (bpm)** | Intervention | 147.0 (15.8) | 140.2 (17.0) | p < 0.001 / r = 0.89<br>95% CI [0.79, 0.99] | Mann–Whitney (Δ score) / p<0.001 / r=0.83<br>95% CI [0.69, 0.97] |
| | Control | 145.9 (24.6) | 145.3 (21.4) | p = 0.732 / r = 0.08<br>95% CI [–0.18, 0.34] | |
| **RR (bpm)** | Intervention | 52.6 (5.0) | 48.4 (5.4) | p< 0.001 / r = 0.88<br>95% CI [0.77, 0.99] | Mann–Whitney (Δ score) / p<0.001 / r=0.85<br>95% CI [0.73, 0.99] |
| | Control | 54.6 (6.4) | 53.8 (4.8) | p = 0.634 / r = 0.36<br>95% CI [0.09, 0.63] | |

Note:
- Within-group comparisons were conducted using the paired t-test for normally distributed variables (Values reported as Mean ± SD) and the Wilcoxon signed-rank test for non-normally distributed variables (Values reported as Median (IQR)).
- Between-group comparisons were performed using ANCOVA (Adjusted for baseline values) for normally distributed outcomes and the Mann–Whitney U test on change scores (Post–pre) for non-normally distributed variables.
- Effect sizes (Cohen's d, r, $\eta^2$) and their 95% confidence intervals are reported to support the clinical interpretation of findings.
CI: Confidence Interval

## Discussion

The findings of this randomized controlled trial demonstrate that neonate massage significantly improved feeding tolerance and physiological stability in preterm neonates admitted to the NICU. These results align with existing evidence on the benefits of tactile stimulation in preterm neonates while providing novel insights into its effects on gastric function and cardiorespiratory parameters.

The significant reduction in GRV and vomiting frequency, along with increased stool frequency in the intervention group, suggests that massage enhances gastrointestinal motility. This is consistent with previous studies indicating that tactile stimulation activates the vagus nerve, promoting peristalsis and gastric emptying (23,24). The observed decrease in abdominal circumference further supports massage's role in reducing abdominal distension, a common issue in preterm neonates (25). The significant improvements in $SaO_2$ levels and reductions in RR and HR in the intervention group indicate that massage may help regulate autonomic nervous system function. Similar findings were reported by Zhang et al., who found that massage improves oxygen saturation and strengthens maternal–neonate attachment in preterm neonates (26). The absence of adverse events during massage sessions confirms its safety when performed under supervision, as noted in previous research (27). The structured training protocol, including a 24-hour helpline, ensured maternal competency, reinforcing findings by Pados et al. (28) that parental involvement in NICU care improves outcomes.

Our results corroborate earlier work by Field (23) and Diego et al. (24), who reported enhanced weight gain and reduced hospital stays with massage. However, our study uniquely highlights massage's impact on feeding intolerance, a critical challenge in preterm care (25).

This study had several limitations: a short-term follow-up preventing assessment of long-term effects, a single-center design limiting generalizability, unquantified variations in parental massage technique, and a narrow population focus reducing broader applicability. Environmental factors (e.g., NICU noise) and unmeasured maternal emotional states during interventions may also have influenced outcomes. Future studies should address these through longer-term, multicenter designs with standardized adherence monitoring and broader participant inclusion.

One of the limitations of this study was the absence of a placebo or sham intervention in the control group. While the intervention group received structured neonate massage, the control group only received routine care without any additional physical contact. This lack of a placebo (e.g., non-massage touching) may have limited our ability to fully control for the potential placebo effect or the impact of human touch itself, which could influence the outcomes independently of the massage technique. Future studies are recommended to include a sham-touch control group to better isolate the specific effects of neonate massage.

## Conclusion

Maternally administered neonate massage demonstrated potential benefits in improving feeding tolerance and physiological indicators in this study. As the sample was drawn from a single hospital, caution is warranted when generalizing the findings to the broader NICU population. Larger, multicenter studies with more diverse samples are needed to confirm these results.

Future research should examine long-term neurodevelopmental outcomes, variations in oils and massage durations, and potential confounding factors such as antibiotic and probiotic use. The impact of neonate massage on parental mental health also warrants investigation through multicenter trials.

Integrating neonate massage into NICU care as a non-pharmacological intervention may enhance feeding tolerance and physiological stability. Training mothers to provide neonate massage, as piloted in this study, could further strengthen family-centered care models.

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None.

## Ethical statement

This study was approved by the Ethics Committee of Islamic Azad University, Isfahan (Khorasgan) Branch (IR.IAU.KHUISF.REC.1401.409) and registered at the Iranian Registry of Clinical Trials (IRCT20130812014333N199). Written informed consent was obtained from all parents/guardians, with emphasis on voluntary participation, unrestricted withdrawal, and confidentiality. To ensure equity, control group mothers received massage training after the study period if their neonates remained hospitalized. The study adhered to the Declaration of Helsinki.

## Conflicts of interest

The authors declare no conflicts of interest or funding.

## Author contributions

F.R: Conceptualization, Data collection, Investigation, Methodology, Writing - Original draft. M.R: Conceptualization, Project administration, Supervision, Validation, Writing - Review and Editing. N.S: Investigation, Advisor, Writing draft. M.M: Formal analysis, Writing - Review and Original draft.

## Data availability statement

Data will be made available upon reasonable request, subject to review by the research team and consideration of data confidentiality.

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