# Assessment of Leg Massage on Hemodynamic Parameters of Intensive Care Patients: A Parallel Single-Blinded Randomized Controlled Trial

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## Abstract

**Objective:** We aimed to determine the effectiveness of leg massage by a nurse and patients' families on hemodynamic parameters in patients admitted to intensive care units.

**Methods:** This parallel single-blinded randomized clinical trial involved 75 patients admitted to the intensive care units at Shahid Bahonar Hospital in Kerman, Iran. Patients were assigned to 3 groups by the minimization method (massage by a nurse, massage by the patient's family, and the control group). Swedish massage was used on both legs (each leg for 5 minutes) once a day for 6 days, and the hemodynamic parameters of patients were measured before intervention, at the end of intervention, and 1 week later.

**Results:** The results showed that mean arterial pressure decreased in all 3 groups 1 week after intervention, which was not statistically significant. Mean heart rate also decreased in all 3 groups 1 week after intervention, which was statistically significant except for massage by family. Mean arterial oxygen saturation significantly decreased in all 3 groups 1 week after intervention but remained normal. The 3 hemodynamic parameters did not differ significantly among the 3 groups.

**Conclusion:** According to the results of this study, the use of massage has no effect on hemodynamic parameters. (J Chiropr Med 2020;19;111-118)

**Key Indexing Terms:** *Massage; Hemodynamics; Intensive Care Units; Nurses; Family*

## Introduction

Hospitalization in the intensive care unit (ICU) is associated with complications such as stress, anxiety, pain, and fear of the unknown environment, which can cause hemodynamic instability and disturbance in the level of consciousness in patients.[1,2] Individuals in the ICU often experience agitation after invasive life-protection measures, disease conditions, injuries, and environmental conditions.[3] Agitation induced by mechanical ventilation not only causes incompatibility with the mechanical ventilation but also leads to unstable vital signs.[3,4]

The physiological state of the body in response to physical, environmental, and psychological stressors is exhibited as vital signs that show sudden changes and changes that occur progressively over a period.[5] Basic vital signs including heart rate, arterial blood pressure, respiratory rate, body temperature, and pain reflect the health status of a person.[6] Monitoring of hemodynamic parameters (systolic blood pressure, diastolic blood pressure, mean arterial pressure, heart rate, and arterial oxygen saturation) is necessary in nursing assessments, especially in patients admitted to ICUs; control of vital signs is a valuable criterion for understanding the physiological condition of patients and adopting appropriate nursing interventions.[7,8] It has been shown that 13.9% of the mortality rate in ICUs is due to changes in physiological parameters.[9]

Different medications are frequently used to control agitation and prevent physiological changes and vital-sign instability in ICUs.[10] Deep sedation is more common than light in ICUs.[11] However, inappropriate and excessive use of sedatives can lead to unstable physiological parameters.[12] To avoid the side effects of drugs, nonpharmacologic interventions can be widely considered a complementary approach

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to drug therapy. Complementary and alternative medicine includes medicinal systems, health care, actions, and products that can be used in collaboration with modern medicine[13]; according to the US National Center for Complementary and Integrative Health, complementary and alternative medicine may be included in the care and treatment of people. In Iran, 45.9% to 94.4% of patients with different diseases report using complementary and alternative medicines.[14-17] One of these therapies, massage therapy, is a technique that stimulates the nerves, tactile receptors, and skin baroreceptors, after which nerve impulses are transmitted to the brain.[18] Massage may reduce blood pressure and heart rate and gives a sense of comfort and relaxation.[19] After the relaxation of the muscles, the production of endorphin is increased, which improves sleep quality, relieves muscle pain and cramps, increases a sense of delight, and reduces the need for sedatives.[20] Jamaati et al[21] report that arterial oxygen saturation increases and systolic blood pressure, respiratory rate, and heart rate decrease in ICU patients who receive whole-body massage, whereas diastolic blood pressure and temperature do not change. Da Silva et al[22] have shown that diastolic and systolic blood pressure, mean arterial pressure, and respiratory and heart rates decrease in ICU patients after Swedish foot massage. Adib-Hajbaghery et al[23] also have shown that massage by a patient's relative decreases systolic blood pressure and heart and respiratory rates in critical care unit patients, whereas diastolic blood pressure and temperature do not change.

According to the results of our literature review, there are still unknowns regarding the effect of massage on ICU patients' vital signs. On the one hand, it is very important to monitor hemodynamic parameters in the ICU and keep them stable. On the other hand, the use of sedatives and narcotics to keep these parameters stable has side effects and risks that lead nurses to use nonpharmacologic strategies. It seems that nurses can use simple, nonpharmacologic, inexpensive, and practical methods of complementary medicine, like massage, to control some complications of hospitalization in ICUs, such as instability in hemodynamic parameters. In addition, nurses may ask patients' families to provide some nonpharmacologic modalities. The involvement of a patient's family in caregiving may have an additional effect in maintaining hemodynamic stability. Therefore, the current study tested the hypothesis that mean vital signs in ICU patients would be different among 3 groups—leg massage by a nurse, leg massage by a family member, and the control group (routine treatment)—at the end of the intervention and 1 week afterward.

## Materials and Methods

### Study Design and Setting

This study was a parallel single-blinded randomized controlled clinical trial conducted in ICUs at Shahid Bahonar Hospital in Kerman, Iran. Shahid Bahonar Hospital has 3 trauma intensive care units, with a total of 46 beds, and is the trauma ICU center in the southeast of Iran.

### Sample Size and Sampling

The samples were selected using convenience sampling and divided into 3 groups (2 intervention groups and 1 control group) by a minimization method (the 3 groups were matched according to sex and addiction history).[24,25] The first participant was allocated to a group by drawing dice. Subsequent participants were allocated to other groups according to their sex and addiction history. This process continued until the end of sampling. The first author enrolled the participants and assigned them to the 3 groups. Inclusion criteria were tracheal tube or tracheostomy[26]; noncontinuous infusion of sedative drugs, such as midazolam or propofol[27]; noncontinuous infusion of narcotics, such as fentanyl[28]; age between 15 and 50 years[26]; no withdrawal syndrome[29]; no vascular disorders, such as deep venous thrombosis with physician diagnosis[30]; absence of fractures in the lower limbs[30]; and absence of skin disease, leg ulcers, and infections.[30] Exclusion criteria were extubation,[26] no referral of the patient's family for massage for more than 2 days, death,[26] and discharge.[26] Previous studies were used for estimation of sample size.[31] The confidence coefficient was calculated to be 95%, the confidence interval was 1.96, and type II error was calculated to be 10% (1.63). The sample size was adjusted based on the number of study groups. Thus, for the 3 study groups, the number of participants needed for each group was 21. Accounting for the probability of dropout, 75 participants were considered (25 per group; Fig 1).

### Measurements

Data collection in this study included a background information questionnaire and a hemodynamic-parameters form. The background information questionnaire (demographic information and patient information) included age, sex, marital status, occupation, level of education, history of admission to ICUs, history of other illness, history of addiction, history of smoking, history of seizure, history of hypertension, length of hospitalization in the ICU, history of surgery during admission, and type of disease. The hemodynamic-parameters form was used to evaluate physiological parameters, including systolic blood pressure, diastolic blood pressure (DBP), mean arterial pressure (MAP), heart rate, and oxygen saturation ($SpO_2$). An Alborz monitoring device made by Saadat, placed at the top of the patient's bed, was used to measure blood pressure, heart rate, and $SpO_2$. All devices were the same and calibrated by medical engineers before the study. Measurements of blood pressure, heart rate, and $SpO_2$ were postponed by 15 minutes to 1 hour in case of suctioning, agitation, or

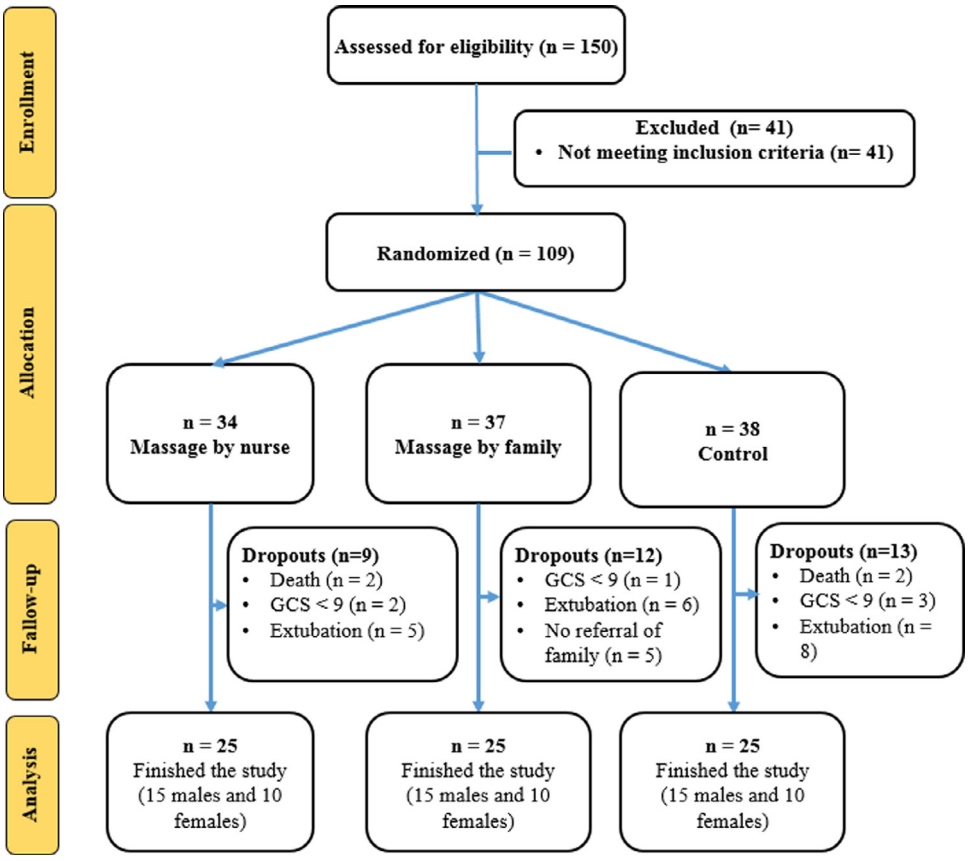


**Fig 1.** *The flow diagram of the study.*

excessive use of sedatives.[12,32,33] Blood pressure was measured at 5-minute intervals to ensure accurate measurement, and the means were recorded as the patient's blood pressure. $SpO_2$ waves must be properly regulated and free of noises to ensure a true reading of arterial oxygen saturation; if there had been parasites, the probe would have been placed on another area and the arterial oxygen saturation checked. Similarly, electrocardiography must be free of arrhythmias or parasites to ensure an accurate reading of heart rate; if there had been a noise, the chest leads would have been replaced to determine the exact heart rate. MAP is the average blood pressure in an individual during a single cardiac cycle, calculated as DBP + (1/3 × pulse pressure). In the present study, MAP was calculated automatically by the monitoring device. All measurements in all 3 groups were performed by a coresearcher who was a nurse and was not aware of the participant allocation.

### Data Collection and Intervention

Hemodynamic parameters were measured in all 3 groups before intervention. The nurse or family member communicated with the participant before and during the intervention. They introduced themselves and performed Swedish massage on the participant's legs. Then the hemodynamic parameters were evaluated again immediately after the intervention and 1 week later. The study was single-blinded because the coresearcher who measured the hemodynamic parameters did not know how participants were allocated to groups. A qualified physiotherapist instructed the researcher how to provide leg massage for 3 sessions.

The control group received routine care for 6 consecutive days, with hemodynamic parameters recorded at the same time intervals as the intervention groups. Although patient visitation is restricted in ICUs, family members were allowed to visit their patients by the permission of the head of the ICUs. In addition, the ward's routine care was performed for all 3 groups. In the intervention groups, the participant's legs (from the knees to the toes) were massaged by a nurse or a family member once a day for 10 minutes (each leg for 5 minutes) on 6 consecutive days. The procedure was as follows: First, the participant was placed in a supine position with a pillow under the legs, so that the legs were bent slightly, and the head was placed at an angle of 30° to 45°. The massage-area cover was removed from 10 cm above the participant's knee, with the rest of the body covered. Then the researcher moved to the bottom of the participant's legs and provided the massage

after examining the legs for the presence of massage barriers. In this study, Swedish massage was used that included stroking, effleurage, vibrations, and kneading. Baby oil was used for the massage so that the area was slippery and easy to massage (about 1 to 2 $cm^3$ per leg); it had no other therapeutic value. The massage was performed between 3 PM and 5 PM, the workload of the intensive care unit was low. Upon completion of the massage, the residual oil on the participant's legs was cleaned. The control group received only routine care. In the group with massage by participants' family, a family member who was mostly present at the bedside was trained for the massage under the supervision of the researcher and initiated the intervention after the researcher's confirmation. Massage was performed by a maximum of 2 family members. Data collection lasted from November 2017 to July 2018 (8 months).

### Data Analysis

Data were analyzed with SPSS version 18. Descriptive statistics (frequency, percentage, mean, and standard deviation) were used to describe participants' demographic characteristics and disease information. The mean and standard deviation were used to describe the hemodynamic parameters (MAP, heart rate, and SpO2). The $\chi^2$ test and analysis of variance (or its nonparametric equivalent, the Kruskal −Wallis test) were used to examine the similarity of the 3 groups in terms of the study variables. Repeated-measures analysis of variance was used to compare hemodynamic parameters (MAP, heart rate, $SpO_2$) before, immediately after, and 1 week after intervention.

### Ethical Considerations

The ethics committee of Kerman University of Medical Sciences approved the study (ethics code ir.kmu.rec.1396.1460, Iran Registry of Clinical Trials code IRCT201707317844N12). The researcher obtained written consent from participants' guardians after coordination with the head of the hospital and the authorities of the intensive care units, and after explaining the research goals and method.

## Results

The mean age of participants was 41.12 ± 9.29 years in the group with massage by family, 39.49 ± 10.79 years in the group with massage by nurse, and 42.8 ± 6.65 years in the control group ($P = .42$). Across all 3 groups, 60% of participants were men. In the group with massage by family, 68% of participants were married, 76% in the group with massage by nurse, and 84% in the control group ($\chi^2 = 1.75$, $P = .42$). There was no statistically significant difference between groups regarding occupation or education level ($P > .05$).

In the group with massage by family, 8% of participants had a history of hospitalization in the ICU, 16% in the group with massage by nurse, and 8% in the control group. Also, 11% of participants in the group with massage by family, 12% in the group with massage by nurse, and 12% in the control group had a history of other illnesses. There was no statistically significant difference between groups on the variables of history of hospitalization in the ICU, history of other diseases, current history of addiction, history of smoking, history of seizure, hypertension, history of using hypertension drugs, history of surgery during the current admissio, or type of disease ($P > .05$).

Level of consciousness in all 3 groups was assessed as a 9 on the Glasgow Coma Scale. The length of hospitalization in the ICU before the start of the study was on average between 5 and 6 days in all 3 groups, and the groups did not differ in this regard ($P > .05$). In the group with massage by family, 84% of participants had a tracheal tube, 88% in the group with massage by nurse, and 92% in the control group; the rest had a tracheostomy, and the groups did not differ in this regard ($P > .05$). There was no statistically significant difference among the 3 groups in amount of spontaneous breathing, amount of assisted spontaneous breathing, percentage of inspired oxygen, or positive end-expiratory pressure ($P > .05$). Administration of narcotics (midazolam, propofol, morphine, methadone, fentanyl, and opium) and nonnarcotics (nitroglycerin, metoral, hydrochlorothiazide, propranolol, and dopamine) were not significantly different among the 3 groups before the intervention ($P > .05$).

Mean arterial pressure in the group with massage by family decreased from 131.97 mm Hg before the study to 126.75 mm Hg at 1 week after the intervention, which was not statistically significant. In the group with massage by nurse, it decreased from 128.88 mm Hg before the study to 125.55 mm Hg at 1 week after the intervention, which was again not statistically significant. And in the control group it decreased from 134.59 mm Hg before the study to 131.56 mm Hg at 1 week after the intervention, which was yet again not statistically significant. The results of repeated-measures analysis of variance showed that there was no significant difference in mean arterial pressure among the 3 groups during the study (Table 1).

Mean heart rate in the group with massage by family decreased from 86.84 beats/min before the study to 82.52 beats/min at 1 week after the intervention, which was not statistically significant. In the group with massage by nurse it decreased from 84.44 beats/min before the study to 78.8 beats/min at 1 week after the intervention, which was statistically significant. And in the control group it decreased from 86.67 beats/min before the study to 81.53 beats/min at 1 week after the intervention, which again was statistically significant. There was no statistically significant difference in heart rate among the 3 groups during the study (Table 2).

**Table 1.** *Comparison of Mean Arterial Pressure (mm Hg) in the 3 Study Groups*

| Timing | Group With Massage by Family | | Group With Massage by Nurse | | Control Group | | Repeated-Measures ANOVA | *P* |
|---|---|---|---|---|---|---|---|---|
| | Mean | SD | Mean | SD | Mean | SD | | |
| Before intervention | 131.97 | 14.69 | 131.57 | 10.23 | 126.75 | 7.34 | 1.29 | .28 |
| Immediately after intervention | 128.88 | 15.63 | 126.74 | 23.53 | 125.55 | 11.86 | | |
| 1 wk after intervention | 134.59 | 18.37 | 132.58 | 32.16 | 131.56 | 6.48 | | |
| Sphericity | 2.97 | | 0.37 | | 0.39 | | | |
| *P* | .06 | | .69 | | .68 | | | |

*ANOVA*, analysis of variance; *SD*, standard deviation.

**Table 2.** *Comparison of Heart Rate (beats/min) in the 3 Study Groups*

| Timing | Group With Massage by Family | | Group With Massage by Nurse | | Control Group | | Repeated-Measures ANOVA | *P* |
|---|---|---|---|---|---|---|---|---|
| | Mean | SD | Mean | SD | Mean | SD | | |
| Before intervention | 86.84 | 13.36 | 84.44 | 12.77 | 86.67 | 12.82 | 2.66 | .08 |
| Immediately after intervention | 83.44 | 7.63 | 79.76 | 7.98 | 86.36 | 9.14 | | |
| 1 wk after intervention | 82.52 | 6.08 | 78.8 | 9.87 | 81.53 | 9.04 | | |
| Greenhouse−Geisser test | 1.64 | | 3.92 | | 3.73 | | | |
| *P* | .21 | | .03 | | .03 | | | |

*ANOVA*, analysis of variance; *SD*, standard deviation.

Mean arterial oxygen saturation in the group with massage by family decreased from 98.84% before the study to 97.88% at 1 week after the intervention, which was statistically significant. In the group with massage by nurse it decreased from 98.72% before the study to 97.6% at 1 week after the intervention, which again was statistically significant. And in the control group it decreased from 99.04% before the study to 98.16% at 1 week after the intervention, which yet again was statistically significant. There was no statistically significant difference in arterial oxygen saturation among the 3 groups during the study (Table 3). It should be noted that although arterial oxygen saturation decreased in all 3 groups, it remained in the normal range. In addition, none of the participants experienced discomfort or side effects during the intervention or 1 week afterward. The causes of mortality in 2 participants in the group with massage by nurse were subdural and epidural hemorrhage.

## Discussion

The results of this study show that mean arterial pressure and mean heart rate decreased in all 3 groups 1 week after the intervention. Mean arterial oxygen saturation decreased in all 3 groups at 1 week after the intervention but remained above 97.5% in all groups. The hemodynamic changes in all 3 groups were not clinically important.

Several studies have investigated the effect of massage on hemodynamic parameters in patients admitted to intensive care units. Similar to the present study, Vahedian-Azimi et al[34] examined the effects of massage by patients' families on the vital signs of patients in the general ICU, and found no significant difference in heart rate between the intervention and control groups. Rigi et al[35] studied the effect of leg reflexology massage on hemodynamic parameters in individuals undergoing coronary artery bypass surgery, and found no significant difference in heart rate between the intervention and control groups. Kaur et al[9] also studied the effect of leg reflexology massage on ICU patients, and found no significant difference in arterial oxygen saturation before and after intervention.

Some other studies, however, do not support the present study. For example, da Silva et al[22] have shown that Swedish foot massage for 30 minutes reduces vital signs (heart rate, respiratory rate, systolic arterial pressure, diastolic arterial pressure, and mean arterial pressure) immediately after massage, with significantly decreased heart rate 30 minutes after massage compared to before it. Adib-Hajbaghery et al[23] have shown that in comparison with a

**Table 3.** *Comparison of Arterial Oxygen Saturation (%) in the 3 Study Groups*

| Timing | Group With Massage by Family | | Group With Massage by Nurse | | Control Group | | Repeated-Measures ANOVA | *P* |
|---|---|---|---|---|---|---|---|---|
| | Mean | SD | Mean | SD | Mean | SD | | |
| Before intervention | 98.84 | 1.77 | 98.72 | 1.7 | 99.04 | 1.88 | 0.51 | .61 |
| Immediately after intervention | 98.4 | 1.76 | 97.8 | 1.47 | 98.12 | 2.07 | | |
| 1 wk after intervention | 97.88 | 1.72 | 97.6 | 1.32 | 98.16 | 1.95 | | |
| Sphericity | 5.72 | | 6.34 | | 5.19 | | | |
| *P* | .006 | | .004 | | .009 | | | |

*ANOVA*, analysis of variance; *SD*, standard deviation.

control group, whole-body massage by a family member for 60 minutes at 1 occasion on the third day of admission to the critical care unit reduced systolic blood pressure, heart rate, and respiratory rate in individuals 15 minutes after massage, but with no significant difference in diastolic blood pressure or body temperature between the intervention and control groups. Hatefi et al[36] have shown that whole-body massage of ICU patients by family members for 45 minutes causes a significant decrease in systolic blood pressure 1 and 3 hours after intervention in addition to diastolic blood pressure, respiratory rate, and heart rate 1 hour after intervention. They have also shown a significant difference between intervention and control groups in arterial oxygen saturation and pH and partial pressure of oxygen, but no significant difference between the 2 groups in partial pressure of carbon dioxide or bicarbonate. Azami et al[30,37] have shown that compared with a control group, foot massage for 5 minutes in ICU patients causes a significant decrease in mean arterial pressure and a significant increase in arterial oxygen saturation 1 and 5 minutes after massage.

The difference between the results of the present study and those of some other studies might be due to differences in the study population, research setting, participant level of consciousness, lack of mechanical ventilation, duration of massage, areas undergoing massage, and different evaluation times of vital signs. For example, in some studies participants are not attached to mechanical ventilation.[22,23] Because attachment to mechanical ventilation can lead to hemodynamic instability,[3,38] the lack of effect of massage on vital signs in the present study may be related to the fact that all participants in the present study underwent mechanical ventilation. Also, in the foregoing studies massage was performed only once, and vital signs were measured before and afterward. In the present study, vital signs were measured on days 6 and 13, before and 30 minutes after the massage. In other words, the short-term (30 minutes afterward) and long-term (1 week afterward) effects of massage were investigated in the current study (there was no significant differences between them)—but in most studies, only the short-term effect of massage is investigated.[22,23,30,34-36]

### Limitations

The first limitation of this study is disturbances due to administration of sedatives, narcotics, and suctioning and to changes in position, which we attempted to reduce by postponing the measurement of hemodynamic parameters in these conditions. Second is the lack of cooperation from some families, due to a lack of information about the disease and the effect of massage on the patient, which was reduced by training the family and reducing their concerns. Third, despite being trained about the safety of the study, some families did not accept the intervention. This limitation was reduced by contacting families at a different time who were not present. In the case of their absence, the massage would have been performed by another person after training. Finally, as this study was conducted in 1 center, generalization of our results to other centers should be done with caution. We recommend that further studies be conducted with a larger sample size in different research settings and communities to determine the optimal frequency, techniques, and duration of massage therapy. We also recommend additional studies to clarify the effects of massage therapy on various systems of the body.

## Conclusion

Our results showed no effect of Swedish leg massage on hemodynamic parameters in the ICU patients who participated in this study.

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No funding sources or conflicts of interest were reported for this study.

## Contributorship Information

Concept development (provided idea for the research): M.D.
Design (planned the methods to generate the results): M.M., M.A., M.D., M.A.N.
Supervision (provided oversight, responsible for organization and implementation, writing of the manuscript): M.A., M.D., M.A.N.
Data collection/processing (responsible for experiments, patient management, organization, or reporting data): M.M.
Analysis/interpretation (responsible for statistical analysis, evaluation, and presentation of the results): M.D.
Literature search (performed the literature search): M.M., M.D.
Writing (responsible for writing a substantive part of the manuscript): M.M., M.D.
Critical review (revised manuscript for intellectual content, this does not relate to spelling and grammar checking): M.D., M.A., M.A.N.

**Practical Applications**

- Mean arterial pressure and mean heart rate decreased in the massage groups and the control group 1 week after intervention, but remained in the normal range; the decreases were not clinically important.
- Mean arterial oxygen saturation decreased significantly in all 3 groups 1 week after intervention but remained above 97.5%.
- Mean arterial pressure, heart rate, and mean arterial oxygen saturation remained the same and in the normal range in all 3 groups during the study.
- Massage by a nurse or a family member had no statistically or clinically significant impact on patients in the intensive care unit with stable hemodynamic parameters.

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