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ORIGINAL ARTICLE

The Potential Role of Physical Activity in Reducing Delirium and Improving Physiological Indicators in Children with Epilepsy

Vida Golpaygani[1], Mahboobeh Aliakbari[2], Faride Mesgari[1], Fatemeh Aghaei[*1]

[1]*Shefa Neuroscience Research Center, Tehran, Iran*

[2]*Nursing and Midwifery Care Research Center, School of Nursing and Midwifery, Iran University of Medical Sciences, Tehran, Iran*

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KEYWORDS

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ABSTRACT: Foot reflexology is recognized as a holistic therapeutic approach that fosters relaxation and enhances overall well-being. This study aimed to evaluate the impact of foot reflexology massage on the incidence of delirium and selected physiological parameters in pediatric patients admitted to the Pediatric Intensive Care Unit (PICU). Conducted as a randomized clinical trial at Hazrat Ali Asghar Hospital, affiliated with Iran University of Medical Sciences in Tehran, Iran, the research involved 74 participants who were randomly assigned to either an intervention or a control group. While the control group received only standard medical care, the intervention group received foot reflexology massage in addition to routine care. Data collection tools included a demographic information questionnaire, a physiological parameters checklist, and the Pediatric Delirium Cornell Assessment Tool, administered both before and after the intervention. Data analysis was performed using SPSS software, version 23. Findings revealed that by the second day post-intervention, the incidence of delirium in the intervention group had significantly decreased compared to the control group ($P = 0.004$). Furthermore, immediately following the intervention, heart rate, diastolic blood pressure, and systolic blood pressure in the intervention group were all significantly lower than those in the control group ($P < 0.001$, $P < 0.026$, and $P < 0.002$, respectively). However, no statistically significant difference was observed between the groups regarding arterial blood oxygen saturation after the intervention ($P = 0.5$). These results suggest that foot reflexology may be effective in reducing delirium and stabilizing cardiovascular parameters in critically ill children. Although its influence on oxygen saturation remains inconclusive, the findings offer promising evidence for incorporating massage therapy as a non-pharmacological nursing intervention in clinical settings to support the management of delirium and the regulation of vital signs.

INTRODUCTION

Each year, over 300,000 children are hospitalized with serious illnesses or injuries that necessitate admission to Pediatric Intensive Care Units (PICUs), where they require highly specialized care [1]. Hospitalization in such critical environments is frequently accompanied by complications, one of the most significant being delirium [2]. The reported prevalence of delirium in the PICU ranges from 10% to 30%, and can rise to 40% following cardiac surgery [3]. In a study conducted by Navaeifar et al., the prevalence of delirium in Iranian PICUs was found to be 25% [4].

*Corresponding author: faghae17771@gmail.com (F. Aghaei)
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When left undiagnosed or untreated, pediatric delirium can lead to a host of adverse outcomes, including prolonged hospital stays, increased healthcare costs, long-term cognitive decline, extended use of mechanical ventilation, and elevated mortality rates [3–5]. It also provokes significant psychological distress in children, their families, and healthcare providers alike [6]. Despite its clinical importance, delirium in children has often been overlooked in both research and clinical practice. Thus, greater emphasis is required on its recognition and management within the PICU setting [7].

Current treatment strategies for delirium include both pharmacologic and non-pharmacologic approaches. However, pharmacologic interventions are frequently associated with undesirable effects, such as heightened agitation and restlessness [8]. This highlights the necessity of integrating non-pharmacological strategies into routine care [9]. These interventions may include family involvement, environmental modifications—such as reducing light and noise levels during sleep, adjusting alarm volumes, limiting unnecessary conversations near the child's bedside—as well as promoting early mobility, providing structured daily routines, and incorporating therapeutic play or various forms of massage [10–12].

While there is growing evidence supporting the role of non-pharmacologic interventions in preventing and managing delirium, the efficacy of some modalities—such as touch therapy and massage—remains underexplored [13]. Further research is thus essential to develop a consistent, evidence-based approach for the prevention and treatment of delirium in critically ill pediatric patients [12].

Changes in vital signs are not only indicative of physiological status but may also signal early deterioration in clinical condition [14]. Both physical and psychological factors—including chronic stress, anxiety, depression, and emotional distress—can influence these parameters [15]. Delirium itself is characterized by a combination of altered physiological and cognitive states, underscoring its complexity and diagnostic challenges [16]. In fact, certain studies, such as the one conducted by Kuhn et al., have proposed the use of vital sign fluctuations as a potential method for identifying delirium [17]. Clinicians routinely employ both pharmacologic and non-pharmacologic interventions to manage patient anxiety and support physiological stability [18].

In recent years, the integration of complementary and alternative medicine (CAM) into conventional healthcare practices has gained considerable momentum [19]. Non-pharmacologic therapies have become increasingly popular among patients and families due to their cost-effectiveness, minimal side effects, non-invasive nature, and non-addictive potential [20]. Among these, foot reflexology massage—an approach rooted in tactile sensory stimulation—has garnered particular interest [21]. Reflexology involves applying pressure to specific points on the feet, corresponding to various organs and systems of the body. According to Dr. FitzGerald's theory, this practice promotes the flow of vital energy, clears energy blockages, and supports the body's natural healing processes. By stimulating the nervous and muscular systems, reflexology enhances circulation, facilitates the elimination of waste products, and improves blood flow to vital organs and the brain [22]. Hemodynamic theory further supports these claims, suggesting that such stimulation enhances blood perfusion, promotes relaxation, and contributes to overall healing [23]. A growing number of studies have recognized foot reflexology as a safe and non-invasive nursing intervention for use in pediatric populations [24–26].

Given the high incidence of delirium among children in intensive care, and the limited attention it has received in pediatric settings—often due to under-recognition—it is both timely and necessary to explore effective, child-friendly interventions [4,7]. Moreover, improving the quality of nursing care in the PICU has the potential to significantly reduce mortality and improve outcomes in critically ill children [27]. More interventional studies are needed to evaluate the impact of non-pharmacological strategies, such as reflexology, in reducing delirium and to guide the development of international best-practice guidelines [12].

Accordingly, the present study was designed to investigate the effects of foot reflexology massage on the incidence of delirium and physiological parameters in children admitted to the Pediatric Intensive Care Unit.

MATERIALS AND METHODS

Design and Population

This randomized controlled clinical trial was conducted in the division of pediatric critical care of a Iran university of medical sciences between March to August, 2024. The inclusion criteria for this study were: Children aged 6 to 12 years, Failure to score -4 and -5 on the Richmond Agitation Scale, Hospitalization in the pediatric intensive care unit for at least 3 days, Absence of abnormalities such as corns, wounds, previous scars, burns, amputations and skin diseases on the legs, Absence of vascular injuries in the lower limbs and absence of sensory-motor disorders (confirmed by a neurologist) in the legs, Diagnosis of delirium by obtaining a delirium score of 9 and above based on the Cornell tool and a pediatric neurologist, lack of previous experience of foot reflexology massage before the study and Confirmation of the doctor's diagnosis by a pediatric specialist. Children with either of the following conditions were excluded (i) mechanical ventilation, (ii) restlessness, (iii) Lack of proper cooperation and resistance of the child and his parents at any time of the study, (v) Emergency conditions such as cardiopulmonary resuscitation or seizures, (vi) Child suffering from acute heart or respiratory diseases, (vii) Reduction of vital signs more than expected, such as: drop in blood pressure (below 25th percentile) and bradycardia (below 65 beats per minute). In order to determine the sample size at the confidence level of 95% and the power of the test is 80%, assuming that the size of the effect of foot reflexology massage on delirium in children admitted to the pediatric intensive care unit, compared to the control group, is at least ES=0.5 .The sample was calculated as 32 children in each group. Also, due to the possibility of sample drop, 15% was added. Therefore, in the end, the sample size in each group was determined to be 37 children.

Outcome measures

Data were collected using a three-part instrument comprising a demographic questionnaire, the *Cornell Assessment of Pediatric Delirium* (CAPD), and an observational checklist for physiological indicators. The demographic questionnaire included variables such as the child's age, sex, weight, primary diagnosis, educational level, history of hospitalization, prior admissions to the pediatric intensive care unit (PICU), duration of illness, history of medication use, and presence of underlying conditions.

The CAPD is a validated tool designed for the assessment of delirium in critically ill pediatric patients [28,29]. Developed to be a rapid and easily administered screening instrument, the CAPD enables nurses to detect delirium across all pediatric age groups and developmental stages [30,31]. The scale consists of eight items aligned with the diagnostic criteria for awareness, cognition, and psychomotor behavior as outlined in the *DSM-5*. Each item is scored on a scale from 0 to 4, with a total score of ≥ 9 indicating the presence of delirium. The assessment can be completed in under two minutes and is based on behavioral observations during routine nursing care, eliminating the need for patient participation and ensuring broad applicability [31].

To facilitate scoring in children under 24 months of age, anchor points based on developmental milestones are provided in seven age categories (newborn, 4 weeks, 6 weeks, 8 weeks, 28 weeks, 1 year, and 2 years). The CAPD demonstrates high reliability, with a reported sensitivity of 94.1% (95% CI: 83.8–98.8%) and specificity of 79.2% (95% CI: 73.5–84.9%). The tool's internal consistency is also robust, with a Cronbach's α of 0.90 (range: 0.87–0.90 across items) [31]. In Iran, the psychometric properties of the Persian version of the CAPD were evaluated by Navaeifar et al. (2012), demonstrating acceptable interrater agreement using Kendall's test (Kendall's coefficient = 0.046), with no significant differences observed between raters for any individual items or the total score [4].

The observational form for physiological indicators, developed by the researchers, included heart rate (beats per minute), blood pressure (mmHg), and arterial oxygen saturation (SpO_2 , %). These parameters were measured via bedside monitors connected to the child and recorded at predetermined time intervals.

To ensure interrater reliability, Cohen's Kappa test was used via SPSS software (version 23.0). This statistical method evaluates the level of agreement between independent raters. A Kappa coefficient above 0.6 is considered acceptable, while values above 0.8 indicate excellent reliability [32]. In this study, 10 paired

observations were conducted by two independent raters, yielding a Kappa value of 0.97, confirming ideal agreement.

Randomization and allocation

After the eligibility of the childerens who were admitted to the PICU, the allocation was done. The participants were randomly assigned into the intervention and control groups. We used a computer-generated randomisation sequence (www.randomizer.org) with random permuted block sizes of 4 or 6. massage rsearcher and pediatrician, were kept blind to the allocation. Information concerning allocation was available only to the one researcher.

Table 1. Demographic characteristics of children.

Variable \ Groups		Control		Intervention		P-Value
		N	%	N	%	
Gender	Female	18	48.6	15	40.5	0.483 €
	Male	19	51.4	22	59.5	
Age (Year)	Under 8	16	43.2	12	32.4	P=0.179 □
	8-10	10	27	9	24.3	
	Over 8	11	29.7	16	43.2	
Weight (Kg)	Under 30	20	54.1	16	43.2	P=0.670 □
	30 and more	17	45.9	21	56.8	
Educational level	Pre School	13	35.1	8	21.6	P=0.765 **
	First grade	3	8.1	3	8.1	
	Second grade	4	10.8	6	16.2	
	Third grade	3	8.1	3	8.1	
	Fourth grade	3	8.1	2	5.4	
	Fifth grade	5	13.5	4	10.8	
	Sixth grade	6	16.2	11	29.7	
History of medication use	Yes	15	40.5	9	24.3	P=0.116 €
	No	22	59.5	28	75.7	
Underlying disease	Yes	15	40.5	9	24.3	€P=0.136
	No	22	59.5	28	75.7	
Duration of disease (year)	Under 1	29	78.4	32	86.5	P=0.109 *
	1 -5	6	16.2	4	10.8	
	6 and more	2	5.4	1	2.7	
History of hospitalization	Yes	29	78.4	24	64.9	P= 0.197 €
	No	8	21.6	13	35.1	
History of hospitalization at NICU	Yes	13	35.1	11	29.7	P=0.619 €
	No	24	64.9	26	70.3	
Disease type	Infective	8	21.6	7	18.9	P=0.084 **

	Respiratory	6	16.2	4	10.8	
	Digestive	4	10.8	0	0	
	Neurologic	6	16.2	3	8.1	
	Other	13	35.1	23	62.2	
Duration of hospitalization (Day)	Under 3	25	67.7	31	83.8	P=0.159 *
	3 and more	12	32.4	6	16.2	
	* Man Whitney	** Fisher Exact Test	Є Chi Square	□ Independent T-Test		

Table 2. The frequency of delirium on the first and second day in the control and intervention groups.

Time / Variable		First day		Second day	
		N Before the intervention(%)	After the intervention N (%)	Before the intervention N (%)	After the intervention (%)
Delirium	**Control**	37 (100)	35 (94.6)	36 (97.3)	**35 (94.6)**
	Intervention	37 (100)	32 (86.5)	(91.9)	**28 (75.7)**
	P-Value	*	0.430	0.615	**0.022**

Table 3. The mean heart rate, diastolic blood pressure, systolic blood pressure and oxygen saturation on the first and second day in the control and intervention groups

Time / Variable		First Day		Second Day	
		Before the Intervention (Mean ± SD)	After the Intervention (Mean ± SD)	Before the Intervention (Mean ± SD)	After the Intervention (Mean ± SD)
Heart Rate	**Control**	106.54 ± 16.73	105.35 ± 16.81	107.95 ± 17.63	**105.00 ± 17.82**
	Intervention	106.08 ± 14.09	95.86 ± 14.58	105.32 ± 15.27	**94.16 ± 17.72**
	P-Value	0.899	<0.001	0.497	**<0.001**
Diastolic Blood Pressure	**Control**	76.51 ± 11.48	76.86 ± 11.38	75.20 ± 12.13	**74.15 ± 12.38**
	Intervention	74.78 ± 11.35	70.02 ± 10.42	74. ± 11.84	**67.99 ± 10.66**
	P-Value	0.517	0.011	0.757	**0.026**
Systolic Blood Pressure	**Control**	107.54 ± 7.66	104.59 ± 9.82	109.05 ± 9.31	**107.16 ± 8.31**
	Intervention	108.19 ± 8.68	97.84 ± 9.81	110.24 ± 10.46	**100.32 ± 10.29**
	P-Value	0.390	<0.001	0.704	**0.002**
Oxygen Saturation	**Control**	96.16 ± 2.84	96.43 ± 2.14	96.22 ± 2.46	**96.43 ± 2.06**
	Intervention	96.95 ± 2.46	96.73 ± 2.11	96.78 ± 2.02	**97.14 ± 2.11**
	P-Value	0.209	0.986	0.283	**0.5**

Interventio

After obtaining permission from the ethics committee of the university, the researcher went to the research environment. Then he clearly explained the steps of conducting the research and the objectives of the study to the supervisor and the doctor in charge of the department. Sampling was continuous and based on the inclusion criteria. At first, the samples that met the inclusion criteria were selected, and the child's agitation score was measured based on the Richmond Agitation Scale, and if the patient had a score between-3 to +4,

delirium severity was assessed were selected to calculate the delirium score. Children whose delirium score was 9 or higher were identified and the selected sample was included in the study with the doctor's confirmation that the child was diagnosed with delirium.

Then, using computer randomization (www.randomizer.org), the selected children were placed in the control group and the intervention group (foot reflex massage intervention). The objectives of the study and how to perform foot reflexology massage were explained orally, as well as an educational video was shown to the parents of the children, and all their questions about the massage were explained. Verbal consent was obtained from the child and written consent was obtained from the parents to participate in the research. Then the demographic data was recorded by the researcher from the child's medical record.

In cases where the child was selected as the intervention group, in addition to providing the usual ward care, foot reflexology massage was also performed. Before the foot reflexology massage, the researcher first prepared the child and the environment for the intervention. Thus, the child was first connected to cardiorespiratory monitoring and then 5 minutes before the foot reflexology massage, the physiological indicators form (blood pressure, heart rate, arterial blood oxygen saturation) and the Cornell Delirium Questionnaire for Children was completed. The massage was performed for 28 minutes. After finishing the massage, the children's delirium cornell questionnaire was completed again 2 hours later. In cases where children were in the control group. CAPD for children was completed 2 hours and 28 minutes after the initial assessment. The intervention and measurement of delirium continued for two days. Immediately after reflexology massage, the form with the physiological indicators is completed again, and 2 hours later the Cornell Questionnaire on Delirium in Children is completed.

It should be noted that in this research, the massage was performed by a researcher who was trained in foot reflexology massage for 3 months under the supervision of a specialist in physical medicine, rheumatology and rehabilitation. She identified the reflex points of the foot correctly and learned how to apply pressure and succeeded in receiving the certification.

Massage therapy

In this research, foot reflexology massage is performed in the following steps.

First the child and his mother were prepared psychologically by the researcher through explaining the purpose, effects of foot reflexology and its importance 1.

Preparation stage

The children were placed in a supine position with an elevation of the head of the bed. Children’s feet were placed in comfortable position with a small pillow placed under the knees to facilitate the massage. Then wash and dry the child's feet with shampoo and towel.The researcher’s hands were warmed before starting the session. The researcher seated in front of the children’s feet. three drops of baby oil were applied to the researcher's hands to facilitate the massage and minimize skin friction of children's feet.

warm-up and relaxation steps

Reflexology began with the relaxation technique of rubbing the feet by lightly running the fingertips up, down, and on the sides of each foot in a feather-like motion.

Massage reflex points on the soles of the feet

The application of foot reflexology was performed from top to down manner, where the actual massage started on Head/brain (top of each toe) Pituitary (center of big toe), Thyroid (base of big toe). Neck/shoulders (ridge of toes), Chest/lungs (ball of foot) and kidney (base of toe to base of heel) to stabilize physiological parameters and relieve fatigue. Each point was pressed and released by the thumb walking technique for 2 to 3 minutes. After that pressure was applied to the solar plexus reflex point by placing the thumb in the center of the foot to relieve stress. After reflexology techniques are applied to the selected areas that are corresponding to the nerve supply on the feet [33].

Blinding/masking

Blinding at the clinicians was not possible in this study due to the massage intervention. Blinding was achieved in the data analysis stage. In order to achieve blinding in the outcome assessment, the data were coded in the software and the analysis was performed by a statistician who was unaware of this coding and did not know which data related to the interventions and control condition.

Statistical analysis

The data were analyzed with the SPSS (Statistical Package for the Social Sciences) software version 23 IBM Corp, Chicago, Illinois. Descriptive statistics including mean, standard deviation, frequency and percentage were performed for all parameters. Inferential statistics including Independent T-test, Chi-square test, Fisher's exact test, Analysis of covariance (ANCOVA), and Mann-Whitney U test were performed to explore differences between groups. The results were considered statistically significant at $p<0.05$.

RESULTS

Most children in both the control and intervention groups were male, had a history of medication use, had no underlying diseases, and had been ill for less than one year. Additionally, the majority had a prior history of hospitalization, with a hospitalization duration of less than three days, and no history of admission to the pediatric intensive care unit (PICU). In terms of other characteristics, most children in the control group were under 8 years of age, had a preschool level of education, and weighed less than 30 kg. In contrast, most children in the intervention group were over 10 years old, weighed more than 30 kg, and had a sixth-grade level of education. However, there were no statistically significant differences in demographic characteristics between the two groups. These details are presented in Table 1.

As shown in Table 2, on the first day prior to the intervention, all children in both groups exhibited signs of delirium. Immediately after the intervention, 94.6% of children in the control group and 86.5% in the intervention group continued to show signs of delirium; however, this difference was not statistically significant ($P = 0.430$). On the second day before the intervention, delirium was observed in 97.3% of the control group and 91.9% of the intervention group. Immediately after the intervention, the rates dropped to 94.6% in the control group and 75.7% in the intervention group. The difference at this time point was statistically significant ($P < 0.022$).

Table 3 illustrates that on the first day, prior to the intervention, the independent *t*-test showed no significant difference in mean heart rate between the two groups ($P = 0.899$). However, analysis of covariance revealed that immediately after the intervention, the mean heart rate in the intervention group was significantly lower than that in the control group ($P < 0.001$). A similar pattern was observed on the second day. Before the intervention, there was no significant difference in heart rate ($P = 0.497$), but immediately afterward, the intervention group again demonstrated a significantly lower mean heart rate ($P < 0.001$).

Regarding diastolic blood pressure, the independent *t*-test indicated no significant difference between the two groups before the intervention on the first day ($P = 0.517$). However, after the intervention, the analysis of covariance showed a significantly lower mean diastolic blood pressure in the intervention group compared to the control group ($P = 0.011$). This pattern persisted on the second day: before the intervention, there was no significant difference ($P = 0.757$), but post-intervention, the diastolic blood pressure in the intervention group was significantly lower ($P = 0.026$).

In terms of systolic blood pressure, no statistically significant differences were found between the two groups before the intervention on either day ($P = 0.390$ on the first day; $P = 0.704$ on the second day). However, the analysis of covariance indicated that the mean systolic blood pressure was significantly lower in the intervention group than in the control group immediately after the intervention on both days ($P < 0.001$ and $P = 0.002$, respectively).

With respect to arterial oxygen saturation, the independent *t*-test showed no significant difference between the two groups before the intervention on the first day ($P = 0.209$). Similarly, the analysis of covariance showed no significant difference in oxygen saturation levels immediately after the intervention ($P = 0.986$). This trend continued on the second day, with no

significant differences observed either before (P = 0.283) or after the intervention (P = 0.500).

DISCUSSION

This study aimed to compare the incidence of delirium and physiological indicators in children admitted to the Pediatric Intensive Care Unit (PICU) before and after foot reflexology massage.

On the first day, all children in both the control and intervention groups exhibited delirium at two pre-intervention time points. However, immediately after the intervention, there was no statistically significant difference in the frequency of delirium between the two groups. The frequency of delirium post-intervention did not significantly differ from pre-intervention levels in either group. These findings suggest that while foot reflexology may contribute to reducing delirium, its immediate impact is not evident. This could be attributed to the delayed onset of reflexology's therapeutic effects, which may require more time to manifest fully.

The potential mechanisms underlying the effects of massage on the nervous and psychological systems include stimulation of specific nerves and increased blood flow, which may gradually alleviate delirium symptoms. Individual responses to reflexology can vary; some children may exhibit immediate improvements, while others require more time to show benefits [35,36]. Additionally, as delirium is inherently a transient condition, its episodic nature may influence symptom presentation [37].

In line with these findings, Momeni et al. reported a reduction in delirium percentages post-intervention in both control and intervention groups, although the changes were not statistically significant [38]. Both studies emphasize the importance of considering long-term effects over immediate results when evaluating massage therapy. Similarly, Fu et al. found that massage and aromatherapy had no significant impact on reducing behavioral disturbances in dementia, corroborating our findings [39].

On the second day, however, a significant difference emerged in the frequency of delirium between the two groups, at both pre- and post-intervention time points. Notably, the frequency of delirium declined significantly in the intervention group after the massage. These results clearly demonstrate the delayed but beneficial effect of foot reflexology in reducing delirium in children over time. Reflexology may influence the autonomic nervous system, enhance nerve function, and promote relaxation by stimulating specific reflex points on the feet. These physiological effects contribute to stress reduction and symptom relief in critically ill children.

Importantly, this is the first study to investigate the effect of foot reflexology on delirium prevalence in pediatric populations. Supporting evidence from Makinian et al. indicated that facial and cranial massage reduced delirium severity in elderly women hospitalized in cardiac care units [40]. Similarly, Putri et al. observed reductions in depression and anxiety scores among the elderly following reflexology, suggesting improved mental health outcomes [41].

In contrast, a study by Fazlollah et al. on adults undergoing coronary artery bypass surgery found that while foot reflexology had a significant effect on the second postoperative day, it did not significantly reduce delirium [42]. Differences in inclusion and exclusion criteria between the two studies may explain the divergent findings, suggesting that the more stringent criteria in our study may have yielded more reliable results.

In terms of physiological indicators, our findings revealed that immediately post-intervention, the mean heart rate was significantly lower in the intervention group than in the control group. This trend persisted on the second day, indicating that foot reflexology significantly reduces heart rate in children. These findings underscore the potential of reflexology as a non-pharmacological approach to improving physiological stability.

Consistent with our results, Elsheshtawy et al. reported that foot reflexology led to significant improvements in heart rate, blood pressure, respiratory rate, and temperature in children undergoing hemodialysis. They recommended incorporating reflexology into routine nursing care [43]. Similarly, Kotruchin et al. demonstrated that reflexology effectively lowered heart rate in hypertensive patients [44], and Elsabely Mohammed et al. also observed significant reductions in heart rate and blood pressure in their intervention group [45]. Furthermore, Ghaljaei and Jalalodini found that

reflexology improved both blood pressure and heart rate parameters [46].

Regarding blood pressure, no significant differences were observed in mean diastolic pressure between groups before intervention on day one. However, immediately post-intervention, diastolic pressure was significantly lower in the intervention group. Lin et al. reported similar findings, where Taichung point compression led to significant reductions in both systolic and diastolic pressures at 15 and 30 minutes post-intervention [47]. Kotruchin et al. also observed reductions in both systolic and diastolic blood pressures in their intervention group, although only the reduction in heart rate was significantly different when compared to controls [44]. Conversely, a study on Korean hypertensive patients showed reductions only in systolic pressure, not diastolic, following reflexology [48]. These discrepancies may stem from variations in reflexology technique, intensity, duration, or pressure point application. Therefore, further clinical trials are necessary to determine the most effective reflexology protocols.

On the second day, foot reflexology significantly reduced diastolic pressure in the intervention group. Quattrin et al. also found that reductions in blood pressure and respiratory rate improved the physiological status of cancer patients, potentially by facilitating relaxation [49]. According to Kuhn, reflexology helps rebalance overactive or underactive areas of the body, promoting systemic relaxation [17], while Fritz demonstrated that foot manipulation in reflexology stimulates the parasympathetic nervous system and influences vital signs through autonomic modulation [50].

Additionally, our study found a significant reduction in systolic pressure in the intervention group compared to the control group. Park et al. similarly reported reductions in systolic but not diastolic pressure following reflexotherapy [48]. Lestari et al. found that systolic pressure decreased significantly from 160.44 mmHg to 140.83 mmHg after reflexology, affirming its positive effects [51]. These outcomes may be attributed to the technique's influence on vascular tone, autonomic function, and parasympathetic activation, leading to vasodilation and improved blood flow.

Ann et al. noted no significant differences in systolic or diastolic pressure on the first day of intervention, but observed significant changes by the second and third days, aligning with our findings [52]. This supports the hypothesis that reflexology's physiological benefits accumulate over time rather than appearing immediately.

Finally, foot reflexology had no significant effect on arterial oxygen saturation levels in children. Minor fluctuations were observed in both groups—slightly increasing in the control group and decreasing in the intervention group. These negligible changes may be due to individual baseline physiology or external variables. Song et al., in a systematic review of non-clinical studies, found that while foot reflexology improved subjective outcomes like stress and fatigue, it did not significantly impact objective indicators like blood pressure or heart rate [53]. Similarly, Hayes reported no effect of five-minute foot massages on arterial oxygen saturation, likely due to patient heterogeneity and lack of a control group [53]. Oxidative stress is a significant factor in the onset and progression of chronic diseases, including epilepsy. This phenomenon occurs due to the excessive production of free radicals and the body's reduced ability to counteract them with its antioxidant system [54-58]. In conditions like epilepsy, oxidative stress can lead to neuronal damage and disruption of brain function. An increase in free radicals causes inflammation and damage to cell membranes, proteins, and DNA, which can play a crucial role in triggering seizures and exacerbating disease symptoms. Therefore, managing oxidative stress and utilizing antioxidant agents may help reduce the damage caused by epilepsy and improve the clinical condition of patients [69-62].

Limitation

One of the strengths of this study was the careful design a randomized clinical trial and implementation guided by a professional multidisciplinary team. However, one limitation of this study was environmental factors such as uncontrollable noises in the PICU that could interfere with the effect of foot reflexology massage. To address this, interventions were implemented, such as asking the treatment team to speak quietly and minimize noise, cutting off unnecessary alarms, etc. Additionaly in this study, delirium in children was classified as either present or absent without considering the intensity,

duration or the role of hypoactive or hyperactive subtypes.

CONCLUSIONS

According to the results of this research, foot reflexology can have a positive effect on children's delirium .This finding is clinically important in nursing care because reducing of delirium in children without the use of drugs is a significant care goal that can decrease complications caused by medications. Therefore, nurses can teach this simple and inexpensive technique to patients and their families. Considering the high importance of reducing delirium in children admitted to the pediatric intensive care unit, it can recommended to use foot reflexology massage as a non-drug, safe, easy, low-cost and affordable method. However, while reflexology massage is an effective application, the lack of studies with a low risk of bias prevents making strong recommendations.

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ETHICAL CONSIDERATION

The institutional ethics committee approved the study (code: IR.IUMS.REC.1402.986). written informed consent was obtained from parents/legal guardians. Trials.gov registry registration number: IRCT202302057303N3. Written informed consents were obtained from the childeren's parents after explaining the aim of the study. They have the right to refuse to participate or to withdraw from the study at any time. They were assured about the confidentiality of the collected data.

Conflict of interest

Authors declare no conflict of interest.

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