



## The Effect of Foot Reflexology on the Time of Full Consciousness Recovery and Weaning from Mechanical Ventilation in Patients with Brain Tumor after Craniotomy

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### Abstract

**Background:** Patients with brain tumor experience multiple complications, including impaired consciousness and delayed extubation of endotracheal tubes, after craniotomy. The purpose of the present study was to determine the effects of foot reflexology on the time of full consciousness recovery and weaning from mechanical ventilation in patients with brain tumor after craniotomy.

**Methods:** This single blind clinical trial was performed on 60 craniotomy patients. The participants were assigned to the control and intervention groups using a block randomization method. Two checklists, including the time of full consciousness and withdrawal from the ventilator, were completed for the two groups after the intervention. In the intervention group, in addition to routine care for these patients, the first author performed foot reflexology for 30 min (15 min for each foot) twice a day, in the morning and evening, for a week. The control group received routine care for patients with brain tumor and craniotomy. Data was analyzed using SPSS version 16 software.

**Results:** The results showed that there was no significant difference in terms of demographic characteristics between the two groups ( $p > 0.05$ ). The results indicated that the mean scores regarding the time needed for regaining full consciousness and weaning from mechanical ventilation were significantly lower in the intervention group compared to the control group ( $p < 0.001$ ).

**Conclusion:** The results showed that foot reflexology was effective in reducing the time needed for full consciousness recovery and weaning from mechanical ventilation in craniotomy patients.

**Keywords:** Reflexology; Consciousness; Ventilator weaning; Craniotomy; Brain tumor

### Background

In the United States, about 80,000 people are diagnosed with a Primary Brain Tumor (PBT) annually. In patients with a malignant brain tumor, the average survival rate is 35%. The most common form of primary malignant brain tumor in adults is glioblastoma multiforme. In patients with glioblastoma multiforme, a five-year survival rate is 5.6% [1]. In Iran, primary brain tumor incidence is higher in males than females (ratio: 2-1). In this country, glioblastoma is the most common form (15.1%) of primary malignancy in brain [2].

Craniotomy is the common treatment for patients with brain tumor [2]. Craniotomy is a temporary removal of a bone flap from the skull for accessing the brain. A craniotomy may involve a small or large removal of a bone flap depending on the medical problem in the brain. Craniotomy is used in different medical problems in the brain, such as tumors, hematomas, aneurysms, traumatic injury, foreign objects, inflammation, and infection. The removed bone flap is typically returned at the end of the surgical procedure. In the postoperative period of this procedure, the most common complications include decreased level of consciousness [3], cerebral vasospasms [4], refractory seizures [5], reoperations, hemiparesis, and hematomas [6]. Additional complications that are common in non-elective surgeries include intracranial hypertension, seizures, and delayed extubation [5,7].

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Patients undergoing craniotomy commonly need mechanical ventilation. For the patients on a ventilator, weaning from the ventilator and the endotracheal tube are important parts of the care plan that can improve the patients' recovery after surgery [4]. Chanif et al. [8] indicated that sensory stimulation interventions in the first week after surgery can be effective to prevent sensory deprivation and improve the healing process. Sensory stimuli include auditory, visual, olfactory, taste, and tactile stimuli that can be provided through massage, relaxation techniques, acupuncture, and reflexology [9]. Sensory deprivations, especially touch deprivation, are common in Intensive Care Units (ICUs). Tactile stimuli and reflexology can stimulate the sense of touch and improve level of consciousness. In different countries, reflexology has been reported as an ancient and common practice for the management of psychological problems [10,11]. Reflexology is a method that involves applying pressure on the reflex points in patients' feet and hands that can lead to the stimulation of specific body parts and organs nervous system and blood circulation. This stimulation can reduce pain or discomfort related to the specific body parts [12]. It is also reported that reflexology is effective in reducing stress and tension and increasing blood circulation in general [13].

Elsayed et al. [14] and Kandemir and Ozteki [13] indicated that foot reflexology after open heart surgery can increase the level of consciousness and decrease the time that the patient can be extubated and weaned off the ventilator. Lee stated that reflexology can increase the flow of energy throughout the body that leads to an improved healing process [15]. They also indicated that applying pressure on the feet reflex points stimulates the peripheral and central nervous systems related to the visceral organs and the secretory glands. Therefore, energy can be released and flow throughout the body. It is also indicated that placebo-like effects of this intervention in addition to the other effects can have significant therapeutic effects on patients [16]. Moreover, these effects have been explained by theories that address the balance of energy in the body, including the gate control, neural impulse, lactic acid, and endorphins theories [17].

Quattrin et al. [16] indicated that reflexology is effective in maintaining a balance in the body through stimulating typically dormant parts and relaxing the overactive parts of the body. Ebadi et al. [18] found that foot reflexology was effective in shortening the length of weaning time in patients after open heart surgery. However, a systematic review of the relevant studies could not support the use of reflexology for the management of medical conditions [18]. Additionally, studies indicated that there was no significant effect associated with the reflexology technique among patients with different medical conditions [19,20]. Taking the contradictory results of the relevant studies into account, systematic reviews reported a need for more studies to confirm the effects of reflexology intervention on different groups of patients [19,20]. Furthermore, due to the small number of studies that address the effects of reflexology on the level of consciousness after surgery, there is a need for further studies to advance evidence-based practice related to this intervention.

To the authors' knowledge, the present study was the first study that investigated the effect of foot reflexology on full consciousness recovery and weaning from mechanical ventilation in patients with brain tumor after craniotomy. The purpose of the present study was to determine the effects of foot reflexology on the time of full consciousness recovery and weaning from mechanical ventilation in patients with brain tumor after craniotomy. Weaning from mechanical ventilation is a process that includes multiple steps for

removal of ventilatory support which concludes in the patient being extubated and breathing spontaneously [15,18]. In this study, weaning from mechanical ventilation refers to the time of endotracheal tube removal and the patient's spontaneous breathing. Moreover, the time of full consciousness or full consciousness recovery is defined as the time that the patient regain the maximum conscious state based on the Glasgow Coma Scale (GCS=15).

## Methods

This single-blind randomized controlled clinical trial was conducted in a neurosurgery ICU at Shahid Beheshti Hospital, Iran, Kashan. In the intervention group, foot reflexology was performed by the first author. The data collection was completed by ICU nurses, who were unaware of the participants' group assignment. The statistical specialist was also unaware of the participants' group assignment.

Using the Cohen's sample size formula [21], the sample size of each group was estimated to be 25 participants. The sample size in each group was calculated based on the following assumptions:  $d$  (mean difference between the two groups) =0.7,  $\alpha$ =0.05, and  $\beta$ =0.2. Considering a possible attrition rate of 10%, the optimal sample size was estimated to be 30 participants in each group.

A total of 74 brain tumor patients undergoing craniotomy were assessed regarding the eligibility to participate in the study. Of the 74 patients, 10 patients did not meet the inclusion criteria, and 4 patients declined to participate in the study. A total of 60 participants were randomly assigned to the intervention ( $n=30$ ) and control ( $n=30$ ) groups using a block randomization method (Figure 1). Inclusion criteria for the patients were: Age of 18 to 65 years old, a diagnosis of primary brain tumors, an admission to the hospital for an elective craniotomy surgery, the level of consciousness from 5 to 7 according to the Glasgow Coma Scale (GCS) after surgery at the time of admission to the ICU, mechanical ventilation under ventilator, and stable vital signs. The exclusion criteria were vascular and other chronic diseases, impaired skin integrity in the lower extremities, a need for reoperation for the patient, decreased level of consciousness during the study, receiving narcotics and sedatives during the study, and the use of other complementary therapies.

The study instruments were a demographic questionnaire (including questions about age, gender, education, marital status, underlying diseases, occupation, anesthesia medications, length of surgery, and level of consciousness), a checklist for recording the time of regaining a full consciousness according to the Glasgow Coma Scale (GCS), and a checklist for recording the time of weaning or withdrawal from mechanical ventilation support. The GCS was developed in 1974 by Tysdal et al. The GCS contains three components for assessing patients' level of consciousness. The components include eye-opening, verbal, and motor responses to commands or painful stimuli. The total GCS score ranges from 3 (severe neurological disorders) to 15 (full consciousness) [22]. Enriquez et al. [23] confirmed the validity and reliability of this scale (correlation coefficient of 94% and Cronbach's alpha of 96%).

This study was performed from December 2020 to May 2021 in a neurosurgery ICU. Before craniotomy, the potential participants were admitted to the neurosurgery department. The researcher reported to the neurosurgery department the day before surgery, and demographic questionnaires were provided for the participants to complete. Written informed consent was also obtained from the participants. After the surgery, the participants were transferred to

the neurosurgery ICU for post-operative care. During the study in the ICU, the intervention group participants received a foot reflexology intervention in addition to the routine care for these patients, including dressing changes, monitoring vital signs, GCS assessment, and antibiotic administration. The intervention group participants received a 30-min foot reflexology, which consisted of 15 min for each foot, twice a day, in the morning and evening, for a maximum of a week. The foot reflexology intervention was initiated one hour after the admission to the ICU and continued until the participant achieved a GCS score of 15, or automatically ended if the patient reached the one week maximum. The participants in the control group received routine care related to craniotomy patients in ICU.

The participants' GCS scores were routinely monitored and recorded in the patient's medical records every hour by ICU nurses and anesthesiologists. The results of the Kappa agreement test showed that there was no significant difference between the reported scores by the ICU nurses and anesthesiologists. Furthermore, the time of weaning or withdrawal from mechanical ventilation support was recorded (in hour) by the ICU nurses and anesthesiologists. The researcher (first author) reported to the ICU every day and completed the study checklists based on the participants' medical records.

### Foot reflexology protocol

The first author who has a certificate of reflexology training performed the foot reflexology method on the participants based on Embong et al. [24]. The intervention was performed at the participant's bedside in the ICU; a privacy curtain was stretched around the bed. Before the intervention, basic foot hygiene, including washing and drying their feet and cutting their nails if necessary, was performed. No cream or lotion was applied on the participants' feet. The participants were placed in a supine position. The participants' legs were positioned *via* smooth lifting of the feet and placing a small pillow under knees to prevent muscle strains and fatigue.

A three-stage foot reflexology was applied on each foot for 15 min. Based on Alinia-Najjar et al. [25]; the pressure points of the feet were selected. According to Bahunar et al. [25] the foot reflexology includes three steps:

(1) General foot massage. This step includes a foot rotation, Achilles stretching, and foot extension and stretching for a minute on each foot. In the right foot, the bottom of the heel was kept with the left hand, and the metatarsal arch of the same foot was held with the other hand. Then, the foot was rotated clockwise and counterclockwise three times in each direction. The same technique was performed on the left foot.

(2) The solar plexus (the relaxation point) stimulation. This stimulation was applied for 12 min on each foot. Stimulation of this point can lead to calmness, balance, relaxation, reduced panic reaction, and reduced depression and stress. Rotational pressure with thumb was applied to stimulate the solar plexus.

(3) Stimulation of the reflex point. Applying pressure on the reflex point can stimulate the hypothalamus gland, pituitary gland, heart, lung, and adrenal gland. The hypothalamus gland's function is related to the secretion of hormones and the balance of autonomic nervous system. The pituitary gland controls other endocrine glands, balances the secretion of hormones, and promotes emotional and physical balance. The lung and heart regulate breathing and the oxygen level. The adrenal glands function is related to the secretion of adrenaline and hydrocortisone, which improves balance and reduces depression

and stress [26]. In this step, the stimulation was performed by applying circular pressure with the thumb on the reflex point for two minutes. The stimulation of the points related to the lungs and heart was performed by pulling back the toes and biting movements from above the diaphragm area of the sole towards the toes by the thumbs [25,26]. The pressure points in each foot correspond to the organs in the same side of the body. For example, to stimulate the heart, the pressure was applied on the related point in the left foot. In this study, the location of the pressure points was selected based on Figure 2.

This study was approved by the Institutional Review Board and the ethics committee of Kashan University of Medical Sciences. The research objectives were explained to the participants, and written informed consent was obtained. This study was registered at the Iranian Registry of Clinical Trials (no. IRCT20111210008348N47).

Data was analyzed using the SPSS software version 22 (SPSS, Inc. Chicago, Illinois, USA). Normality was assessed using the Kolmogorov-Smirnov test. The t-test was used to analyze normal quantitative variables, and the Chi-square test was used to analyze qualitative variables. The independent t-test was used to compare the mean scores of the time of full consciousness and time of weaning or withdrawal from mechanical ventilation support in the two groups. The level of significance was set at 0.05.

## Results

The results of the present study showed that 51.2% of the intervention group and 48.8% of the control group were male. The education level in 45.9% of the intervention group and 54.1% of the control group was less than a high-school diploma. Midazolam and Fentanyl had been administered for induction of anesthesia in 49.1% of the intervention group and 50.9% of the control group. The results did not show a statistically significant difference between the two groups in terms of sociodemographic characteristics including age, gender, education, marital status, underlying diseases, occupation, anesthesia medication, and length of surgery ( $p > 0.05$ ) (Table 1).

The results showed that the time interval between the admission to ICU and weaning or withdrawal from mechanical ventilation support was  $92.03 \pm 34.22$  h in the intervention group and  $209.73 \pm 65.87$  h in the control group. Furthermore, the time interval between the admission to ICU and full consciousness in the intervention group was  $92.56 \pm 36.05$  h and in the control group was  $215.06 \pm 65.28$  h. The independent t-test showed a significant difference between the two groups in terms of the time of weaning or withdrawal from mechanical ventilation support ( $p < 0.001$ ). The groups' difference related to the time of full consciousness was also significant ( $p < 0.001$ ) (Table 2).

## Discussion

In the present study, we investigated the effect of foot reflexology on the time of full consciousness recovery and ventilation support withdrawal in patients with brain tumor after craniotomy. A total of 60 patients participated in this study. The results showed that foot reflexology was effective to reduce the time interval between admission to ICU and full consciousness as well as withdrawal from the ventilation support in the participants. As the studies on the effects of reflexology on recovery after craniotomy are rare, we discuss similar interventions in this section.

Consistent with our results, Vahedian-Azimi et al. [11] showed that a general body massage in ICU patients was effective to increase

**Table 1:** Sociodemographic characteristics of the intervention and control groups.

Variable	Groups		P value	
	Intervention group (n=30)	Control group (n=30)		
	Mean ± SD <sup>a</sup> N(%) <sup>b</sup>	Mean ± SD <sup>a</sup> N(%) <sup>b</sup>		
Age (year)	29.44 ± 4.16	26.58 ± 4.48	<sup>c</sup> 0.001	
Length of surgery (hours)	4.75 ± 2.82	3.43 ± 2.19	<sup>c</sup> 0.001	
Sex	Female	8 (47.1)	9 (52.9)	<sup>d</sup> 0.77
	Male	22 (51.2)	21 (48.8)	
Education <sup>b</sup>	Elementary	17 (45.9)	20 (54.1)	<sup>d</sup> 0.42
	Higher than elementary	13 (56.5)	10 (54.3)	
Marital status <sup>b</sup>	Single	4 (44.4)	5 (55.6)	<sup>d</sup> 0.71
	Marriage	26 (51)	25 (49)	
Underlying diseases <sup>p</sup>	No	19 (57.6)	14 (42.4)	<sup>d</sup> 0.29
	Yes	11 (40.7)	16 (59.3)	
Job status <sup>b</sup>	Employed	21 (50)	21 (50)	<sup>d</sup> 1
	Unemployed	9 (50)	9 (50)	
Anesthesia medication <sup>b</sup>	Midazolam and Fentanyl	28 (49.1)	29 (50.9)	<sup>d</sup> 0.55
	Other	2 (66.7)	1 (33.3)	

<sup>a</sup> Standard Deviation (SD); <sup>b</sup> number (percent); <sup>c</sup> independent samples t-test; <sup>d</sup> Chi-square test

**Table 2:** Comparison of the time to reach full consciousness and to wean from the ventilator in the intervention and control groups.

Variable	Intervention group (n= 30)	Control group (n=30)	<sup>b</sup> P value
	Mean ± Sd <sup>a</sup>	Mean ± Sd <sup>a</sup>	
Time to reach full consciousness (hours)	92.56 ± 36.05	215.06 ± 65.28	P=0.001
Time weaning from the ventilator (hours)	92.03 ± 34.22	209.73 ± 65.87	P=0.001

<sup>a</sup> Standard Deviation (SD); <sup>b</sup> Independent samples t-test

the level of consciousness one to four hours after the intervention. Studies explained that stimulating the nerve fibers and the skin, which contains tactile and pressure receptors, through massage can improve patients' health outcomes, such as the level of consciousness [11,26]. Mandeep [27] showed that in patients with traumatic brain injuries in a coma, early stimulation using arousal therapy can significantly increase the level of consciousness. Kurt and Can indicated that massage can improve the body blood flow and the renal blood flow and, as a result, toxins can be removed from the body. The increased level of consciousness can also be associated with the improved levels of arterial blood oxygenation and oxygen supply for the brain [28].

Elsayed et al. [14] showed that a single time 60-min reflexology (30 min in each foot) could improve the level of consciousness and reduce the total time of mechanical ventilation in patients undergoing open heart surgery hospitalized in ICU. Kandemir and Oztekin [13] also showed that foot reflexology (30 min in each foot) was effective to increase the level of consciousness and reduce the time needed for weaning from the ventilator in open-heart surgery patients in ICU. Allahbakhhsian et al. [26] showed that a single time 30-min foot reflexology (15 min in each foot) was effective to reduce the weaning time from the ventilator in patients with open heart surgery admitted to the ICU. In these studies, the duration of intervention and the type of disease were different; however, they agreed with the effectiveness of reflexology on patients' consciousness recovery and weaning from the ventilator.

However, there were studies that showed contradictory results regarding the effects of foot reflexology. Ebadi et al. [18] found that foot reflexology was not significantly effective in shortening the

length of weaning time in patients post open-heart surgery. In their study, their participants received a one-time 20-min foot reflexology on each foot an hour after admission to the ICU regardless of their level of consciousness. Further, the researchers did not provide a clear definition of weaning time [18]. Kavei et al. [29] also found that foot reflexology was not effective to reduce patients' agitation after open-heart surgery. Furthermore, a systematic review of the relevant studies failed to support the effectiveness of reflexology for patients with different medical conditions [30].

Patients with chronic problems experience multiple health issues related to their disease and treatments. Traditional treatments, such as surgery and long-term pharmacological interventions, may cause additional complications for patients with chronic diseases [31]. It is important to design creative and innovative interventions based on patients' conditions and unmet needs [32]. In general, studies that examined the effects of foot reflexology on different groups of patients reported contradictory results. Moreover, the effects and designs of foot reflexology interventions in craniotomy patients have not been widely studied. Future studies are needed to confirm the effectiveness of foot reflexology and the effective designs of this intervention in patients with different health conditions.

We recruited the participants from a single hospital. Recruiting participants from multiple sites in future studies can increase the generalizability of the findings. There were several confounding factors that we did not control. For example, we did not collect data on the amount of blood loss during the surgery or in the ICU. We also did not collect data regarding analgesic medications used in the operating room. These factors may have affected the study results and



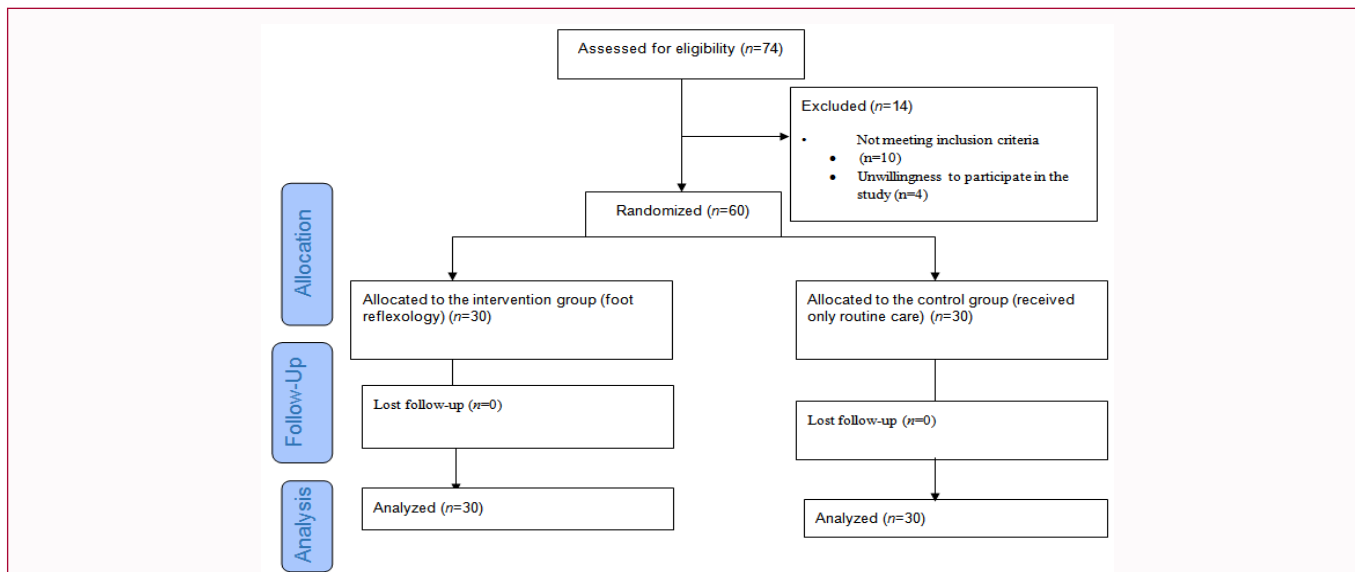


Figure 1: CONSORT flow diagram.

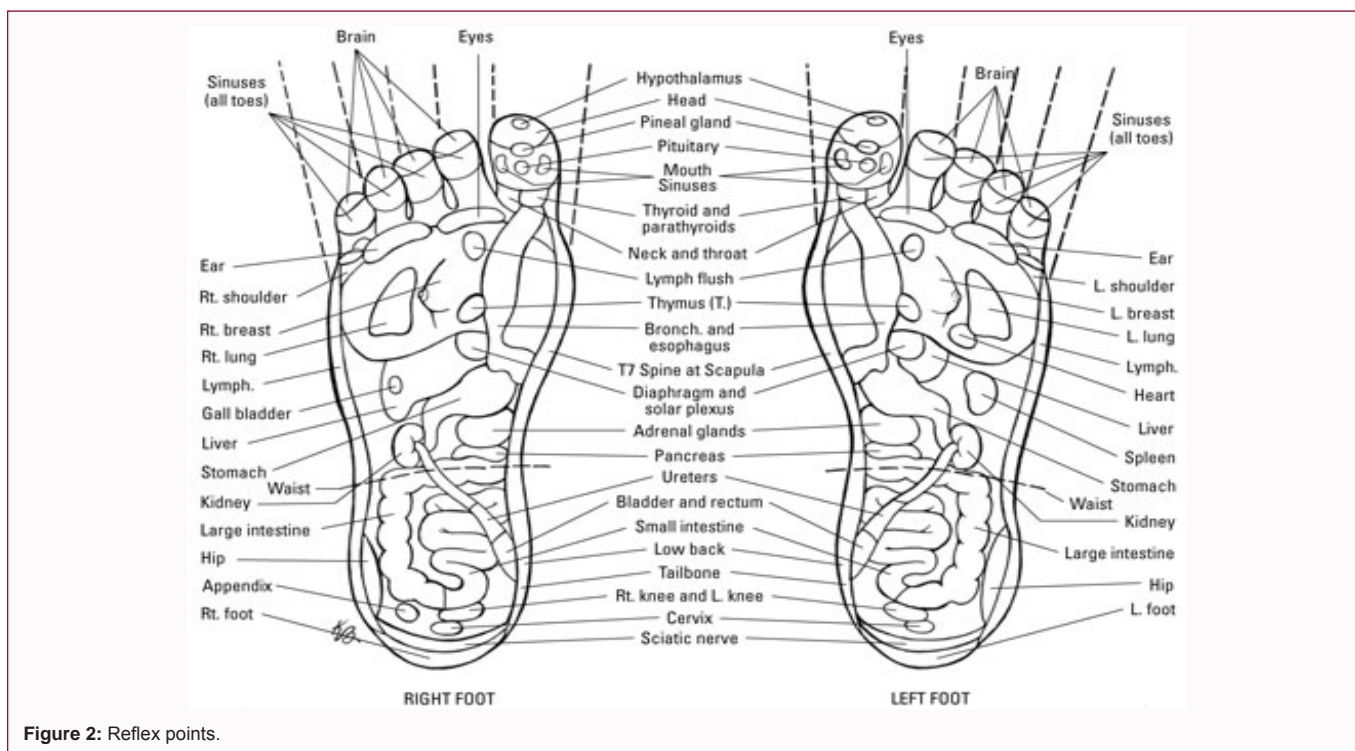


Figure 2: Reflex points.

are worth considering in future studies. For future investigations, we also recommend studies to examine the effectiveness of reflexology on other patients' outcomes, such as the length of hospital stay and patient acceptance and satisfaction.

### Conclusion

In this study, we found that foot reflexology was effective on the time of full consciousness recovery and ventilation support withdrawal. We recommend this intervention as an effective nursing intervention for ICU and craniotomy patients. However, there is a need for further studies to verify the results of the present study.

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### Author Contributions

NMA and MI participated in the Conceptualization, Project administration, Supervision, Writing original draft; MI data gathering, Project administration, Writing original draft; Writing review & editing; NMA and MG participated in the methodology, and Supervision, ZR and ZS participated in the data creation, Formal analysis and results interpretation, writing original draft.

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