### **Original Article**



# Ofuro bath effects on relaxation and weight gain of premature newborns in neonatal care units

## Efeitos da ofuroterapia no relaxamento e ganho de peso em recém-nascidos prematuros na unidade de cuidados neonatal

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RESUMO | INTRODUÇÃO: Os métodos de banho humanizado

são os mais indicados na assistência de recém-nascidos pré-ter-

mos (RNPT's) de baixo peso, por proporcionar a estes uma melhor

resposta adaptativa ao ambiente extrauterino, contribuindo para

melhora na organização dos sistemas comportamentais, motores

e fisiológicos, assim como no desenvolvimento saudável dessa po-

pulação, através do relaxamento decorrente da imersão do corpo

em água morna, evitando assim o gasto energético. OBJETIVO:

Investigar os efeitos da ofuroterapia no relaxamento e ganho de

peso de RNPT's, clinicamente estáveis, admitidos em uma Unidade

de Cuidados Intermediários Neonatais (UCIN). MÉTODO: Trata-se

de um estudo quantitativo, de caráter descritivo e quase explora-

tório, com uma amostra de 10 recém-nascidos admitidos na UCIN

Canguru, do Hospital Maternidade Almeida Castro, Mossoró/RN,

Brasil. A população estudada, de baixo peso, foi submetida a 2 ses-

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ABSTRACT | INTRODUCTION: Humanized bathing methods are the most indicated for the care of low weight premature newborns (PTNB), for providing them with a better adaptive response to the extra-uterine environment, contributing to the improvement of the organization of behavioral, motor and physiological systems, as well as to the healthy development of this population, through relaxation resulting from immersion of the body in warm water, thus avoiding energy expenditure. OBJECTIVE: Investigate the effects of ofuro bath on relaxation and weight gain of PTNB, clinically stable, admitted to a Neonatal Intermediate Care Unit (NICU). METHOD: This is a quantitative, descriptive and almost exploratory study, with a sample of 10 newborns admitted in NICU kangaroo of Almeida Castro Maternity, Mossoró/RN, Brazil. The studied population, of low weight, was submitted to 2 weekly sessions of application of the method, for 10 minutes on alternate days. RESULT: There was no statistically significant difference in weight gain (p=0,127). In the hemodynamic variables, the study population showed an increase in respiratory frequency on day 2 (p=0,028), and decrease in body temperature on day 1 (p=0,014) and on day 2 (p = 0.005). Regarding the evaluation of pain, there were no statistically significant differences in the two days. CONCLUSION: Despite being observed the relaxation provided to the study population by applying the method, no statistically significant data were obtained to prove the relationship between the relaxation provided by ofuro bath and the weight gain of the PTNB studied in the present study.

**KEYWORDS:** Humanization of assistance. Prematurity. Neonatology. Complementary therapies. Hydrotherapy.

sões semanais de aplicação do método, por 10 minutos em dias alternados. RESULTADOS: Não houve diferença significativa estatisticamente no ganho de peso (p=0,127). Nas variáveis hemodinâmicas, a população estudada apresentou aumento na frequência respiratória (FR) no dia 2 (p=0,028), e diminuição da temperatura corporal no dia 1 (p=0,014) e no dia 2 (p=0,005). Em relação a avaliação da dor, não houve diferenças significativas estatisticamente em ambos os dias. CONCLUSÃO: Apesar de ser observado o relaxamento proporcionado à população do estudo através da aplicação do método, não foram obtidos dados significativamente estatísticos que comprovem a relação entre o relaxamento proporcionado pela ofuroterapia e o ganho de peso dos RNPT's estudados no presente estudo. PALAVRAS-CHAVE: Humanização da assistência. Recém-

nascido prematuro. Neonatologia. Terapias complementares. Hidroterapia.

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### Introduction

One in ten births worldwide occurs before completing the 37th week of gestation. According to the World Health Organization (WHO), more than 1 million children die each year due to complications of preterm birth. Thus, prematurity becomes the most important cause of death in the first critical month of life. Brazil, among all countries, has the 10th highest number of preterm births, with 279,000 deliveries per year, which corresponds to 9.2% of alive births<sup>1-4</sup>.

Prematurity is due to termination of pregnancy before the fetus is adequately matured for extrauterine life, causing the birth of the newborn (NB) with variable risks<sup>5,6</sup>. The transition of the newborn between the intrauterine and extrauterine environment is a delicate period marked by several changes. This adaptation requires a large energy expenditure and this, associated with gastrointestinal immaturity and frequent oral dysfunctions that hinder nutrition, may result in difficulty in gaining body weight<sup>3,7,8</sup>.

During the period of hospitalization in the Neonatal Intermediate Care Unit (NICU), premature newborns are exposed to uncomfortable situations, which can trigger behavioral and physiological stress responses, in addition to respiratory, cardiovascular, immunological, hormonal modifications, among others. Thus, the exposure of NB to the performance of invasive techniques and procedures may cause impacts that will affect their quality of life, as well as their neuropsychomotor development<sup>8-10</sup>.

Due to the degree of complexity in the care of the premature newborn (PTNB) in NICU, there is a need to use multidisciplinary therapeutic techniques and resources based on humanized care. Thus, the Ministry of Health (MS) of Brazil, through the Ordinance GM/MS n° 1,683, 12 of July 2007, introduces in the Brazilian health units the Kangaroo care, which is a model of perinatal assistance aimed at improving the quality of care, bringing together humanized and biopsychosocial intervention strategies, among which the ofuro bath stands out<sup>8,11</sup>.

The ofuro therapy, also known as the "ofuro bath", consists in a hydrotherapy modality, which is used as a conduct to humanize the assistance to clinically stable PTNBs. Through body immersion, positioning and

water properties, the application of ofuro therapy in PTNBs will cause sensations similar to the intrauterine space, such as safety and relaxation, in addition to favoring them an appropriate neuropsychomotor and affective development. 2.12-16.

Studies have pointed out that the humanized bathing methods, in addition to being the most suitable for assisting low weight PTNBs, provide them with a better adaptive response to the extrauterine environment, contributing to the improvement in the organization of behavioral, motor and physiological systems, as well as in healthy development of this population, through relaxation resulting from immersion of the body in warm water, thus avoiding energy expenditure<sup>17,18</sup>.

Therefore, the present study has as main objective to investigate the effects of ofuro therapy on the relaxation and weight gain of PTNBs, clinically stable, admitted to a NICU. The specific objectives are: To identify the maternal and child profile of the PTNBs included in the study; analyze the body weight of the PTNB; analyze the behavioral state of PTNB pain before, during and after applying the method; and assess the hemodynamic clinical status of PTNB before and after applying the method.

### **Methods**

This is a quantitative, descriptive and almost exploratory study. The Ethics and Research Committee (CEP) of Universidade Potiguar approved the research (Opinion Number: 2,823,297; CAAE 94767018.3.0000.5296). collection Data performed at Hospital Maternity Almeida Castro (HMAC), located in Juvenal Lamartine Street, number 344, Bom Jardim - Mossoró/RN, Brazil, in the period between 23 August and 23 October 2018. The target population of this study was low weight PTNBs admitted to the Kangaroo Neonatal Intermediate Care Unit (UCINCa). The study population was selected using the convenience sampling technique, which was chosen due to the high turnover of PTNBs at UCINCa. All PTNBs who passed through the sector during the period of this study were invited to participate, being necessary to meet the inclusion criteria previously established.

### **Inclusion and Exclusion Criteria**

As inclusion criteria, PTNBs were included: who had body weight on the first day of intervention equal to or above 1,500g; who were hemodynamically stable; who were not using Continuous Positive Airway Pressure - CPAP or mechanical ventilation; who had a medical prescription for physiotherapy. As exclusion criteria, PTNBs were excluded: who had conditions such as hyperthermia, open wound, infectious disease, uncontrolled seizures historic, use of peripheral venous catheter and hypotension or hypertension; who were being treated with phototherapy; who worsened in their clinical condition after being included in the study; who did not adapt to the ofuro therapy program proposed in this study.

Initially, 24 low weight PTNBs were evaluated and submitted to ofur otherapy. Of these, 14 were excluded from the study: 7 did not adapt to the method, showing irritation and tears during the first 2 minutes of application of the method; 1 was transferred to the Conventional Neonatal Intermediate Care Unit (UNCINCO); 3 were discharged from the hospital after the first session; and 3 mothers gave up applying the method after the first session. Thus, 10 PTNBs were included in the present study. (Figure 1).

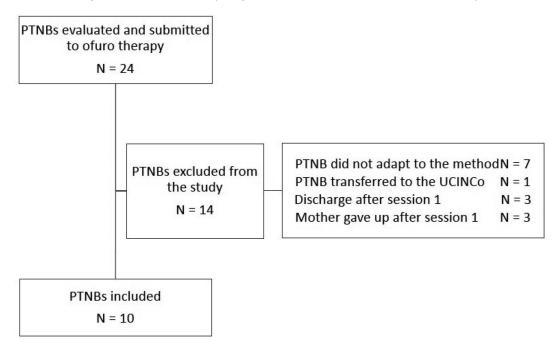


Figure 1. Flowchart of the study design, of the PTNBs included and excluded from the study.

Source: research data, 2018.

### **Procedures**

Initially, the mother, or legal guardian, of the PTNB was informed about the purpose of the study, as well as the benefits of applying the method. After that, it was asked for her authorization for the participation of the PTNB in the study, by signing the Free and Enlightened Nod Term (Termo de Assentimento Livre e Esclarecido – TALE). Then, the PTNB was evaluated and had his Follow-up Form filled out.

PTNBs were evaluated under behavioral clinical aspects, where the following variables were verified: Peripheral Oxygen Saturation (SpO2) and Heart Rate (HR), verified via portable pulse oximeter (Bioland®), model AT101C; Respiratory Rate (RR), observed through thoracoabdominal movements for 1 minute, with the assistance of the stopwatch (Kikos®), model CR20; Body Temperature, observed with the assistance of the Incoterm's ecologic clinical thermometer; Scale "Neonatal Infant Pain Scale - NIPS", this is used to assess the level of pain in NBs 5 minutes before and 5 minutes after the application of the method; "Neonatal Facial Coding System - NFCS", used to assess the level of pain in NBs during the session, in 5 minutes of application of the method.

In the NIPS evaluation scale, behavioral signs are considered: facial mimicry, crying and motor activity, being its maximum score 7, and pain is pointed out when the value is greater than or equal to 4 points<sup>12, 21</sup>. In the NFCS evaluation scale, the pain assessment is validated through eight facial movements, considering 8 its maximum score, in which indicative of pain is the value equal to or greater than 3 points<sup>22,23</sup>.

The PTNB, which was hemodynamically stable in the initial evaluations, was submitted to the application of the Ofuro therapy, where the Ofuro baby tub was used (Adoleta Bebê®), with a capacity of 17.5 liters and, dimensions of 37cm x 37cm x 34 cm (height x width x depth). The bathtub was positioned on a table with a height of 90cm and then the PTNB was positioned within it in an upright position, with upper limb restraint (MMSS) and lower limbs (MMII) in flexor pattern, your body being wrapped by a diaper (Cremer®) in 100% cotton fabric, with dimensions 70cm x 70cm. Heated water was used (between 36.5°C and 37.0°C), being its temperature verified with the assistance of the bath thermometer (Buba®), model BUBA5240. The body of the PTNB was immersed to shoulder height, where in the floating position, light movement was performed in the water, supported by the applicator who, in your turn, positioned his hands between the mandible and the cervical region of the PTNB. The application of the method lasted a total of 10 minutes. At the end of the session time, the PTNB was removed from the ofuro baby tub and wrapped by a bath towel, in fuzzy fabric 100% cotton, with dimensions 50cm x 50cm; and after 5 minutes, the final vital signs were checked.

### **Interventions**

Two researchers applied the method and each PTNB included in the study was submitted to two weekly sessions of ofuro therapy, the second application is always performed on the second day after the first application, thus establishing the application on alternate days. Applications were performed at times between 10:30 AM and 12:30 PM, thus meeting the criterion of routine bathing hours of the HMAC itself. The ofuro baby tub was sanitized with neutral soap and alcohol at 70%, before and after each use. The diapers and towels used during the application of the method were washed and sterilized following the hygiene standards of the HMAC. The nursing team of the sector measured the body weight of the PTNB and the researchers recorded the value obtained on the days of application of the method.

### **Statistical Analysis**

The descriptive analysis was performed with the distribution of quantitative variables in mean (±), standard deviation (SD) and qualitative variables in frequency and percentage. The normal distribution of variances was carried out using the Shapiro-Wilk test. It used the paired t-test or Wilcoxon test to compare the variables in the pre- and post- intervention moments. The analysis was executed in the software Statistical Package for Social Science (SPSS), Chicago, IL, USA, version 20.0, considering a significance level of p<0.05 and confidence interval (CI) of 95%.

### **Results**

The PTNBs included in the present study were mostly female (70%), with their birth predominantly through cesarean section (70%). Regarding the historic of pregnancy, most mothers did not present any disease during this period (90%), as well as there were no complications at the time of delivery in the vast majority of cases (90%), as can be seen in Table 1.

Table 1. Maternal-infant Data

VARIABLES	N = 10	%
SEX		
Female	7	70%
Male	3	30%
TYPE OF DELIVERY		
Cesarean	7	70%
Natural	3	30%
DISEASES IN PREGNANCY		
Do not have	9	90%
Hypertension / Preeclampsia	1	10%
COMPLICATIONS IN CHILDBIRTH		
Do not have	9	90%
Amniotic Fluid Leak	1	10%
CONGENITAL DISEASES		
Do not have	9	90%
Pneumoperitoneum	1	10%

Source: research data, 2018.

The mothers of the PTNBs included in the study presented a mean age of 25 years, and the gestational age with a mean age of 32 weeks. According to table 2, it can also observe the average body weight and height at birth of PTNBs.

Table 2. PTNBs' Birth Data

VARIABLE	Mean ± SD	P
MATERNAL AGE	25.9 ± 7.1	0.232
GESTATIONAL AGE	32.7 ± 2.4	0.007*
BIRTH WEIGHT	1876.2 ± 473.9	0.149
HEIGHT	42.0 ± 2.8	0.708

<sup>\*</sup> Statistically significant value.

Source: research data, 2018.

The population of this study, according to Graph 1, showed a variation in the mean of body weight between the days of application of the method, where on day 1 the mean was 1928.5±243.6 grams, and on day 2 the mean was 1957.5±221.7 grams, and this increase was not statistically significant (p=0.127).

Graph 1. PTNBs' Average Body Weight



Source: research data, 2018.

PTNBs were evaluated in their hemodynamic clinical aspects, according to the data presented in Table 3. According to the results, there was statistical significance only in the variables: body temperature (in day 1 and 2) and respiratory rate (in day 2).

Table 3. Behavior of hemodynamic variables

VARIABLE	Mean ± SD	Mean ± SD	
	INITIAL	FINAL	— р
HEART RATE (HR)			
Day 1	129.2 ± 17.7	126.6 ± 15.8	0.310
Day 2	127.7 ± 21.7	124.9 ± 16.7	0.639
RESPIRATORY RATE (RR)			
Day 1	41.8 ± 8.5	46.1 ± 6.7	0.252
Day 2	46.0 ± 11.1	52.1 ± 9.8	0.028*
PERIPHERAL OXYGEN SATURATION (SpO2)			
Day 1	93.8 ± 3.5	96.6 ± 2.1	0.112
Day 2	95.5 ± 3.7	94.7 ± 4.0	0.542
BODY TEMPERATURE (T°)			
Day 1	36.2 ± 0.3	35.6 ± 0.4	0.014*
Day 2	36.2 ± 0.3	35.5 ± 0.4	0.005*

<sup>\*</sup> Statistically significant values.

Source: research data, 2018.

In the assessment of the pain level of PTNB, using the assessment scales NIPS and NFCS, there were no statistically significant differences in the evaluations in both scales on the days of application of the method, as can be seen in the data presented in Table 4.

Table 4. PTNBs' level of pain assessment (NIPS e NFCS)

Mean ± SD	Mean ± SD	Р
INITIAL	FINAL	r
0.7 ± 2.2	0.7 ± 2.2	0.317
0.7 ± 2.2	0.6 ± 1.0	1.000
	Mean ± SD	Р
	TOTAL	r
	0.5 ± 1.0	0.180
	0.1 ± 0.3	0.160
	INITIAL 0.7 ± 2.2	INITIAL   FINAL

Source: research data, 2018.

### **Discussion**

According to the MS, at birth, some NBs have characteristics associated with a higher risk of death and illness, among which are prematurity (< 37 weeks of gestational age), and low birth weight (< 2,500 g), the latter being the most important isolated risk factor for infant mortality<sup>19</sup>. Thus, the PTNBs included in the present study presented profiles related to these characteristics. Regarding the body weight gain presented in the study after the application of the method, although it is not statistically significant, it is believed this may have been influenced by the application of this, because the body relaxation provided by the immersion of the body in heated water, reduces the stress levels of the PTNB and also assists in reducing energy expenditure, causing it sensations that are similar to those felt in the intrauterine environment. In the present study, the mothers and the nursing team responsible for the care of PTNBs reported, spontaneously, that after the application of the method the PTNBs had behavioral changes, such as greater relaxation and decreased irritability, as well as improvement in the sleep cycle, which is longer after the intervention.

Nevertheless, the weight gain showed in the present study cannot be considered exclusively due to the application of the method, because in addition to the small sample, making it difficult to achieve a more accurate result, there are other multi-professional care and recommended by the Kangaroo care, that can also assist in this gain and that were also provided to the PTNBs in this study during the period of application of the method.

A study conducted in an UCINCo of the Regional Hospital of Mato Grosso do Sul investigated the influence of hydrotherapy in bathtub on body weight gain, in 30 PTNBs, where they were submitted to 2 sessions of the method, lasting 10 minutes. In general, the study observed that there was a significant increase in body weight over the days of intervention<sup>3</sup>. It is believed that this result, different found in the present study, is more conclusive due to the fact that the number of PTNBs included in this is higher, achieving statistically significant data.

Another study aimed to identify the care technologies used in NICU in Federal University Hospitals in southeastern Brazil, points to ofuro therapy as a new prominent method among the new technologies applied in neonatal care, because the relaxation that the method provides to PTNB facilitates breastfeeding and, consequently, body weight gain<sup>20</sup>.

In the present study, when analyzing the behavior of hemodynamic variables HR, RR, SpO2 and T°, although these do not present statistical significance in most of the time, it was observed that the application of the method did not present risks to PTNBs in relation to the stability of vital signs. Thus, going against what was described in another study that, after applying the method to 12 clinically stable PTNBs admitted to a NICU, showed that the method was also safe in relation to vital signs<sup>14</sup>.

Regarding the HR means of the present study, a decrease was observed at the end of the application of the method on both days, although there is no statistical significance in relation to these differences. Thus, a similar result was found in another study with 21 PTNBs admitted to the NICU, evidencing that after the application of the method, the studied population presented a decrease in HR, but there was also no statistical difference. However, clinically there were favorable responses to the conduct, where it was observed that during the application of the technique

the neonates remained calm and relaxed, and showing comfort during the conduct<sup>13</sup>.

In your study, SILVA<sup>3</sup>, reports that HR did not present immediate alteration, and this variable decreased 30 minutes after the intervention. She also describes that there was no increase in heart rate, because the hydrostatic pressure in the immersion in the bath bucket was not enough to increase this and that the heated water may have been an important factor for the decrease in HR within 30 minutes of the application of the method.

Regarding the means of RR in the present study, on day 1, the mean did not present statistically significant difference. On day 2, the mean presented a statistically significant difference. Therefore, it is believed that the difference between the initial and final RR is related to the hydrostatic pressure of the water, which exerts greater intrapleural pressure and, consequently, increases respiratory work. Also in the present study, it was observed that some PTNBs, when they were removed from the water due to the end of the time of application of the method, they presented behavioral change, such as crying and irritability, thus being this triggering factor in increased respiratory work. Thus, it can be observed that the application of the method although relaxing for PTNBs that adapt to the aquatic environment during application, may cause irritability and, consequently, increased respiratory work of these at the time of immersion out of the body of water, therefore it is necessary that strategies be considered and adopted so that in cases where this happens, can be reduced the handling time of these PTNBs after applying the method and minimize not to lose the body relaxation that was provided by the method.

In the study of SILVA<sup>3</sup>, there were no significant changes in RR after the application of the method. The author reports that the PTNBs submitted to the method had no respiratory alterations, because the hydrostatic pressure in the bath bucket is not enough to cause changes in thoracic displacement. It also reports that the absence of immediate response in respiratory parameters may be related to immaturity of pulmonary structures, for being in the process of formation and development.

The study of VIGNOCHI<sup>14</sup>, evidences that the PTNBs' respiratory rate showed a significant reduction after the application of the method, especially one hour

after the end of the procedure, believing this finding may be linked to behavioral changes to a stat of deep sleep, as well as by pain reduction. This finding corroborates the observations made in the present study, where in some cases the PTNBs fell asleep during the application of the method.

In relation to the means of the SpO2 of the present study, as can be observed, although there was an increase in this on day 1, there were no statistically significant differences in the evaluation of this variable on both days.

In the study of VIGNOCHI<sup>14</sup>, shows that after the application of the method, there were a statistically significant increase in the means of SpO2 of the PTNBs, especially one hour after application, believing this is related to the reduction of crying and pain, since before the application of the method, the population studied was weeping and agitated.

The study of SILVA<sup>3</sup>, reports that there were no significant changes in SpO2 after the application of the method. The author states that the hydrostatic pressure in the bath bucket is insufficient to cause an increase in venous return, justifying this with the fact that in their study the PTNBs had no increase in blood flow, since there were also no immediate changes in HR.

In relation to the mean of body temperature (measured in Degrees Celsius) of the present study, it is observed that the differences in the means of this variable presented statistical significance. It was also observed that the water temperature remained constant during the application of the method (mean 37 °C), thus preventing the PTNB from decreasing his body temperature due to the influence of water temperature. However, after the PTNBs outflow from the water, they were not immediately heated, because the mothers preferred to perform the care related to their clothing, thus not immediately performing skin-to-skin contact recommended by the Kangaroo mother care. As in the present study, the final temperature was only checked 5 minutes after the PTNB departure from the bathtub, it is believed this time interval is enough for the reduction in the their body temperature. Thus, it is evident that the loss of temperature of the PTNB after application of the method can be avoided, to do so it is necessary to minimize the handling time of the PTNB after his outflow from the water.

TOBINAGA<sup>4</sup> reports that in his study, there was no significant difference in the temperature of PTNBs before and after the application of the method. However, the author evidences a finding that corroborates that of the present study, in which it exposes that if the water temperature is kept close to the temperature of NBs, the mechanisms of convection and conduction do not cause heat loss.

In the study of VIGNOCHI<sup>14</sup>, the water temperature used in the application of the method was kept in 37°C. Therefore, the study also showed that the PTNBs' temperature remained within the normal standard, not suffering variations after the intervention. The author justifies that this finding may be related to water temperature, since it is kept close to NBs' temperature.

The population studied in the present study was initially present, in most of the time, with absence of irritation and crying. At the beginning of the application of the method, they were comfortable and safe in the aquatic environment, being observed through facial expressions, indicative of the occurrence of relaxation provided by heated water, justifying the fact that PTNBs sleep during the period of application of the method. With the end of the application of the method, although irritability is observed at the time of removal of the studied population from the aquatic environment, it was observed that after 5 minutes, they were drowsy, calm and relaxed. Thus, it is believed that the abovementioned facts justify the absence of differences in the means evaluated in the pain scales.

The finding of the present study corroborates with the study of TOBINAGA<sup>4</sup>, where the author describes that in your research there were no significant difference in the NIPS scale, but that the clinical relevance cannot be disregarded, since a zero score was observed in all PTNBs participants after the intervention, showing no pain and adverse responses to the procedure.

In your study, VIGNOCHI<sup>14</sup>, reported that the mean NFCS scale decreased significantly after the application of the method and describes that this result is due to the physiological effects of water, which provides muscle relaxation and pain relief<sup>14</sup>.

### **Conclusion**

With the present study, it can be concluded that ofuro therapy proved to be a safe humanized method, because it presents no risks in its application in clinically stable PTNBs admitted to NICU. Although the relaxation provided to the study population is observed through the application of the method, no statistically significant data were obtained to prove the relationship between the relaxation provided by ofuro therapy and weight gain of PTNBs studied in the present study. It is believed that this result is due to the short period of data collection established for the present study, as well as the number of established sessions, which resulted in a small sampling to obtain significantly statistical data. Nevertheless, the clinical relevance of the present study cannot be ruled out, because it can be observed that the method promotes relaxation to PTNBs that adapt to it, thus causing a decrease in stress levels and harmful stimuli, greater energy retention and, consequently, possible body weight gain. The application of the method also contributes to the humanization of assistance and comprehensive care of the study population.

Thus, it is suggested that further studies on the subject be conducted, in longer periods of time, with a larger sample and, if possible, with the existence of a control group, so that you can prove the relationship between relaxation and weight gain through the ofuro therapy. Through these, the effects and benefits of applying the method can be verified, with statistically significant data, in addition to contribute to support this application and make it more frequent in NICUs.

### **Author contributions**

GC e Almeida TVC participated in the conception, design, search and statistical analysis of the survey data, interpretation of the results and writing of the scientific article. Medeiros AIC participated in the statistical analysis of the research data, interpretation of the results and orientation of the research. Pinto MM participated in the orientation of the research.

### **Competing interests**

No financial, legal or political competing interests with third parties (government, commercial, private foundation, etc.) were disclosed for any aspect of the submitted work (including but not limited to grants, data monitoring board, study design, manuscript preparation, statistical analysis, etc.).

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