

# Maternal and perinatal parameters after non-pharmacological interventions: a randomised, controlled clinical trial

Parâmetros maternos e perinatais após intervenções não farmacológicas:

um ensaio clínico randomizado controlado

Parámetros maternos y perinatales luego de intervenciones no


farmacológicas: un ensayo clínico aleatorizado controlado

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## Descriptores

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## Abstract

**Objective:** To analyse the effects of warm shower, perineal exercises with a Swiss ball or both during the labour in maternal and perinatal parameters.

**Methods:** Randomised controlled trial with 101 low-risk birthing women admitted in two public midwife-led birth centres, between June, 2013 and February, 2014, with minimal age 18 years, full-term gestation, single live foetus in cephalic presentation, cervical dilation 3-8 cm, pain score  $\geq 5$ , without clinical or obstetric pathologies or mental illness, non-users of psychoactive drugs or synthetic or natural corticosteroids and who had not used tobacco, caffeine and analgesics in the previous two, four and six hours before inclusion in the study, respectively. The non-pharmacological interventions were for 30 minutes performed. Maternal and perinatal parameters were assessed before and 30 minutes after the interventions, including: maternal blood pressure, heart rate, respiratory rate, uterine contractions, cervical dilation, foetal heart rate, baseline, variability, accelerations and decelerations using cardiotocography and Apgar score (at the 1<sup>st</sup> and 5<sup>th</sup> minutes after birth); The participants were randomly assigned in group A warm shower (33), B Swiss ball (35) and C combined interventions (33).

**Results:** Concerning maternal parameters, systolic blood pressure was kept above 100 mmHg, with a little increase in the group B. Diastolic blood pressure decreased in all the groups, however was maintained above 70 mmHg. The heart rate decreased in the group B and C and was above 80 bpm. The respiratory rate was above 20 rpm in all groups after the interventions, while the cervical dilation before the interventions were in average 5.0 cm and increased 1.3 cm after the interventions in all groups. Concerning the foetal parameters, foetal heart rate was normal in more than 90% in all groups at both evaluation times, transient acceleration was present in more than 80% in all groups at both evaluation times and no decelerations were found before the intervention in approximately 58.4% of the cases. Decelerations were observed in 52.5% of the cases, mainly in the groups A and B. Variability was normal in more than 80% of the cases, and the Apgar score 7 at the first minute after birth was observed in 14 cases only. No significant differences were found in maternal blood pressure, pulse rate, foetal heart rate including the occurrence of transient accelerations, variability or decelerations and Apgar at the inter and intragroup analysis or by evaluation time. By comparing maternal parameters before and 30 minutes after the interventions, increased maternal respiratory rate ( $p=0.037$ ) and cervical dilation ( $p<0.001$ ) were found for the all intervention groups. At the intergroup analysis, group A ( $p=0.041$ ) and group C ( $p=0.021$ ) stimulated labour progression regarding the uterine contractions increased in comparison to the group B.

**Conclusion:** The interventions alone or in combination are a safe way for childbirth assistance as they do not result in negative effects on maternal and perinatal parameters.

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**Conflicts to interest:** Despite being Associate Editor for Acta Paulista de Enfermagem, Francisco AA was not involved in manuscript assessment.

## Resumo

**Objetivo:** Analisar os efeitos do banho quente, de exercícios perineais com bola suíça ou de ambos durante o trabalho de parto em parâmetros maternos e perinatais.

**Métodos:** Ensaio clínico randomizado controlado incluindo 101 gestantes de baixo risco admitidas em dois centros obstétricos entre junho de 2013 e fevereiro de 2014 com idade mínima de 18 anos, gestação a termo, feto único em apresentação cefálica, dilatação cervical entre 3 e 8 cm, escala de dor  $\geq 5$ , sem patologias clínicas ou obstétricas ou doença mental, não usuárias de drogas psicoativas ou de corticosteroides naturais ou sintéticos, e que não fizeram uso de produtos de tabaco, cafeína e analgésicos duas, quatro e seis horas antes de serem incluídas no estudo. Os parâmetros maternos e perinatais foram avaliados antes e 30 minutos após as intervenções, incluindo: pressão arterial materna, frequência cardíaca e respiratória, contratilidade uterina, dilatação cervical, frequência cardíaca fetal, linha de base, variabilidade, acelerações e desacelerações usando cardiocografia e escala de Apgar (no 1º e 5º minutos após o nascimento). Os participantes foram alocados aleatoriamente em três grupos: A) banho quente (33); B) bola suíça (35); e C) intervenções combinadas (33).

**Resultados:** Em relação aos parâmetros maternos, a pressão arterial sistólica foi mantida abaixo de 100 mmHg, com um pequeno aumento no grupo B. A pressão arterial diastólica diminuiu em todos os grupos, mantendo-se, contudo, acima de 70 mmHg. A frequência cardíaca apresentou diminuição nos grupos B e C e esteve acima de 80 bpm. A frequência respiratória ficou acima de 20 rpm em todos os grupos após as intervenções, enquanto a dilatação cervical foi de 5,0 cm em média antes das intervenções com aumento de 1,3 cm após as intervenções em todos os grupos. Em relação aos parâmetros fetais, 90% dos fetos em todos os grupos apresentaram frequência cardíaca normal nos dois períodos avaliados, acelerações transitórias estiveram presentes em mais de 80% dos fetos em todos os grupos em ambos os períodos analisados. Não foi constatada desaceleração antes da intervenção em aproximadamente 58,4% dos casos. Observou-se desacelerações em 52,5% dos casos, principalmente nos grupos A e B. A variabilidade foi normal em mais de 80% dos casos, e um valor  $< 7$  na escala de Apgar no primeiro minuto após o nascimento só foi observado em 14 casos. Não foram encontradas diferenças significativas na pressão arterial e frequência cardíaca materna e fetal, incluindo a ocorrência de acelerações transitórias, variabilidade ou desacelerações e valores na escala de Apgar tanto na análise inter e intragrupo quanto nos períodos avaliados. Ao comparar os parâmetros maternos antes e 30 minutos após as intervenções, observou-se aumento na frequência respiratória ( $p=0,037$ ) e na dilatação cervical ( $p<0,001$ ) em todos os grupos de intervenção. Na análise intergrupo, a progressão do trabalho de parto estimulada dos grupos A ( $p=0,041$ ) e C ( $p=0,021$ ) em relação às contrações uterinas aumentou em comparação com o grupo B.

**Conclusão:** As intervenções isoladas ou combinadas são uma forma segura de assistência ao parto uma vez que elas não afetam negativamente os parâmetros maternos e perinatais.

## Resumen

**Objetivo:** Analizar los efectos del baño caliente, de los ejercicios perineales con pelota suiza o de ambos durante el trabajo de parto en parámetros maternos y perinatales.

**Métodos:** Ensayo clínico aleatorizado controlado con 101 mujeres embarazadas de bajo riesgo, admitidas en dos centros obstétricos entre junio de 2013 y febrero de 2014. Todas ellas tenían edad mínima de 18 años, gestación a término, feto único en presentación cefálica, dilatación cervical entre 3 y 8 cm, escala de dolor  $\geq 5$ , sin patologías clínicas ni obstétricas ni enfermedad mental, no usuarias de drogas psicoactivas o de corticosteroides naturales o sintéticos, y no habían consumido productos de tabaco, cafeína o analgésicos dos, cuatro y seis horas antes de ser incluídas en el estudio. Los parámetros maternos y perinatales se evaluaron antes de las intervenciones y 30 minutos después e incluyeron: presión arterial materna, frecuencia cardíaca y respiratoria, contractilidad uterina, dilatación cervical, frecuencia cardíaca fetal, línea basal, variabilidad, aceleraciones y desaceleraciones usando cardiocografía y escala de Apgar (en el 1º y 5º minuto después del nacimiento). Las participantes fueron asignadas aleatoriamente en tres grupos: A) baño caliente (33); B) pelota suiza (35); y C) intervenciones combinadas (33).

**Resultados:** Con relación a los parámetros maternos, la presión arterial sistólica se mantuvo inferior a 100 mmHg, con un pequeño aumento en el grupo B. La presión arterial diastólica bajó en todos los grupos y se mantuvo superior a 70 mmHg. La frecuencia cardíaca presentó reducción en los grupos B y C y fue superior a 80 ppm. La frecuencia respiratoria fue superior a 20 rpm en todos los grupos después de las intervenciones, mientras que la dilatación cervical fue en promedio 5,0 cm antes de las intervenciones, con un aumento de 1,3 cm luego de las intervenciones en todos los grupos. Con relación a los parámetros fetales, el 90% de los fetos en todos los grupos presentaron frecuencia cardíaca normal en los dos períodos evaluados, hubo aceleraciones transitorias en más del 80% de los fetos en todos los grupos, en ambos períodos analizados. No se constató desaceleración antes de la intervención en el 58,4% de los casos aproximadamente. Se observaron desaceleraciones en el 52,5% de los casos, principalmente en el grupo A y B. La variabilidad fue normal en más del 80% de los casos y se observó un valor  $< 7$  en la escala Apgar en el primer minuto después del nacimiento en 14 casos. No se encontraron diferencias significativas en la presión arterial y frecuencia cardíaca materna y fetal, inclusive en casos de aceleraciones transitorias, variabilidad o desaceleraciones y valores en la escala de Apgar, tanto en el análisis inter e intragrupo como en los períodos evaluados. Al comparar los parámetros maternos antes de las intervenciones y 30 minutos después, se observó un aumento de la frecuencia respiratoria ( $p=0,037$ ) y de la dilatación cervical ( $p<0,001$ ) en todos los grupos experimentales. En el análisis intergrupo, el progreso del trabajo de parto estimulado del grupo A ( $p=0,041$ ) y C ( $p=0,021$ ) con relación a las contracciones uterinas aumentó en comparación con el grupo B.

**Conclusión:** Las intervenciones aisladas o combinadas son una forma segura de asistencia al parto dado que no afectan negativamente los parámetros maternos y perinatales.

## Introduction

Although childbirth is among the most common causes of severe pain, this association is different in

various cultures and social groups, involving cultural, environmental, emotional and existential factors associated with past experiences and the context in which pain is perceived.

In the presence of acute pain, women during the childbirth may present with physiological manifestations, such as increased blood pressure, heart rate and respiratory rate, sweating, nausea and vomiting, among others.<sup>(1)</sup> Also, stress and anxiety, which are usually present during labour, appear to be mechanisms of adjustment and defence of the body and activate a neuroendocrine response, which will result in an overload of the respiratory, circulatory and metabolic systems and may have an impact on the foetus or the newborn.<sup>(2)</sup>

Interventions that minimise the consequences of pain on the course of labour and increase women pain tolerance at this childbirth stage are often necessary.

The use of pain relief methods is relevant to obstetric care and should be encouraged in addition to promoting comfort and contribute to the quality and safety birth.<sup>(3,4)</sup>

Adoption of these practices is intended to make childbirth as natural as possible and to reduce the number of interventions, medication administrations and unnecessary caesarean sections.<sup>(3-5)</sup> They also can enable women as the protagonist of the labour and birth, ensuring that this process is a milestone for women's and their family, and promoting changes on the behaviour for healthcare professionals involved with childbirth assistance and the community.<sup>(5)</sup>

Sometimes, the use of elements that stimulate the senses and invasive practices increase pain, while freedom of movement, companionship, use of a warm shower and perineal exercises with a Swiss ball, either alone or in combination, are related to comfort and empirical reduction in pain.

Hydrotherapy, particularly warm shower, is widely used during labour and are well accepted by women. The warm shower provide comfort, relaxation and improvement of pain, anxiety and stress, increases cervical dilation, decreases blood pressure and reduces the use of pharmacological analgesia.<sup>(3,6)</sup>

The Swiss ball is used during labour for performing perineal exercises as a way of stimulating the cervical dilation, progression foetal through the pelvis and perineal relaxation muscles, resulting in pain relief and comfort in the perineum.<sup>(7)</sup>

However, few studies have analyzed the direct relationship between the effects of non-pharmacological methods on clinical and neuroendocrine responses of stress and uterine contractility as well as the clinical conditions of the foetus and newborn.

This study aims to analyse the effects of warm shower, perineal exercises with a Swiss ball or both during the labour in maternal and perinatal parameters.

## Methods

### Study design

This randomised controlled trial is nested in the main study "Effect of non-pharmacological interventions during labour on women's perception of pain, anxiety, clinical, obstetric and stress neuroendocrine parameters".<sup>(8)</sup>

### Participants

Low-risk birthing women admitted for labour and birth at the birth centre, minimal age 18 years, full-term gestation, single live foetus in cephalic presentation, cervical dilation 3-8 cm, pain score  $\geq 5$  on the visual analogue scale (0-10), without clinical or obstetric pathologies or mental illness, non-users of psychoactive drugs or synthetic or natural corticosteroids and who had not used tobacco, caffeine and analgesics in the previous two, four and six hours before inclusion in the study, respectively. Women indicated for elective caesarean section or who used analgesia for labour was excluded.

### Setting

Two public midwife-led birth centres in São Paulo, Brazil.

### Interventions

Data were collected from medical records, structured interviews and physical examination with the participants, between June, 2013 and February, 2014, from Monday to Friday for approximately twelve hours per day, by five trained nurse-midwives. The warm shower was performed in the standing position or seated with a warm water jet

directed towards the lumbosacral region at an average temperature of 37°C as measured with an Akso® digital thermometer in a single 30-minute session. Perineal exercises with a Swiss ball (60-cm diameter, Gynboll®) were performed on a firm and non-slip surface. Participants sat on the ball with her legs flexed at a 90° angle, knees apart, and the soles of the feet resting on the floor and performed pelvic thrust and rotation movements in a single session lasting for 30 minutes. The surface of the ball was covered by plastic PVC film (changed for each use), cleaned with soap, clean water and disinfected with 70% alcohol. The combined interventions, warm shower and perineal exercises with a Swiss ball, were performed simultaneously during a single 30-minute session using the same techniques for the individual interventions.

### Sample

Due to this is a nested study the sample size was calculated based on the primary outcome of the main study.<sup>(8)</sup> Therefore it was based on a pilot study with 15 low-risk birthing women who used the warm shower and perineal exercises with a Swiss ball, either alone or combined, using the visual analogue scale (VAS) and had compared the analgesic effects on women. The results showed a significant reduction in pain intensity during labour ( $p=0.0026$ ). A  $p$ -value  $<0.05$  was considered significant.<sup>(9)</sup> The sample should be of 137 women.

### Randomisation

The 137 eligible women were assessed to ensure they met the inclusion criteria and were asked to provide written informed consent. Before the randomisation, nine were excluded. Therefore, 128 participants were randomly allocated into one of three intervention groups: warm shower, perineal exercise with the Swiss ball and the combined intervention group. Opaque envelopes containing either card with numbers that corresponded to an intervention group and were randomly selected by women when they entered into the study. The participants and researchers were not aware regarding which treatment group would be allocated.

## Outcomes

Maternal and perinatal parameters assessed before and 30 minutes after the interventions.

### Maternal parameters

- **Blood pressure:** measured with a sphygmomanometer at the upper limbs when the participant was seated after five minutes rest. Estimating the systolic pressure by palpation of the radial pulse at the brachial artery and the stethoscope was placed on the cubital fossa, the cuff was rapidly inflated up to 20-30 mmHg above the estimated level and then slowly deflated. The systolic blood pressure was determined in the Korotkoff phase I (first sound heard, weak and followed by regular beats) and the diastolic blood pressure in Korotkoff phase V (disappearance of sound).
- **Pulse rate:** evaluated with the finger index pulp and middle fingers by the radial artery, counting beats for one minute.
- **Respiratory rate:** evaluated by counting respiratory movements for one minute. The measurements were taken after checking the pulse rate, without the participant being aware of the moment was performed to prevent an altered pattern
- **Uterine contractions:** assessed by manual uterine dynamics or cardiotocography to determine the frequency, intensity and duration.
- **Cervical dilation:** measured in centimetres through the vaginal exam.
- **Type of birth:** normal or caesarean section as recorded in the medical record or birth log book.

### Perinatal parameters

- **Foetal vitality:** measured by basal cardiotocography with the participants in the left lateral decubitus or semi-seated position, with transducers placed in the uterine fundus and foetal back region for 20 minutes. An MT-516 Toitu™ cardiotocograph was used, which was programmed to 1 cm/minute, on thermosensitive paper with simultaneous recording of foe-



tal heart rate (FHR), foetal body movements and uterine contractions. Readings: baseline FHR - mean level of the most horizontal and less oscillatory FHR segments. It is estimated in time periods of 10 minutes and expressed in beats per minute (bpm); FHR variability - oscillations in the FHR signal, evaluated as the average bandwidth amplitude of the signal in one-minute segments; transient accelerations - abrupt increases in FHR above the baseline, of more than 15 bpm in amplitude, and lasting more than 15 seconds but less than 10 minutes; decelerations - decreases in the FHR below the baseline, of more than 15 bpm in amplitude, and lasting more than 15 seconds.<sup>(9)</sup> These variable was evaluated by a specialist not included in the study who was blinded to the type of intervention and the time of recording (before/after the intervention).

- **Apgar score:** evaluated at 1 and 5 minutes after birth.

### Analysis

Data were processed by double entry. A *p*-value <0.05 was accepted as significant. Association between two categorical variables was assessed using the chi-square test or Fisher's exact test. Comparison of the means between the intervention groups was performed using the non-parametric Kruskal-Wallis test. To evaluate the behaviour of the numerical variables means, before and 30 minutes after each intervention group, repeated measures analysis of variances (ANOVA) was used, and in cases of violation of normality, the Wilcoxon and Kruskal-Wallis tests were used to compare the groups by evaluation time. To evaluate the behaviours of the contraction number and basal FHR over time, the intervention, age, colour, parity, use and type of inducer, amniotic membrane integrity at inclusion, ruptured membranes during collection and meconium were used as predictive variables in mixed linear regression models.

### Ethical and legal aspects

The women's participation was voluntary. This study was approved by the Research Ethics Committee of

Federal University of São Paulo (691.440) and registered at Brazilian Clinical Trials Registry (RBR-84xprt).

## Results

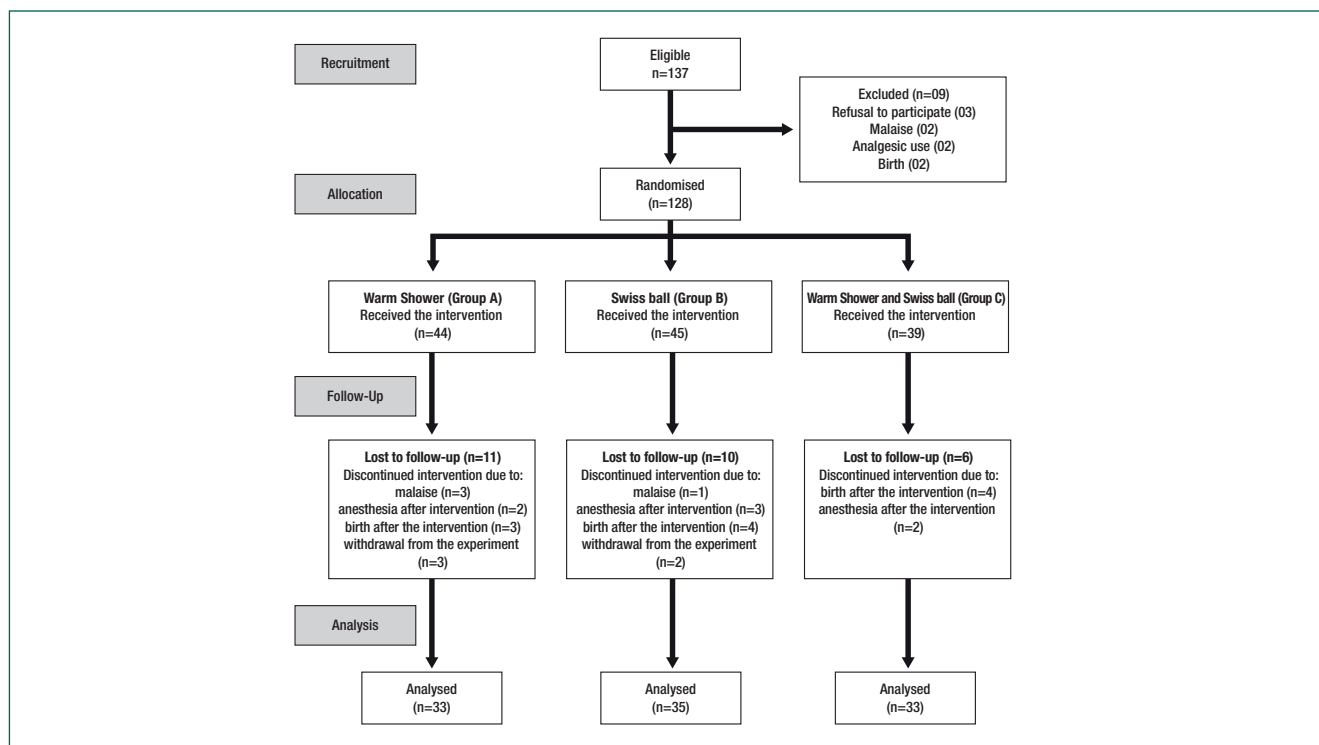
A 137 participants were recruited; 6.57% were excluded before randomisation due to malaise (1.46%), analgesic use (1.46%), refusal to participate (2.19%) and birth (1.46%). After randomised 128 participants, 27 were lost to follow-up: 8.59% in group A, 7.81% in group B and 4.68% in group C, and use of analgesic medication before the second evaluation (3.7%). Therefore, 101 participants distributed in group A (33), group B (35) and group C (33) were analysed (Figure 1).

The mean age of the participants was 25.5 years (SD=5.3 years), as a minimum age of 18 years and a maximum age of 42 years. Most women self-declared as white, had 8 to 11 years of education, were single and did not perform paid work. Most participants used a labour inducer, especially oxytocin, approximately one-third had ruptured amniotic membranes at inclusion, and only 6.9% (7/101) presented meconium staining of the amniotic fluid. Vaginal birth predominated, and only 11.9% (12/101) had a caesarean section. No significant difference was found between the groups regarding sociodemographic and obstetric variables.

No difference in the mean systolic and diastolic blood pressures, pulse rate, respiratory rate and dilation were identified between the intervention groups at each evaluation time.

At intragroup analysis, there were significant differences in all groups for respiratory rate and dilation, with higher mean values at 30 minutes after the intervention than the baseline means. At the intergroup analysis no significance was found (Table 1).

At the intragroup analysis, the number of uterine contractions increased in all groups after 30 minutes by intervention and statistical significance was found ( $p=0,041$ ) at the group A. At the intergroup analysis, no significant differences were found for the number of uterine contractions means at each evaluation times. No significant difference was found for FHR



**Figure 1.** Study design and allocation of participants based on the CONSORT flow diagram

**Table 1.** Comparison intra and intergroup of maternal variables before and after the interventions

Variable	Intervention (n=101)			p-value
	Warm shower	Swiss ball	Warm shower and Swiss ball	
	Mean (SD)	Mean (SD)	Mean (SD)	
Systolic blood pressure				
Before	115.76(13.53)	115.03(10.95)	113.85(10.43)	0.928
After 30 min	114.42(15.52)	115.26(10.29)	112.91(10.51)	0.724
Difference	-1.33(13.94)	0.23(8.17)	-0.94(6.90)	0.799
p-value	0.547	0.876	0.408	
Diastolic blood pressure				
Before	73.94(9.87)	73.80(8.55)	72.39(9.34)	0.752
After 30 min	72.55(10.02)	72.80(7.77)	72.09(9.39)	0.977
Difference	-1.39(8.96)	-1.00(8.43)	-0.30(7.10)	0.385
p-value	0.270	0.502	0.853	
Pulse				
Before	82.09(6.84)	83.29(9.58)	81.61(7.98)	0.653
After 30 min	82.09(10.75)	82.77(11.65)	80.73(11.30)	
Difference	0.00(10.23)	-0.51(10.39)	-0.88(11.28)	
p-value		0.662		
Respiration				
Before	18.82(2.78)	19.57(3.79)	19.45(3.09)	0.309
After 30 min	19.27(3.00)	20.31(3.13)	20.48(3.81)	
Difference	0.45(2.62)	0.74(2.98)	1.03(4.67)	
p-value		0.037		
Cervical dilation (cm)				
Before	4.79(1.08)	5.11(1.28)	4.94(1.22)	0.739
After	6.15(1.33)	6.31(1.55)	6.30(1.86)	
Difference	1.36(1.06)	1.20(1.11)	1.36(1.08)	
p-value		<0.001		

Difference = After 30 min-before

baseline's, and variability means by intra and intergroup or by evaluation time (Table 2).

The FHR was normal in more than 90% in all groups at both evaluation times. Also, no significant differences were observed between the groups before and 30 minutes after the interventions on FHR parameters, including transient acceleration, deceleration, type of deceleration and variability. However, transient acceleration was present in more than 80% in all groups at both evaluation times. No decelerations were found before the intervention in approximately 58.4% of the cases. After 30 minutes of the intervention, decelerations were observed in 52.5% of the cases, mainly in the groups who used the warm shower and perineal exercises with a Swiss ball separately but without statistical significance. The most frequent type of deceleration was an early deceleration in all groups and at both evaluation times. Variability was normal in more than 80% of the cases, with no significant differences between the groups and evaluation times. Regarding the newborn conditions, no differences in the mean Apgar scores at 1 and 5 minutes were observed by intervention group. Also, no differences in the dis-

**Table 2.** Maternal and foetal variables according cardiocography before and 30 minutes after the interventions

	Intervention (n=101)			p-value
	Warm shower	Swiss ball	Warm shower and Swiss ball	
	Mean (SD)	Mean (SD)	Mean (SD)	
Baseline FHR				
Before	139.27(10.46)	139.57(14.12)	141.36(9.95)	
After 30 min	142.30(9.04)	137.97(12.52)	141.76(9.04)	0.653
Difference	3.03(9.72)	-1.60(9.90)	0.390(8.11)	
p-value		0.662		
Variability				
Before	11.55(2.93)	10.51(3.49)	10.36(3.15)	
After 30 min	9.67(2.61)	10.74(3.61)	9.85(2.80)	0.612
Difference	-1.88(3.59)	0.23(4.22)	-0.52(3.99)	
p-value		0.069		
Number of contractions				
Before	2.76(0.83)	3.14(0.88)	3.18(1.24)	0.193
After 30 min	3.06(0.75)	3.34(0.94)	3.45(0.75)	0.082
Difference	0.30(0.81)	0.20(0.87)	0.27(1.28)	0.640
p-value	0.041	0.167	0.150	

tribution of Apgar scores at 1 minute by the intervention group were found. The Apgar score <7 at the first minute after birth was observed in 14 cases only. However, in the evaluation at the fifth minute, all Apgar scores were higher than 7 (Table 3).

## Discussion

This study investigated the effect of the non-pharmacological interventions during labour on maternal and perinatal parameters in order to fulfil a gap in the literature regarding safety of those methods. Our results show that these methods alone or in combination are safe due to the absence of adverse maternal and perinatal parameters and therefore should be components of the humanisation in the childbirth.

The groups were similar regarding sociodemographic and obstetric characteristics prior to the interventions and were therefore comparable. After the interventions, no unfavourable effects were observed for mothers' and babies' parameters. However, after the interventions, maternal respiratory rate, cervical dilation and the number of uterine contractions increased significantly in all groups with no differences intergroup.

Blood pressure and pulse rate usually change significantly during labour.<sup>(2,10)</sup> However, in our re-

**Table 3.** Perinatal characteristics according intervention groups

Perinatal characteristics	Warm shower n(%)	Swiss ball n(%)	Warm shower and Swiss ball n(%)	p-value
Baseline FHR (before)	33(100.0)	35(100.0)	33(100.0)	1.000
Mild tachycardia (160 to 180 bpm)	2(6.1)	2(5.7)	1(3.0)	
Normal baseline (110 to 160 bpm)	31(93.9)	33(94.3)	32(97.0)	
Baseline FHR (after 30 min)	33(100.0)	35(100.0)	33(100.0)	1.000
Mild tachycardia (160 to 180 bpm)	0(0.0)	1(2.9)	1(3.0)	
Normal baseline (110 to 160 bpm)	33(100.0)	34(97.1)	32(97.0)	
Transient acceleration (before)	33(100.0)	35(100.0)	33(100.0)	0.733
Yes	28(84.8)	32(91.4)	30(90.9)	
No	5(15.2)	3(8.6)	3(9.1)	
Transient acceleration (after 30 min)	33(100.0)	35(100.0)	33(100.0)	0.171
Yes	26(78.8)	28(80.0)	31(93.9)	
No	7(21.2)	7(20.0)	2(6.1)	
Desacceleration (before)	33(100.0)	35(100.0)	33(100.0)	0.859
Yes	13(39.4)	14(40.0)	15(45.5)	
No	20(60.6)	21(60.0)	18(54.5)	
Type of desacceleration (before)	13(100.0)	14(100.0)	15(100.0)	0.322
Early	11(84.6)	9(64.3)	10(66.7)	
Late	1(7.7)	3(21.4)	5(33.3)	
Prolonged	1(7.7)	2(14.3)	0(0.0)	
Desacceleration (after 30min)	33(100.0%)	35(100.0)	33(100.0%)	0.370
Yes	19(57.6%)	20(57.1)	14(42.4%)	
No	14(42.4%)	15(42.9)	19(57.6%)	
Type of deceleration (after)	19(100.0)	20(100.0)	14(100.0)	0.792
Early	12(63.1)	16(80.0)	11(78.6)	
Late	4(21.1)	2(10.0)	2(14.3)	
Prolonged	3(15.8)	2(10.0)	1(7.1)	
Variability (before)	33(100.0)	35(100.0)	33(100.0)	0.240
Non-normal	2(6.1)	7(20.0)	6(18.2)	
Normal	31(93.9)	28(80.0)	27(81.8)	
Variability (after 30 min)	33(100.0%)	35(100.0)	33(100.0)	0.906
Non-normal	7(21.2%)	6(17.1)	6(18.2)	
Normal	26(78.8%)	29(82.9)	27(81.8)	
Apgar 1° minute	33(100.0)	35(100.0)	33(100.0)	0.665
Up to 6	3(9.1)	6(17.1)	5(15.2)	
≥ 7	30(90.9)	29(82.9)	28(84.8)	
Apgar 5° minute	33(100.0)	35(100.0)	33(100.0)	-
≥ 7	33(100.0)	3(100.0)	33(100.0)	

search no significant differences in these parameters were found after the interventions. Similarly a case report with six participants at low obstetric risk that assessed the safety of hydrotherapy during labour in which no significant variation in blood pressure and pulse rate were observed after hydrotherapy for 30 minutes, suggesting that the intervention is a safe practice.<sup>(6)</sup> Nevertheless, different from this case report study,<sup>(6)</sup> our research also found a significant difference in the respiratory rate, but no clinical repercussions were observed.

Physiological adjustments of the cardiorespiratory system occur during the labour, and alveolar ventilation can increase 10-20 times to meet the additional oxygen demand and to eliminate carbon dioxide. Pain stimulates maternal breathing, increasing the tidal volume and respiratory rate and subsequently aggravating hypocapnia, which can lead to respiratory alkalosis.<sup>(11)</sup> The effectiveness of non-pharmacological interventions in reducing stress and anxiety has been shown in the literature but there is no evidence of its effectiveness in reducing pain levels and this might justify the increase of respiratory rate found in our study.

Cervical dilation and the number of uterine contractions increased significantly after intervention in the warm shower group in our study. A different result was reported in a clinical trial with 54 women who used an immersion bath for 40 to 60 minutes with the water at their preferred temperature and 54 who did not receive any intervention. The aim was to compare the effect of an immersion bath on the duration of the first stage and the frequency and duration of uterine contractions. After three evaluations with one-hour intervals, no significant difference on the number of uterine contractions was found, but the duration of contractions was statistically lower in the immersion bath group. Also, no significant difference in cervical dilation was observed in the three evaluations.<sup>(12)</sup>

Concerning about the perineal exercise with a Swiss ball, a survey with nurse-midwives in 35 public maternity hospitals in São Paulo, Brazil, suggested that this intervention used for approximately 60 minutes in the active phase of labour effectively shorten the first stage and also have a beneficial effect on the descent and station of the baby head at the maternal pelvis.<sup>(7)</sup> However a study conducted in Brazil with 40 primiparous women divided into control group and Swiss ball group who performed pelvic exercises for 30 minutes in the active phase of labour did not find differences between groups regarding the duration of labour ( $p=0.37$ ).<sup>(13)</sup> Similarly, a study that compared 90 Iranian primiparous women divided into local heat therapy group, Swiss ball group and control group did not found significant difference on the duration of the

active phase of labour in any of the groups studied ( $p=0.562$ ).<sup>(14)</sup>

The perinatal data show no significant differences in the presence of transient acceleration, variability or deceleration as well as in the type of deceleration between the three groups before and after the interventions. There was also no difference in the mean Apgar at 1 and 5 minutes after the birth of the newborn by intervention groups, which shows that the birth conditions were not affected by the presence of any of the three non-pharmacological methods used. This result is similar to those of a study that concluded that a warm shower is a safe option to relieve pain during labour without interfering with its progression and neonatal conditions.<sup>(6)</sup>

A study including 1,237 women compared maternal and neonatal outcomes between women after warm tub bathing for 50 to 60 minutes during labour ( $n=612$ ) and those who do not received this intervention ( $n=625$ ). No significant difference was observed in the occurrence of operative birth, postpartum hospitalization, number of newborns with Apgar less than 7 at 5 minutes of life and neonatal hypoxia or tachypnea.<sup>(15)</sup> Another study with 40 primiparous women evaluated the effect of perineal exercises with a Swiss ball on pain relief and the duration of the active phase of labour showed that 90% of the neonates in the control and experimental groups had Apgar higher than 7 at 1 and 5 minutes, with no statistically significant differences between them ( $p=0.63$ ).<sup>(13)</sup>

A systematic review including 15 Cochrane and three non-Cochrane reviews assessed the efficacy and safety of non-pharmacological and pharmacological interventions to treat labour pain. The authors concluded that the neonatal effects remain minimally explored, and other trials with appropriate methodological quality are necessary to provide reliable evidence in this area.<sup>(16)</sup> The limitation of this study is related to a 20% loss in follow up among participants.

## Conclusion

The interventions alone or in combination are safe due to the absence of adverse maternal and



perinatal parameters, since they do not result in changes in maternal clinical parameters such as blood pressure, pulse and neonatal parameters such as FHR, the presence of transient acceleration, variability or decelerations and Apgar scores at 1 and 5 minutes after birth. The warm shower alone and combined with perineal exercises with a Swiss ball results in an increase in the number of uterine contractions compared to the intervention with a Swiss ball alone.

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Melo PS, Barbieri M, Gabrielloni, Henrique AJ contributed with the project and data interpretation, the writing of the article, the critical review of the intellectual content, and with the final approval of the version to be published. Westphal F, Fustinoni SM e Francisco AA contributed with the critical review of the intellectual content, and with the final approval of the version to be published.

## References

- Brownridge P. The nature and consequences of childbirth pain. *Eur J Obstet Gynecol Reprod Biol.* 1995;59 Suppl:S9–15.
- Hall JE. Guyton and Hall textbook medical of physiology. 13th ed. Philadelphia: Saunders Elsevier; 2015.
- Gallo RB, Santana LS, Marcolin AC, Duarte G, Quintana SM. Sequential application of non-pharmacological interventions reduces the severity of labour pain, delays use of pharmacological analgesia, and improves some obstetric outcomes: a randomised trial. *J Physiother.* 2018;64(1):33–40.
- Brasil. Ministério da Saúde. Secretaria de Ciência, Tecnologia e Insumos Estratégicos. Comissão Nacional de Incorporação de Tecnologias no SUS (CONITEC). Diretrizes nacionais de assistência ao parto normal: versão resumida. Brasília (DF): Ministério da Saúde; 2017.
- Whitburn LY, Jones LE, Davey MA, McDonald S. The nature of labour pain: An updated review of the literature. *Women Birth.* 2018 Apr 20. pii: S1871-5192(17)30629-7.
- Mazoni SR, Faria DG, Manfredo VA. Hydrotherapy during labor: a case report of safe practice. *Arq Ciênc Saúde* 2009;16(1):40-3.
- Silva LM, Oliveira SM, Silva FM, Alvarenga MB. Using the Swiss ball in labor. *Acta Paul Enferm.* 2011;24(5):656–62.
- Henrique AJ, Gabrielloni MC, Rodney P, Barbieri M. Non-pharmacological interventions during childbirth for pain relief, anxiety, and neuroendocrine stress parameters: A randomized controlled trial. *Int J Nurs Pract.* 2018;24(3):e12642.
- Ayres-de-Campos D, Spong CY, Chandraran E; FIGO Intrapartum Fetal Monitoring Expert Consensus Panel. FIGO consensus guidelines on intrapartum fetal monitoring: cardiotocography. *Int J Gynaecol Obstet.* 2015;131(1):13–24.
- Barrett EJ. The adrenal gland. In: Boron WF, Boulpaep EL, editors. *Medical physiology.* 3rd ed. Philadelphia: Elsevier; 2016. p. 1018–34.
- Böing I, Sperandio FF, Santos GM. Use of breathing technique for analgesia in the childbirth. *Femina.* 2007;35(1):41–6.
- da Silva FM, de Oliveira SM. [The effect of immersion baths on the length of childbirth labor]. *Rev Esc Enferm USP.* 2006;40(1):57–63.
- Gallo RB, Santana LS, Marcolin AC, Quintana SM. Swiss ball to relieve pain of primiparous in active labor. *Rev Dor.* 2014;15(4):253–5.
- Taavoni S, Sheikhan F, Abdolahian S, Ghavi F. Birth ball or heat therapy? A randomized controlled trial to compare the effectiveness of birth ball usage with sacrum-perineal heat therapy in labor pain management. *Complement Ther Clin Pract.* 2016;24:99–102.
- Ohlsson G, Buchhave P, Leandersson U, Nordström L, Rydhström H, Sjölin I. Warm tub bathing during labor: maternal and neonatal effects. *Acta Obstet Gynecol Scand.* 2001;80(4):311–4.
- Jones L, Othman M, Dowswell T, Alfirevic Z, Gates S, Newburn M, et al. Pain management for women in labour: an overview of systematic reviews. *Cochrane Database of Sys Rev.* 2012 Mar;(3):CD009234.