





Complementary therapies in labor: randomized clinical trial



Terapias complementares no trabalho de parto: ensaio clínico randomizado
Terapias complementarias en el trabajo de parto: ensayo clínico randomizado

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ABSTRACT

Objective: To evaluate the effect of isolated and combined warm shower bath and perineal exercise with Swiss ball, on perception of pain, anxiety and labor progression.

Method: Randomized, controlled clinical trial with 128 patients allocated into three groups of therapies: isolated and combined bath and ball. Pain and anxiety perception was evaluated before and thirty minutes after therapeutic intervention through visual analogic scales (VAS).

Results: Pain perception score increased, and anxiety decreased in all groups, mainly when using a shower bath. The cervical dilation increased in all groups ($p < .001$), as well as the number of uterine contractions increased, mainly in the group that used combined bath and ball and also showed shorter labor time.

Conclusion: The studied therapies contribute to maternal adaptation and well-being and favor labor's evolution.

Keywords: Anxiety. Hydrotherapy. Labor pain. Labor, obstetric. Complementary therapies. Obstetric nursing.

RESUMO

Objetivo: Avaliar o efeito do banho quente de chuveiro e exercício perineal com bola suíça isolados e de forma combinada, sobre a percepção da dor, ansiedade e progressão do trabalho de parto.

Método: Ensaio clínico randomizado e controlado com 128 parturientes alocadas em três grupos de terapias, banho, bola, isolados e combinados. A percepção da dor e ansiedade foi avaliada antes e trinta minutos após a intervenção terapêutica por meio de escala visual analógica (EVA).

Resultados: Houve aumento no escore de dor e redução da ansiedade em todos os grupos, sobretudo quando utilizaram banho de chuveiro. A dilatação cervical, aumentou em todos os grupos de intervenção ($p < .001$) bem como o número de contrações uterinas, principalmente quem utilizou banho e bola associados como também mostrou menor duração do tempo de trabalho de parto.

Conclusão: As terapias estudadas contribuem para adaptação e bem-estar materno e favorecem a evolução do trabalho de parto.

Palavras-chave: Ansiedade. Hidroterapia. Dor do parto. Trabalho de parto. Terapias complementares. Enfermagem obstétrica.

RESUMEN

Objetivo: Evaluar el efecto de la ducha caliente y del ejercicio perineal con pelota suiza, separadamente y de forma combinada, sobre la percepción del dolor, la ansiedad y la progresión del trabajo de parto.

Método: Ensayo clínico aleatorizado y controlado junto a 128 parturientes asignadas en tres grupos de terapias, ducha caliente, pelota suiza separadamente y de forma combinada. La percepción de dolor y de ansiedad se evaluó antes y treinta minutos después de la intervención terapéutica por medio de escala visual analógica.

Resultados: Hubo un incremento en la puntuación de dolor y una reducción de la ansiedad en todos los grupos, sobre todo cuando se utilizó la ducha. La dilatación cervical aumentó en todos los grupos de intervención ($p < .001$) así como el número de contracciones uterinas, principalmente en el grupo que utilizó las dos terapias combinadas, ducha caliente con pelota suiza. Asimismo se constató menor duración del tiempo de trabajo de parto.

Conclusión: Las terapias estudiadas contribuyen a la adaptación y al bienestar materno y favorecen la evolución del trabajo de parto.

Palabras clave: Ansiedad. Hidroterapia. Dolor de parto. Trabajo de parto. Terapias complementarias. Enfermería obstétrica.

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■ INTRODUCTION

Using complementary therapies as an alternative for pain relief in labor should be encouraged and is part of the national and international strategies for care of gestation and childbirth⁽¹⁻³⁾. Hydrotherapy and ball exercises are available therapies and, when used alone or in combination, promote benefits for maternal well-being and act in labor's evolution⁽⁴⁻⁶⁾.

Pain in labor is the result of complex interactions, with inhibitory and excitatory character, of acute pain characteristic. However, it is a period with particular characteristics, with a neurophysiological, obstetrical, psychological and sociological nature, which may interfere with the threshold of their tolerance⁽⁷⁻⁸⁾.

Labor suffers hormonal influences, where the release of oxytocin is responsible for uterine contractility generating painful stimulus and state of stress. The body, in its turn, releases endogenous endorphins known as natural analgesics, and as they are released they promote a sense of well-being, helping to modify the negative sensory and emotional experiences of the parturition process. During the expulsive period, pain has somatic characteristics, resulting from the distention and traction of the pelvic structures around the vaginal dome and the pelvic floor and perineum, thus increasing the painful stimuli, which contributes to elevating their perception at the labor's end⁽⁸⁾.

Another evident emotional condition during labor is anxiety, which is defined as a transient situation, characterized by apprehension relative to the perception of not being able to control or predict potentially aversive events; physical symptoms of physical tension and deviation from the focus of attention⁽⁹⁾.

Thus, when the individual is exposed to a stressful factor, fear and anxiety are instinctive defense reactions to the encountered danger. In this defense reaction, several brain structures are involved, and as a consequence, increased autonomic nervous system activity, tachycardia, elevated pressure, vasoconstriction in the skin and viscera, vasodilation in striated muscles, and hyperventilation⁽¹⁰⁾. These physiological changes can cause unfavorable outcomes to the labor process and consequently to the birth conditions of the baby. Considering these perspectives, complementary therapies have been used both in the public health network and in the private health network to assist the labor delivery, being a strategy to reduce pain, stress, cesarean rates, reflecting on the quality of obstetric care provided^(6,11).

Hot bath therapies and Swiss ball perineal exercises used as an adjunctive treatment in labor are known

globally^(1,3-4). Hydrotherapy by means of the shower bath for pain relief at a temperature of about 37° for a period, causes cutaneous stimulation capable of reducing levels of stress-related neuroendocrine hormones, regulation in the pattern of uterine contractions, among many different benefits⁽⁶⁾. Performing perineal exercises with a Swiss ball helps in the descent and rotation of the fetal presentation, stimulates the vertical position, brings out psychological benefits, as well as relaxation of the lumbar muscles and pelvic floor, thus offering pelvic discomfort relief⁽¹²⁾.

This study is justified by the lack of scientific knowledge about the relationship between bath and ball therapies during labor and its influence on pain, anxiety and obstetric aspects in order to subsidize obstetric nursing care practice and provide greater autonomy and active participation of women in this period. Responding to the restlessness of the authors, the following was a guiding question: "Does the use of hot bath interventions and perineal Swiss ball exercises during labor influence the perception of pain, anxiety, and obstetric outcome?"

Thus, the objective of this research was to evaluate the effect of using hot shower and perineal exercises with Swiss ball, in an isolated and combined way, on the perception of pain, anxiety and labor progression.

■ MATERIAL AND METHOD

Research Design

It is a randomized and controlled clinical study of the factorial type, using pre- and post-intervention design, from the dissertation named: "Assessing pain and anxiety in labor with using non-pharmacological interventions: randomized clinical controlled trial"⁽¹³⁾. The pregnant women were randomly assigned to one of three different intervention groups: hot shower bath, Swiss ball exercises and the combined bath and ball group.

Location and Participants

The participants were 128 pregnant women with normal obstetric risk admitted to two normal inter-hospital birth centers located in the city of São Paulo, Brazil, to assist in labor and delivery, and meeting the settled inclusion criteria. The two hospitals are linked to SUS (Sistema Único de Saúde – Unique Healthcare System), one being state owned and one municipal owned. Both performed on average 250 deliveries/month and had the same attendance characteristics regarding the assisted population profile, besides to encouraging the presence of the companion.

Data collection was performed from June 2013 to February 2014, from Monday to Friday for about twelve hours daily.

The pregnant women who did not have any clinical and/or obstetric pathology, who were in the active phase of labor, had two to three uterine contractions in ten minutes, minimal cervical dilatation of 3 and maximum of 8 centimeters recorded in the partograph, age gestational age between 37 and 42 complete weeks, calculated by the date of the last menstruation and/or by the result of the early ultrasound, performed until the 20th week, minimum age of 18 complete years, gestation with single fetus, alive, in flexed cephalic presentation and self-reported pain score ≥ 5 , were included.

The pregnant women with an indication of cesarean delivery at the admission time, with analgesia during labor, smokers, patients with mental disorders, psychoactive drug users, who reported having ingested caffeine in the last 10 hours, who performed less than six prenatal consultations and who have used synthetic or natural corticosteroids, were excluded.

Sample Calculation

The sample size was calculated from a pilot study with 15 pregnant women, randomized in this same research design. Statistical analyzes were performed using the software Statistical Package for the Social Sciences (SPSS) version 21.0 (SPSS Inc., Chicago, Illinois), P value <0.05 was designated as significant and the sample size consisted of 39 women in each group. This calculation comes from a larger investigation entitled "Evaluation of non-pharmacological interventions in labor under the perception of pain, anxiety, clinical, obstetrical and neuroendocrine stress parameters"⁽¹²⁾.

Randomization

The therapies were identified on numbered cards and each number corresponded to an intervention group. The cards were placed in an opaque envelope and were randomly selected by the women upon entering the study. There was no knowledge by the participants or the researchers about in which group the women would be allocated at the randomization time.

Measurement

Pain and anxiety perception were evaluated before and 30 minutes after the intervention. These outcomes

were evaluated using the Visual Analogue Scale (VAS), which comprises a horizontal line of 10 cm with extremities indicating the intensity, with zero (0) "no pain" and ten (10) "worst possible pain". VAS is used to measure several subjective clinical phenomena, including pain and anxiety⁽¹⁴⁾.

Complementary Therapies Used

Hot shower bath

The hot shower bath ran 30 minutes using water at 37°C, measured every 15 minutes with a digital Akso® brand thermometer. The water jet was directed to the lumbar sacral region of the pregnant woman, which during this process adopted the standing or seated position, according to her preference.

Perinatal Exercise with Swiss Ball

The perineal exercise with the Swiss ball was performed with the Gynboll® model ball with 60 cm diameter on a firm, non-slipping surface for added safety, for 30 minutes. The pregnant woman sat on the ball with a flexed leg forming a 90° angle, with the knees apart and the plantar area of the feet resting on the ground, performing propulsion (low and rising) and pelvic rotation movements. Ball's cleaning and protection were carried out by washing with soap and water, 70% alcohol disinfection, wrapped with paper-film for re-use.

Combined Therapy

The combined therapy was performed with the pregnant woman sitting on the ball, performing perineal exercises for 30 minutes during the hot aspersion bath. This therapy was in accordance with the techniques and precautions related to each intervention, as previously described.

Data Analysis

Personal, demographic and obstetric data were obtained from the medical records in the patient's registers and interviews with the participants.

Data were stored in a database using the Excell® program with double checking and subsequent analysis. The Statistical Package for Social Sciences (SPSS) version 21.0 (SPSS Inc., Chicago, Illinois) was used. The existence of associations between two categorical variables was verified using the Chi-Square test, or in cases of small samples, Fisher's exact test. The comparison of means between two groups was performed using Student's t-test for independent samples and for more than two groups, one used the

analysis of variances normality of the data in ANOVA, the means were compared using Kruskal-Wallis non-parametric study. A significance level of 5% was utilized for all the statistical tests.

Ethical aspects

The participants voluntarily accepted to participate in the study and signed the Free and Informed Consent Form (FICF). In compliance with the ethical precepts defined by Resolution 466/12 of the National Health Council, the study was approved by the Research Ethics Committee with Humans under No. 691,435, CAAE No. 31492914.9.00005505, as well as by the Ethics Committees of the hospital institutions where data were collected. It was registered in the

database of the Brazilian Registry of Clinical Trials (ReBEC) under No. 84 XPRT.

■ RESULTS

137 pregnant women were eligible during recruitment and were invited to participate in the study, and 09 were excluded prior to randomization for the following reasons: malaise (02), childbirth (02), analgesia (02) and refusal (03). In this way, 128 pregnant women were randomized and allocated randomly in the three groups of therapies - Combined Shower Hot Bath (n=44), Swiss Ball Group (n=45) and Combined Hot Shower Group and Swiss Ball Group (n=39), according to the directive: *CONSORT (Consolidated Standards of Reporting Trials.)*⁽¹⁵⁾ (Figure 1)

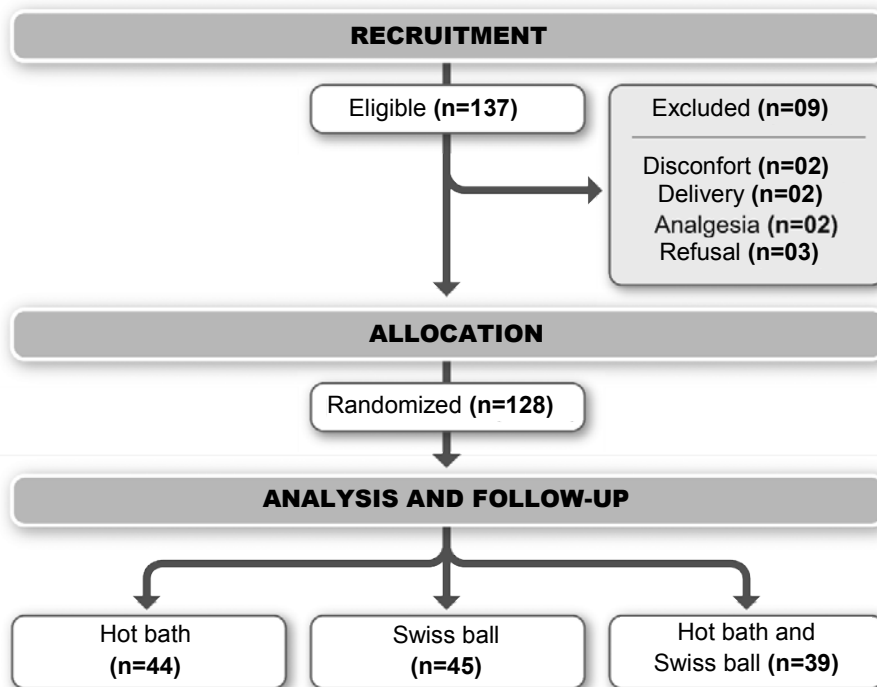


Figure 1 - CONSORT. Flow diagram of study participants

The distributions for the socio-demographic characteristics of the pregnant women were homogeneous among the therapy groups, with a mean age of 26 years old, minimum of 18 years old and maximum of 42 years old, 70.1% having between 8 and 11 years of study, 48.0% considered themselves of white ethnic, 54.3% were single, 52.0% did not work and 33.3% had a family income of 2 minimum wages.

The time elapsing between the intervention and the delivery was smaller in the group of combined therapy, bath and ball, with 216.85 minute duration, followed by the group that used hot bath with 255.05 minutes and by the group that used Swiss ball, under associated form, with 288.41 minutes. However, there was no statistically significant difference. The companion presence was confirmed in 90% of the participants, with the husband and the mother being preferentially eligible (Table 1).

Table 1 – General characteristics of the pregnant women, according to intervention groups. São Paulo, SP, Brazil, 2014

Variable	Total	Hot Bath	Swiss Ball	Hot Bath and Swiss Ball	p
Age (years, mean, SD)	26.02 (5.73)	26.05 (5.41)	27.24 (6.47)	24.56 (4.91)	0.101 ^b
Color	127 (100.0%)	44 (100.0%)	45 (100.0%)	38 (100.0%)	0.157 ^a
Caucasian	61 (48%)	25 (56.8%)	19 (42.2%)	17 (44.7%)	
Black	13 (10.2%)	5 (11.4%)	6 (13.3%)	2 (5.3%)	
Asian	5 (3.9%)	1 (2.3%)	0 (0.0%)	4 (10.5%)	
Brown-skinned	48 (37.8%)	13 (29.5%)	20 (44.4%)	15 (39.5%)	
Schooling	127 (100.0%)	44 (100.0%)	45 (100.0%)	38 (100.0%)	0.644 ^a
0 to 3 years	1 (0.8%)	1 (2.3%)	0 (0.0%)	0 (0.0%)	
4 to 7 years	11 (8.7%)	4 (9.1%)	3 (6.7%)	4 (10.5%)	
8 to 11 years	89 (70.1%)	27 (61.4%)	34 (75.6%)	28 (73.7%)	
12 or more	26 (20.5%)	12 (27.3%)	8 (17.8%)	6 (15.8%)	
Gestational age (weeks; mean, SD)	39.69 (1.06)	39.69 (1.02)	39.78 (1.17)	39.60 (1.00)	0.731 ^b
Number of pregnancies (mean, SD)	2.01 (1.25)	1.95 (1.36)	2.24 (1.33)	1.79 (0.98)	0.193 ^c
Parity (mean, SD)	0.71 (0.97)	0.75 (1.16)	0.80 (0.92)	0.56 (0.75)	0.517 ^c
Number of visits (mean, SD)	8.37 (1.98)	8.86 (2.31)	8.22 (1.96)	7.97 (1.48)	0.098 ^b
First prenatal visit (quarter)					
1st	96 (75.0%)	34 (77.3%)	32 (71.1%)	30 (76.9%)	
2nd	31 (24.2%)	9 (20.5%)	13 (28.9%)	9 (23.1%)	
3rd	1 (0.8%)	1 (2.3%)	0 (0.0%)	0 (0.0%)	
Time of intervention at birth (minutes, mean, SD)	253.43 (153.53)	255.05 (148.00)	288.41 (188.32)	216.85 (124.28)	0.102 ^b
Presence of companion	128 (100.0%)	44 (100.0%)	45 (100.0%)	39 (100.0%)	0.874 ^a
Yes	115 (89.8%)	39 (88.6%)	40 (88.9%)	36 (92.3%)	
No	13 (10.2%)	5 (11.4%)	5 (11.1%)	3 (7.7%)	

Source: Research data, 2014.

SD: Standard Deviation; p: Fisher's Chi-Square or Fisher's exact test descriptive level^(a), ANOVA (°) and Kruskal-Wallis (°);

It can be seen in Table 2 that pain perception was similar in the three groups before the intervention, with a mean score 7.55, increasing in all groups after the therapies, showing a statistically significant difference in the group that received the shower (8.38) ($p=0.001$).

The anxiety score was higher in the Swiss Ball group before the intervention (8.76) than in the other groups. Anxiety was reduced in all 3 groups after the intervention, and the group that

used the ball alone showed a greater reduction in post-intervention scores (8.44), with no statistically significant difference.

The participants showed cervical dilation similar to that of the study (5 cm), increasing in all groups after receiving the therapies with significant differences ($p<0.001$) in the 3 study groups. The group of combined therapies showed the greatest difference in cervical dilation (6.69 ± 2.02), followed by the group that used the bath.

Uterine contraction frequency increased in all three groups after using the therapies. The group that used the combined therapies showed to be higher (3.47 ± 0.76),

followed by the group that used a hot shower bath. However, there was no statistical difference.

Table 2 - Pain and anxiety score by the evaluation time according to intervention groups. São Paulo, SP, Brazil, 2014

Variable	Intervention			p ¹
	Hot Bath	Swiss Ball	Hot Bath and Swiss Ball	
Pain				
Before	7.55 (1.74)	7.56 (1.90)	7.54 (1.71)	0.999
After	8.38 (1.79)	8.02 (1.83)	8.08 (2.19)	0.594
Difference	0.83 (1.44)	0.47 (1.87)	0.54 (1.93)	0.663
p ²	0.001	0.127	0.077	
Anxiety				
Before	7.75 (2.69)	8.76 (2.07)	7.54 (3.15)	0.084
After	7.52 (2.78)	8.44 (2.09)	7.49 (3.02)	0.217
Difference	-0.23 (1.43)	-0.31 (1.55)	-0.05 (1.96)	0.883
p ²	0.291	0.216	1.000	
Cervical dilatation (cm)				
Before	4.86 (1.03)	4.96 (1.24)	5.13 (1.30)	0.706
After	6.41 (1.50)	6.16 (1.68)	6.69 (2.02)	0.369 ^a
Difference	1.55 (1.21)	1.20 (1.22)	1.56 (1.31)	0.208
p ²	<0.001	<0.001	<0.001	
Number of contractions in cardiotocography in 20 minutes				
Before	2.77 (0.84)	3.13 (0.86)	3.19 (1.26)	0.213
After	3.03 (0.75) ^A	3.33 (0.90)	3.47 (0.76) ^B	0.042
Difference	0.26 (0.82)	0.21 (0.83)	0.28 (1.30)	0.610
p ²	0.071	0.124	0.150	

Source: Research data, 2014.

p¹: Descriptive level of the Kruskal-Wallis test ANOVA (A) and (B) show distinct means according to Dunn-Bonferroni multiple comparisons;

p²: Descriptive level of the Wilcoxon test for comparing before and after measurements.

■ DISCUSSION

This study, in an attempt to evaluate the effect of complementary hot bath and perineal Swiss ball therapy in isolated and combined manners on the perception of pain, anxiety and labor progression, found an increase in the pain score in the pregnant women ($p=0.001$), a result that corroborates studies that used pain relief methods performed with 128 participants⁽¹²⁾ and 258 participants⁽¹⁶⁾. However,

despite this increase, there was good acceptance on the part of the pregnant women, when they expressed a sense of security, relaxation and comfort during the intervention. Water heated around 37°C promotes redistribution of muscle blood flow and release of endorphins causing a sensation of comfort, reduction of pain, improvement in the metabolism and elasticity of some tissues^(4,17). Its use must be respected and encouraged by the professionals who provide labor assistance, it is an available intervention that

can be used in isolation or combined, promoting continuous support, maternal well-being, favoring labor evolution.

It is known that the level of pain in labor is proportional to the intensity and uterine contraction frequency, cervical dilatation advancement and the pelvic floor compression by the decrease in fetal presentation, in this way, there was a tendency for the levels of pain felt by our pregnant women being higher once they were evaluated in the active labor's phase.

Data show that at each centimeter of cervical dilation progression there was an increase in pain level, on average, being 0.49 points. When evaluating the cervical dilatation progression before and after the received interventions, we can affirm that in all groups, the pregnant women showed, on average, 1.4 cm progression.

Most of the participants in the study received induction with oxytocin and their use showed no significance in the intensity of the contractions in relation to patients who did not use it. It is a drug widely used in Brazil to accelerate labor, as shown in a national study conducted where oxytocin was used in 40% of deliveries, mainly in primiparous women and under 35 years old, with the highest utilization rate being the southeast region⁽¹⁸⁾. In this way, it is possible to rethink on oxytocin's routine use as a way to accelerate labor's natural evolution, since although it has not demonstrated significant contraction intensity, it is quite common in obstetric practice to obtain reports of pregnant women on increased discomfort and pain felt after this drug is given.

This study also reveals that pregnant women who received a hot aspersion bath when compared to the other interventions had a reduction in anxiety - 0.95 points, and when this data were associated with the self-reported color, those brownish or black-like colored people demonstrated anxiety levels, on average, being one point less than those of white ethnic.

A clinical study using hydrotherapy during labor describes an increase in the sensation of well-being associated with relaxation, greater satisfaction resulting from freedom of movement and privacy⁽¹⁶⁾, which may be related to the reduction in anxiety, a result that can be evidenced by the pregnant women submitted to the bath when verbalizing this type of sensation, and during its realization, the painful sensation of the contraction was more bearable when compared to the period when they remained at rest in the bed. To this effect, we can say that heat accentuates blood circulation decreasing the stress induced by the contractions, in contact with some tissues it improves the metabolism and its elasticity promoting a well-being sensation.

Another study reveals that there are clinical and neuroendocrine changes related to pain and anxiety, as well as

labor's evolution, and their relief begins after 15 minutes and remains for about one hour after ending the therapy⁽⁵⁾.

The time elapsed between the intervention and the birth showed that using the combined therapies was related to faster labor evolution in about one hour, when compared to the therapies performed in isolation. Using the hot aspersion bath for twenty minutes also contributed to the significant reduction in labor's duration for These women when compared to the group that did not receive this intervention⁽⁴⁾.

Although there is no consensus about the influence of complementary therapies on labor's duration, its reduction reduces the time of exposure to pain and stress inherent to this period, contributing to the comfort and greater participation of women in the parturition process. In addition, freedom of movement allows the pregnant women to assume positions that facilitate the fetus's accommodation during labor, favoring physiological delivery and increasing maternal comfort.

It should be emphasized that the result obtained in this study was probably a consequence of the well-being, comfort and calmness generated by the practice of combined aspersion bath therapy and perineal exercises with Swiss ball.

Regarding the choice of the companion, this is a personal decision, which involves social and cultural aspects. The benefits related to the participation of a companion during the labor and delivery process were evidenced in this study and have been widely reported in the national and international literature. This importance is highlighted in a maternity study in the State of São Paulo, pointing out that pregnant women who received the support of companions selected by them had greater satisfaction, security and tranquility with the experience of the delivery process, when compared to the group of women who did not received support from the person living with them⁽¹⁹⁾. Thus, continuous support in labor, in addition to reducing interventionist actions, gives women a series of physical and emotional benefits, as well as allowing greater coverage of the care provided by health professionals, by increasing observation and interlocution of needs for the pregnant woman⁽²⁰⁾.

It should be noted that the presence of the companion during labor occurred in almost all deliveries, the majority being the husband followed by the mother's company, among others. It was found that the maternal presence was close to the significance to reduce the anxiety score. This fact can be attributed to woman's better understanding on the physical transformations, doubts and fears of the pregnant woman, once she had previously experienced the moment of labor.

As a limitation of the study it can be pointed out that we do not have precise instruments for the evaluation of pain and anxiety because it is a multifactorial and specific situation in woman's life. To such an effect, we used analog scales for both parameters, running the risk of their subjectivity. On the other hand, most of the national and international studies for pain and anxiety evaluation use these same scales, although there are other scales translated for such an evaluation, but with contents that are not fully adequate to the specificities of labor changes, as well as their application would not be so adequate to the dynamics of the same in view of the physical, emotional and cognitive changes demonstrated by the pregnant women.

■ CONCLUSION

The therapies used have not interfered in pain reduction during labor, but all women showed a positive effect in terms of shortening the time-period elapsing from labor to delivery, especially when used in combination. This finding leads us to encourage the use of such therapies by obstetric professionals, since that their beneficial effects were evidenced, and because they are therapies that do not require high investments in resources and are easy to apply in most childbirth centers in the country. Anxiety, although it is a subjective variable, the experience and emotional characteristic of each person, was found in the participants of the study, using the therapies for allowing movement, relaxation, diverting the focus of attention from the pain, a constant variable during the work, was reduced. This may suggest that the proposed therapies here were able to promote better maternal adaptation during labor, helping to cope with pain, promoting participatory experience and greater control of their actions and emotions, resulting in a better labor evolution.

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