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Peanut ball use for reducing maternal fatigue during labor: protocol for a randomized clinical trial

Uso da bola amendoim para reduzir a fadiga materna durante o trabalho de parto: protocolo para um ensaio clínico randomizado

Uso de la bola de maní para reducir la fatiga materna durante el parto: protocolo para un ensayo clínico aleatorizado

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Abstract
Objectives: Develop a protocol of the use of the Peanut Ball (PB) to evaluate its effectiveness compared to usual care on decreasing maternal fatigue during labor. *Methods*: This is the development of a randomized clinical trial protocol. Perform an intervention group or use the Peanut Ball through five postures, according to an obstetric assessment. To assess maternal fatigue, the Maternal Perception of Childbirth Fatigue Questionnaire (MCFQ) will be used in the form of an interview. *Results*: The proposed protocol is according to the evolution of labor: height and positioning of the fetal presentation, erasure and uterine dilation and the presence of early blood flow. Postures with fetal presentation in the upper strait: postures with abduction and external rotation hips will be encouraged using PB. Posture according to the fetal position in the upper strait: posture that cancels gravity will be encouraged: lateral decubitus posture with PB between legs. If the parturient feels like pushing or pushing down with the baby tall and cervix before 8-10 centimeters of uterine dilation, posture that nullifies gravity will be encouraged: lateral decubitus with the aid of the ball, with the hips in abduction and external rotation *Conclusion*: A specific protocol was developed with the use of Peanut Ball, through an obstetric evaluation, to reduce maternal fatigue during labor.
Keywords: Labor; Obstetric; Parturition; Physical therapy modalities.

Resumo
Objetivos: Elaborar um protocolo de uso da Bola Amendoim para avaliar sua eficácia em relação aos cuidados usuais na diminuição da fadiga materna durante o trabalho de parto. *Métodos*: Trata-se do desenvolvimento de um protocolo para um ensaio clínico randomizado. No grupo experimental, a parturiente será incentivada a fazer uso da Bola Amendoim por meio de posturas respaldadas pela avaliação obstétrica. Para avaliar a fadiga materna, será utilizado o Questionário de Percepção Materna da Fadiga no Parto (MCFQ) na forma de entrevista. *Resultados*: O protocolo proposto está de acordo com a evolução do trabalho de parto: altura e posicionamento da apresentação fetal, apagamento e dilatação uterina e presença de fluxo sanguíneo precoce. Posturas com apresentação fetal no estreito superior: posturas com abdução e rotação externa do quadril serão estimuladas com PB. Postura de acordo com a posição fetal no estreito superior: posturas que anulem a gravidade serão incentivadas: postura de decúbito lateral com a Bola Amendoim entre as pernas. Se a parturiente sentir vontade de empurrar ou empurrar para baixo com o bebê alto e colo do útero antes de 8-10 centímetros de dilatação uterina, será incentivada a postura que anule a gravidade:

decúbito lateral com auxílio da bola, com os quadris em abdução e rotação externa. *Conclusão*: Foi desenvolvido um protocolo específico com o uso da Bola de Amendoim, por meio de avaliação obstétrica, para reduzir a fadiga materna durante o trabalho de parto.
Palavras-chave: Trabalho de parto; Obstétrico; Parto; Modalidades da fisioterapia.

Resumen
Objetivos: Desarrollar un protocolo para el uso de la Bola de Maní para evaluar su efectividad en relación con los cuidados habituales en la reducción de la fatiga materna durante el trabajo de parto. *Métodos*: Se trata del desarrollo de un protocolo para un ensayo clínico aleatorizado. En el grupo experimental, se incentivará a la parturienta a utilizar la Bola de Maní a través de posturas apoyadas en la evaluación obstétrica. Para evaluar la fatiga materna se utilizará el Cuestionario de Percepción Materna de Fatiga en el Parto (MCFQ) en forma de entrevista. *Resultados*: El protocolo propuesto está de acuerdo con la evolución del trabajo de parto: altura y posicionamiento de la presentación fetal, borramiento y dilatación uterina y presencia de flujo sanguíneo precoz. Posturas con presentación fetal en el estrecho superior: se estimularán con BP posturas con abducción y rotación externa de cadera. Postura según posición fetal en el estrecho superior: se fomentarán las posturas que anulen la gravedad: postura de decúbito lateral con el Bola de Maní entre las piernas. Si la parturienta siente ganas de empujar o empujar hacia abajo con el bebé alto y cuello uterino antes de los 8-10 centímetros de dilatación uterina, se recomienda una postura que niegue la gravedad: decúbito lateral con ayuda del balón, con las caderas en abducción y externa rotación. *Conclusión*: Se desarrolló un protocolo específico con el uso del Bola de Maní, a través de evaluación obstétrica, para disminuir la fatiga materna durante el trabajo de parto.
Palabras clave: Trabajo de parto y parto; Obstétrico; Parto; Modalidades de fisioterapia.

1. Introduction

The use of Peanut Ball (PB) during labor was first introduced in the United States obstetric centers (Tussey, et al., 2015). The available literature (MEDLINE / PubMed, LILCAS, CINAHL, CENTRAL, and SCOPUS) demonstrates its use only with pharmacological analgesia (Tussey, et al., 2015; Roth, et al., 2016; Kwan & Mercier, 2018; Hickey & Savage, 2019). BP helps in changing maternal positions after an epidural. These changes seem to improve maternal and neonatal outcomes, which can be crucial for women with epidural analgesia (Barasinski, et al., 2018; Simarro, et al., 2017). The benefits of changes in position in labor include, decreased pain, better quality of contractions, decreased labor time, facilitated fetal descent, reduced perineal trauma, fewer episiotomies and reduced maternal fatigue (Barasinski, et al., 2018).

Maternal fatigue is a very common symptom during labor and is associated with the general condition of the parturient, in addition to the physical, psychological and emotional dimension, in which its increase can negatively contribute to maternal and fetal outcomes (Delgado, et al., 2019). It has also usually been accepted as part of the parturient's experience during labor (Pugh, et al., 1999). The perception of maternal fatigue is high as a result of intensified uterine contractions, cramps in the lower limbs, in addition to the excessive use of synthetic oxytocin and unsupervised exercises (Zohreh, et al., 2007). The most recent study on maternal fatigue during childbirth, concludes that pain, anxiety and fatigue were significantly correlated, regardless of the use of analgesia (Tzeng, et al., 2008).

Works using Birthball have been more popular in the literature (Lopes, et al, 2003; Taavoni, et al., 2011; Gau, et al., 2011; Gallo, et al., 2014). The use of this tool has been used in various ways during labor and birth since the late 1990s (Tzeng, et al., 2008). A systematic review with seven clinical trials showed that only the use of the Birth Ball reduces pain with differences in the subgroups of 20/30 minutes of use in the birth ball (meandifference (MD) -1.46; 95% CI: -2, 15 to -0.76, P <0.0001), 60 minutes (MD -1.95; 95% CI: -2.68 to -1.22; P <0.00001) and 90 minutes (MD -1, 72; 95% CI: -2.44 to -1.00; P <0.0001). However, only one study with BP was included in this review (Delgado, et al., 2019).

The systematic review of PB after epidural analgesia in four clinical trials with 648 nulliparous and multiparous women in labor, showed trends in a higher incidence of spontaneous vaginal births (RR 1.1, 95% CI 1.0, 1.2) and a lower incidence of cesarean deliveries (RR 0.8, 95% CI 0.6, 1.0) (Grenvik, et al., 2019). However, it did not show results in other maternal and neonatal outcomes, such as maternal fatigue.

Thus, it is noticed that the work with the use of PB in labor is recent, allowing a gap on its effects on maternal and neonatal outcomes, as well as all existing studies are performed after the use of pharmacological analgesia and no studies evaluated its effect on maternal fatigue. In this sense, the objective of this study is to develop a protocol to assess the effectiveness of using PB compared to the usual care in maternal fatigue during labor. In addition, it is also intended to compare the use of PB with the usual care of the service in the following outcomes: pain, duration of the first period of labor, route of birth (vaginal, cesarean and instrumental), perineal laceration, episiotomy, maternal anxiety, maternal satisfaction, Apgar of the 5th minute of life, neonatal resuscitation and admission to the Neonatal Intensive Care Unit.

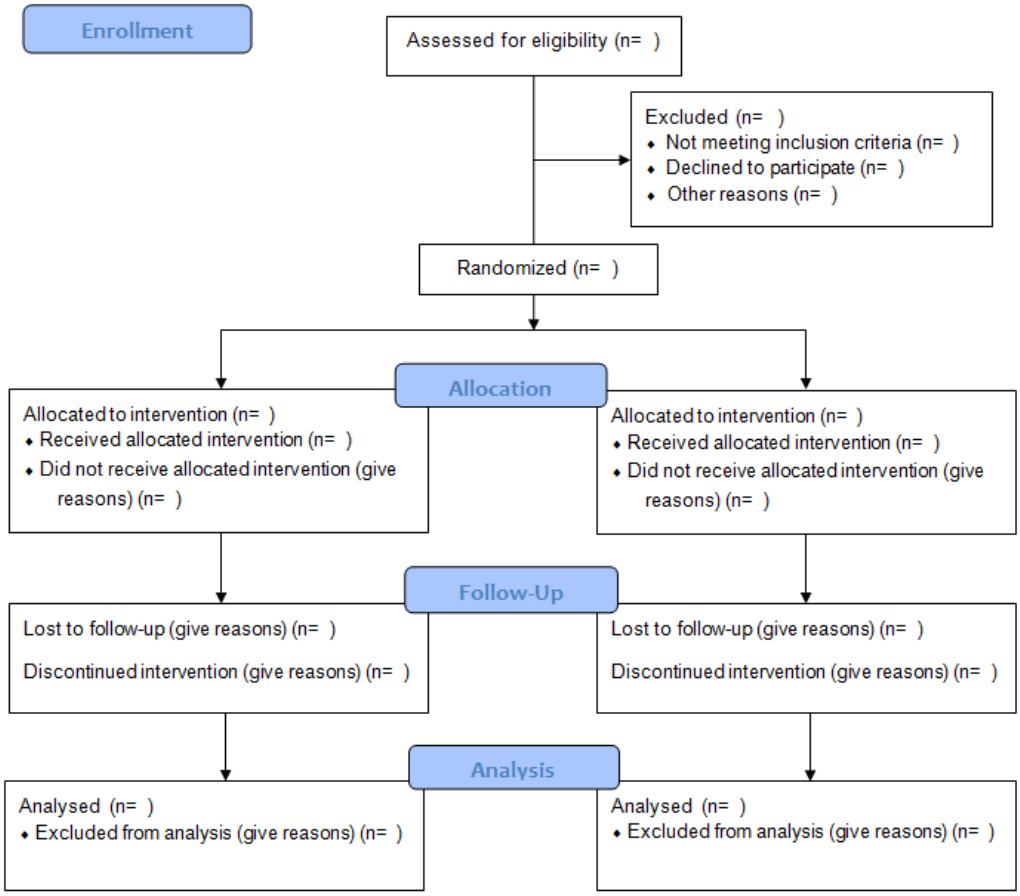
2. Methodology

A randomized clinical trial will be carried out, comparing a group of parturients with the use of PB and a group with Habitual Care of the Service. The hypothesis of the study is that there is a reduction in the level of maternal fatigue with the use of PB in labor compared to the usual care of the service. The research was approved by the ethics committee of Hospital Agamenon Magalhães, in the city of Recife, under the number of opinion 3,670,938 and CAEE 20693719.0.0000.5197.The clinical trial was registered with ReBec (Brazilian Registry of Clinical Trials) (Registry Number): RBR-7z7f5s). The study protocol was developed according to the SPIRIT (Chan, et al., 2013) checklist guidelines.

2.1 Study setting

The research will be carried out at the João Murilo de Oliveira Hospital, located in the municipality of Vitória de Santo Antão- Pernambuco. Figure 1 is a CONSORT (Schulz, et al., 2010) flow diagram of progress in the phases of a randomized study.

Figure 1. Consort flow diagram of the trial.



Source: CONSORT (2010).

The figure shows progress through the phases of a randomized trial. CONSORT is a way for authors to prepare study results reports, facilitating their complete and transparent reports and assisting their critical evaluation and interpretation.

2.2 Randomisation and strata

The randomization of the groups will be carried out according to a table of random numbers, previously generated on a computer, by a statistician who will not participate in the data collection, as this is the most vigorous method of minimizing the selection bias and strengthening the statistical power.

Opaque envelopes will be prepared and numbered sequentially from one to one hundred and twenty-four, with each number, according to the randomization table, corresponding to the patient's designation for the intervention or control group. These envelopes will be prepared by an independent researcher who will not be involved in the research to ensure allocation confidentiality.

2.3 Samplesize

The study sample for the primary outcome (maternal fatigue) was obtained from the result of a pilot study with 40 parturients, found an average maternal fatigue level of 37.9 with 9.7 (DP) in the PB group and 43.4 and (SD) of 11.9 in the Habitual Care group. The calculation was performed in the public domain program Open-epi version 3.019 (Atlanta, GA),

considering a 95% (bilateral) confidence interval, a power of 80% and a sample size ratio of 1. The total sample size found was 124 parturients, divided into 62 for both groups.

2.4 Inclusion and exclusion criteria

Inclusion criteria: pregnant women in the first period of active labor; habitual risk pregnancy; nulliparous, primiparous and multiparous; gestational age between 37 and 42 weeks; gestation of a single fetus in cephalic presentation.

Exclusion criteria: pregnancy with a dead fetus, pregnant women with indication for cesarean section on admission or until the moment of the approach; pregnant women unable to consent; use of psychoactive drugs and epidural analgesia or oxytocin before randomization.

2.5 Intervention and control

In the experimental group, the parturient will be encouraged to use the PB by means of postures supported by the obstetric assessment: fetal height and positioning and the presence of early pull. Five postures will be offered, so that the pregnant woman does not lose her autonomy and consensus to choose the one that promotes her most comfort.

The cervical dilation and the height of the fetal presentation will be evaluated by the professionals who are assisting the parturient at the time of the research. This data will be collected from the participant's medical record or partogram. The height of the fetal presentation will be assessed by the plans of Hodge and DeLee (World Health Organization, 2018). The use of the PB will be indicated when the parturient is in the active phase of labor, regardless of the degree of cervical dilation.

Active phase of labor will be considered when the parturients have a uterine dilation between 5-10 cm and present effective and rhythmic uterine contractions for 10 minutes (World Health Organization, 2018). Early pull will be considered if the pregnant woman is willing to push before 8-10 centimeters of uterine dilation (World Health Organization, 2018).

The researchers will go through training workshops on how to carry out the intervention protocol and how to evaluate the volunteers, in order to minimize the measurement bias. The applications of the postures will be conducted by physiotherapists. The control group will follow the usual routine of the service.

The parturients in the experimental group will use PB during labor. PB is latex and explosion resistant. Pregnant women will start using the ball as soon as they reach 5 cm of uterine dilation. This evaluation will be carried out by the team that accompanies the parturient woman. Positions in PBwill be performed according to the presentation of the fetal head and the stage of labor in which the woman is. You will be guided, if the parturient wants, to change the position every 30 minutes. Three different positions will be used for a total of 90 minutes of use of the ball. These positions will be chosen within the protocol for reducing maternal fatigue in labor developed by the researchers, who have five different postures.

The group of women who will not use PB (control group) will receive the usual care during labor.

2.6 Protocol on the use of the peanut ball in labor

The proposed protocol is according to the evolution of labor: height and positioning of the fetal presentation, erasure and uterine dilation and the presence of early blood flow.

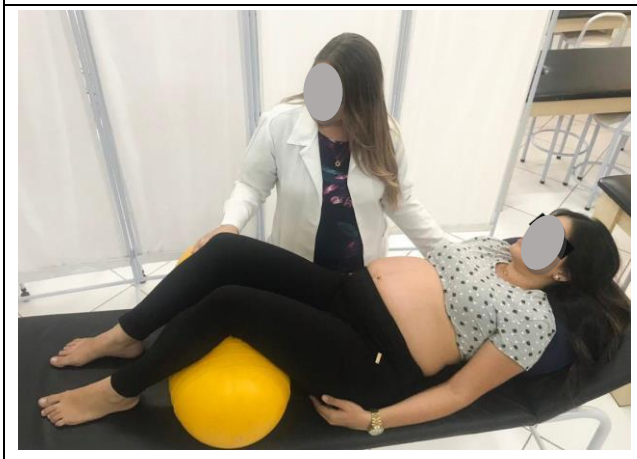
Postures with fetal presentation in the upper strait (DeLee plane -5 to -1 or Hodge plane 1 to 3): postures with abduction and external rotation hips will be encouraged using PB (Figure 2. Posture 1,2,3). These postures promote an opening in the sacriliac joints, increasing the opening of the upper strait, facilitating the sacral counter-movement and favoring the descent of the fetus.

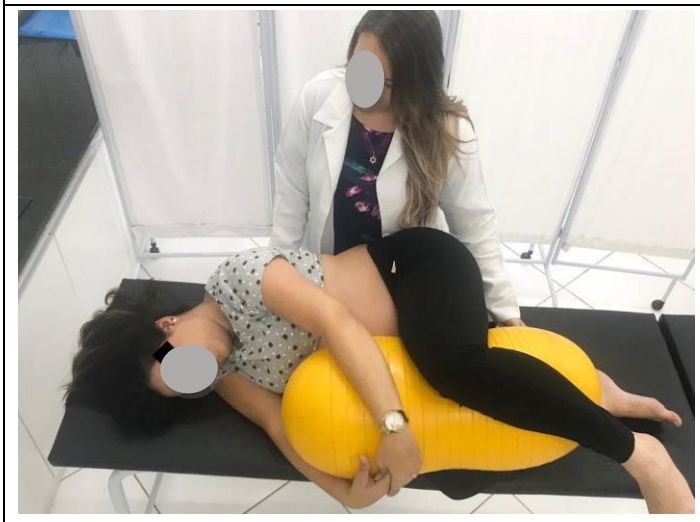
Posture according to the fetal position in the upper strait: fetal presentation in the Posterior Right Occipitus (PRO); Posterior Left Occipty (PLO); Transverse Right Occipit (TRO); Transverse Left Occipit (TLO): posture that cancels gravity will be encouraged: lateral decubitus posture with PB between legs (Figure 2. Posture 4). The hips will be in abduction and

external rotation. This posture helps the rotation of the fetus and promotes an opening of the sacriliac joints, facilitating the sacral counter-movement and increasing the upper narrowing of the pelvis, aiding in the fetal rotation.

Posture according to the presence of early pull in the upper strait: If the parturient feels like pushing or pushing down with the baby tall and cervix before 8-10 centimeters of uterine dilation, posture that nullifies gravity will be encouraged: lateral decubitus with the aid of the ball, with the hips in abduction and external rotation (Figure 2. Posture 5). This posture decreases the pressure of the fetus' weight, decreasing the early desire to push down.

Figure 2: Postures used with PB to reduce maternal fatigue during labor.

Posture 1: PositionSemi-seated	
	The parturient will be semi-reclined on the bed and the upper part of one of the lower limbs rested on the peanut ball in its natural curvature and the other member is in extension next to the peanut ball.
Posture 2: Semi-seatedwith doublesupport	
	The parturient is positioned semi-seated with the head elevated to the maximum, supporting both legs on the curvature of the ball, with 90º flexion of the knee and feet supported on the stretcher.
Posture 3: Externalrotation ofhip	
	The parturient will be semi-seated, with her leg over the curve of the ball. The parturient performs an external rotation of the leg that is on the ball, while the other leg is in extension with external rotation next to the peanut ball.

Posure 4: Lateral decubitus with inclination	
	The parturient is in lateral decubitus. The top leg is at the top of the curve of the peanut ball, however, it is tilted anteriorly. The bottom leg is bent under the curve of the peanut ball.
Posture 5: Bend position	
	It is a lateral decubitus position, in which the legs are directed upwards towards the parturient's head and the ball is brought forward towards the woman's chest so that she can embrace the ball with her arms. This position can also be used at the moment of the pull, except that the inner members are in internal rotation.

Source: Authors.

2.7 Control group protocol:

The volunteers will follow the usual care of the service. They will not be encouraged to use PB and will follow all the health team's conducts.

2.8 Evaluated outcomes:

2.8.1 Primary Outcome

Maternal fatigue will be assessed using the Maternal Perception of Childbirth Fatigue Questionnaire (MCFQ) in the form of an interview before the procedure and every 30 minutes of using the peanut ball during the first period of labor. The instrument is validated and has good measurement properties. It has 15 items and the answers are presented on a 5-point Likert scale: 1 - not at all, 2- a little, 3 - more or less, 4 - a lot and 5 - extremely. The questionnaire categorizes maternal fatigue into: low fatigue (15 to 50 points) and high fatigue (51 to 75 points) (Delgado et al., 2019).

2.8.2 Secondary Outcomes

2.8.2.1 Maternals

The following outcomes will be assessed:

Pain intensity and maternal satisfaction with the use of BP and the experience of labor, using the Visual Analogue Scale (VAS) (Gift, 1989), which varies in discrete numbers from zero to ten, with zero being the total absence of pain and satisfaction ; and then the extreme presence of pain and maternal satisfaction that can be felt.

Pain intensity will be based on perception during the peak of the last uterine contraction at the time of the assessment. This evaluation will be carried out in four moments: 1- before the intervention; 2- after 30 minutes; 3- after 60 minutes and 4- after 90 minutes.

Maternal anxiety will be assessed by the State-Traitanxietyinventory (STAI), adapted for labor in the form of an interview before the procedure and at the end of the first period of labor. The instrument is validated for labor and has good measurement properties (Delgado, et al, 2016). The STAI adapted for women in labor consists of 18 items, the items were classified on a 4-point Likert scale: 1- absolutely not; 2-a little; 3- enough; 4- a lot. The scoring weights for the items related to the absence of anxiety are inverted, that is, the answers marked with 1, 2, 3 or 4 are scored 4, 3, 2 or 1, respectively. The items of absence of anxiety for which the score weights are inverted in the STAI subscale are: 1, 2, 7, 9, 10, 14, 15, 18, 19. Your final score ranges from 18 to 72 points, in the which higher values indicate a higher level of anxiety (Skapinakis, 2014; Biaggio, et al., 1977).

The classification of lacerations was performed by the doctor or nurse who is assisting the volunteer. The evaluation will be through visual inspection of the vulvar introitus and the perineal region, taking into account the degree of laceration (“ACOG Practice Bulletin No. 198,” 2018): 1st degree: involves the skin and/or the vaginal mucosa; 2nd degree: affects the perineal musculature, but does not involve anal sphincter. 3rd degree: involving sphincter muscle of the anus is reached and 4th degree: in addition to the sphincters (internal and external), it reaches the rectal mucosa.

The presence and absence of episiotomy, birth pathways, duration of the second period of labor, use of synthetic oxytocin and epidural analgesia will also be evaluated.

2.8.2.2 Neonatals

Will be evaluated: Apgar of the fifth minute of life, neonatal resuscitation and admission of the neonate to the Neonatal Intensive Care Unit.

A summary of the instruments and questionnaires used to carry out the evaluation of some outcomes are listed in Table 1.

Table1. Instruments and questionnaires used to carry out the evaluation of some outcomes:

Outcomes	Instrumentand/orquestionnaire	MeasurementProperties
Maternal Fatigue	Maternal Perception of Childbirth Fatigue Questionnaire (MCFQ)[7]	α: 0.85 MID: 7 points
PainIntensity	Visual AnalogueScale (VAS)[20]	
Maternal Anxiety	State-trait anxiety inventory (STAI)[21]	α:0,830 MID: 5 points
Satisfaction with the use of the Peanut Ball	Visual AnalogueScale (VAS)[20]	
Satisfaction with the experience of the labor	Visual AnalogueScale (VAS)[20]	
Cronbach's alpha (α)		
Minimal Important Difference (MID)		

Source: Authors.

The table shows all instruments used in the survey for each maternal and neonatal outcome.

2.9 Data Analysis

Data analysis will be performed using the SPSS (Statistical Package for the Social Sciences) software version 23 for Windows. It will be carried out by a "blind" statistician, with the groups identified as A or B and only at the end of the analysis, after the tables have been prepared, will he know about which group corresponds to each letter. The intention to treat principle will be adopted, that is, each patient will be analyzed within the group to which it was originally allocated.

For the characterization of the sample in relation to the maternal and clinical biological variables, a descriptive analysis will be performed, using mean and standard deviation for the quantitative variables. For categorical variables, a frequency distribution analysis will be performed. The baseline characteristics of the groups will be presented in graphs and tables.

To compare the variables, the Student's t test will be used for those with normal distribution (presenting means and standard deviations) and similar variances and Mann-Whitney for the other cases. To compare the ordinal variables, the Mann-Whitney test (with median and interquartile intervals) will be used. To compare the dichotomous variables, the chi-square test will be used. The relative risk will be calculated with a 95% confidence interval. All p values used will be two-tailed and a significance level of 5% will be adopted.

3. Results and Discussion

The PB is a non-pharmacological method used in women during labor in developed countries after the use of pharmacological analgesia. Preliminary studies of randomized clinical trials have obtained clinically significant results (Tussey, et al., 2015; Roth, et al., 2016; Kwan & Mercier, 2018; Hickey & Savage, 2019). Currently, in developing countries, in which women do not have much access to epidural analgesia in their labor, the use of PBis being implemented. However, there is no evidence that this resource has potential clinical benefits for its implementation in hospitals and obstetric centers that do not use routine pharmacological analgesia.

All existing studies (Tussey, et al., 2015; Roth, et al., 2016; Kwan & Mercier, 2018; Hickey & Savage, 2019)., the systematic review (Grenvik, et al., 2019) and a protocol (Stulz, et al., 2018) published with the use of PB, only use this resource after pharmacological analgesia. Therefore, our study is innovative, interesting and feasible, since, we will evaluate

the effectiveness of PB in maternal fatigue in women without the use of pharmacological analgesia, which makes perfect sense, because if we obtain good results, we can implement another method not pharmacological effects during labor, positively impacting public health.

We will try to leave the study pragmatic, and the volunteers will be encouraged to stay as long as possible using PB, but they will be able to adopt other behaviors during the experiment, all this, so that the study will be as natural and similar to the reality of obstetric care humanized. The parturients will be able to fulfill their wants and needs during the entire research. It will be calculated by the researchers, by means of a stopwatch, the time they will remain in the postures. The researchers will go through training workshops on how to carry out the intervention protocol and how to evaluate the volunteers, in order to minimize the measurement bias. The applications of the postures will be conducted by physiotherapists. The control group will follow the usual routine of the service.

If the results are favorable, it will facilitate the implementation of more resources in assisting women during labor. In addition, we will have evidence of the benefits and harms of this resource in the control of fatigue, as well as in maternal and neonatal outcomes. The developed protocol can be used in parturients all over the world, especially in environments with few resources, because it is a low cost resource for the health system.

In addition, it will provide information for future research on resources that can act on maternal fatigue during labor. The survey will also provide an instant result of information on the level of satisfaction of women with the use of PB and their labor, outcomes considered clinical and important, supported by the World Health Organization and a Cochrane review, carried out through consultations with obstetrics specialists and women who experienced labor.

4. Conclusion

A specific protocol was developed with the use of PB, through an obstetric evaluation, to reduce maternal fatigue during labor. If its effectiveness is proven, the protocol will show benefits in relation to the reduction of maternal fatigue, being an innovative, non-invasive, non-pharmacological and low cost method. This protocol can assist in the production of knowledge about another non-pharmacological method used during labor.

It is suggested that further studies can be carried out on the applicability of the protocol with the peanut ball. It is believed that the use of this protocol can help other researches to manage and evaluate other maternal and neonatal outcomes.

Declaration of interest

The authors declare no conflicts of interest.

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