

## Original Research Article

# Effects of antenatal pelvic floor preparation techniques on the perineal integrity: a randomized controlled trial protocol

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## ABSTRACT

**Background:** The objective of the present study was to compare the effects of perineal massage, vaginal dilator and pelvic floor muscles training on the perineal integrity of primiparae women.

**Methods:** Primigravidae women over 18 years old will be selected, from the 32th gestational week and wishing to have a vaginal delivery. Pregnant women will be randomly allocated from a sequence generated by a computer program into three groups: perineal massage, vaginal dilator and pelvic floor muscles training. The technique should be practiced from the 34th week of pregnancy until the beginning of labor. Randomization will be done by a researcher who was not involved with the recruitment, assessment and treatment of the participants. All participants will undergo a clinical and functional assessment of the pelvic floor before the beginning of the technique practice, as well as a reassessment of these items and an assessment of perineal integrity between 45 and 60 days after delivery for a blind physiotherapist regarding the interventional procedures. The evaluative procedures will be done by a 'blinded' physiotherapist in relation to the intervention procedures. The outcome will be determined by the perineal integrity by the presence or absence of perineal laceration as well as their characteristics observed immediately after delivery.

**Conclusions:** The knowledge of the effects of antenatal pelvic floor preparation techniques on the perineal integrity and pelvic floor muscles function after delivery, will allow a better choice about which approach is the best to pregnant women to prevent perineal trauma.

**Keywords:** Pelvic diaphragm, Perineal trauma, Natural birth, Physical therapy

## INTRODUCTION

Perineal trauma due to vaginal delivery has been recognized as the causative agent of several comorbidities that generate losses to women's health.<sup>1-3</sup> Thus, perineal integrity has been a challenge in the practice of pregnant women assistance and parturient, in order to avoid sequelae especially to the neuromuscular structures of the pelvic floor. These structures, when damaged, can lead to disorders, such as urinary and

anorectal disorders, pelvic pain, disabilities of pelvic support and sexual dysfunction.<sup>4,5</sup>

Techniques performed during pregnancy are described as methods that can help to promote perineal integrity after vaginal delivery, such as perineal massage, pelvic floor muscles training and, more recently, the vaginal dilator.<sup>1,3,6-10</sup> However, despite the remarkable importance, no studies were found comparing these antenatal methods in the prevention of perineal trauma.

In a recent systematic review, Beckmann and Stock found four controlled clinical trials comparing perineal massage group with a control group.<sup>3</sup> Perineal massage performed during pregnancy in women with no previous vaginal birth was associated with reduced occurrence of perineal trauma with suturing necessary and perineal pain reduction after three months of delivery.

Brito et al in a systematic review about the Epi-No® observed that the vaginal device did not show to reduce episiotomy rates, the time of the second stage of labor and the need for operative vaginal deliveries. It is worth noticing the low methodological quality of the researches conducted until now involving this type of device.<sup>9</sup>

Another physical therapy approach rarely discussed as a preventive measure of perineal trauma is the pelvic floor muscles training (PFMT). Few studies used PFMT aiming birth outcomes.<sup>11-18</sup> Du et al in a systematic review with meta-analysis found that PFMT during pregnancy was effective in reducing the time of the first and second stages of labor in primiparae.<sup>10</sup> In contrast, it was not found significant association between antenatal PFMT with the reduction in episiotomy rates, need for instrumental vaginal delivery and a reduction at the risk of perineal laceration. The authors pointed out some limitations in the findings as the wide variation in PFMT programs used in the selected studies, such as frequency, intensity and duration of training which may influence the intervention results. Furthermore, authors suggest the implementation of new studies with larger sample sizes and better exclusion criteria delineation, to avoid other factors that may interfere the delivery outcomes.

Considering the beneficial effects of pelvic floor preparation prior to vaginal delivery, the existence of a well-established technique in its effectiveness such as perineal massage and the emergence of new approaches as the vaginal dilator Epi-No® and PFMT, becomes important to carry out studies aiming to compare the effects among the three existing methods in the prevention of perineal trauma.

The aim of this study was to compare the effects of perineal massage, vaginal dilator and PFMT in the pelvic floor preparation for vaginal delivery on the perineal integrity of primiparae.

## **METHODS**

### ***Study design***

The study will be a single blind randomized controlled trial. It was approved by the Research Ethics Committee of the Federal University of São Carlos (UFSCar) under protocol number 1.218.385 and was registered in Clinical-Trial.gov (registration number of the NCT02582580).

### ***Participants***

It will be included in the study usual risk primigravidae women over 18 years old, from the 32nd gestational week and wishing to have a vaginal delivery. It will not be included pregnant women with pelvic or vaginal surgeries, presence of pelvic organ prolapse, intolerance to vaginal palpation, inability to contract the pelvic floor muscles, vaginal infections, neurological and/or cognitive impairments that prevent an understanding of the proposed procedures and pregnant women who used antenatal pelvic floor methods of preparation prior to study enrollment. After the beginning of the study, it will be excluded pregnant women that will undergo cesarean surgery.

The study will be conducted at the research Laboratory on Women's Health (LAMU) of the department of physical therapy, Federal University of São Carlos (UFSCar). Women, who meet the selection criteria and accept to participate in the study, will sign a Free and clarified consent term.

### ***Sample size***

The sample size calculation was performed using the G \* Power software (3.1.5, Germany), in order to compare three study groups formed according to the technique that the pregnant woman will perform. It was considered the application of the Goodness of fit and contingency test with a large effect size ( $f^2 = 0.40$ ), 80% power and 5% of significance level, which resulted in 21 women in each group.

### ***Assessment procedures***

All assessment procedures will be conducted by a blinded physiotherapist regarding interventional procedures. Eligible pregnant women will undergo two assessments: clinical and pelvic floor.

Clinical evaluation will be conducted through a questionnaire about sociodemographic and obstetric history. After delivery, it will be collected the data of the labor process (gestational age at labor, need for interventions during labor such as forceps and analgesia, labor duration, especially the duration of the second stage, the position adopted at second stage) by using a structured form to be completed by the health professional responsible for assisting the participant's labor process. The pelvic floor assessment will be made by digital palpation with the participant in the supine position with hips flexed approximately 60° and with 45° of knees flexion and feet resting on the examination table. This assessment will be done at the time of initial evaluation (before the intervention) and between 45 and 60 days after delivery.

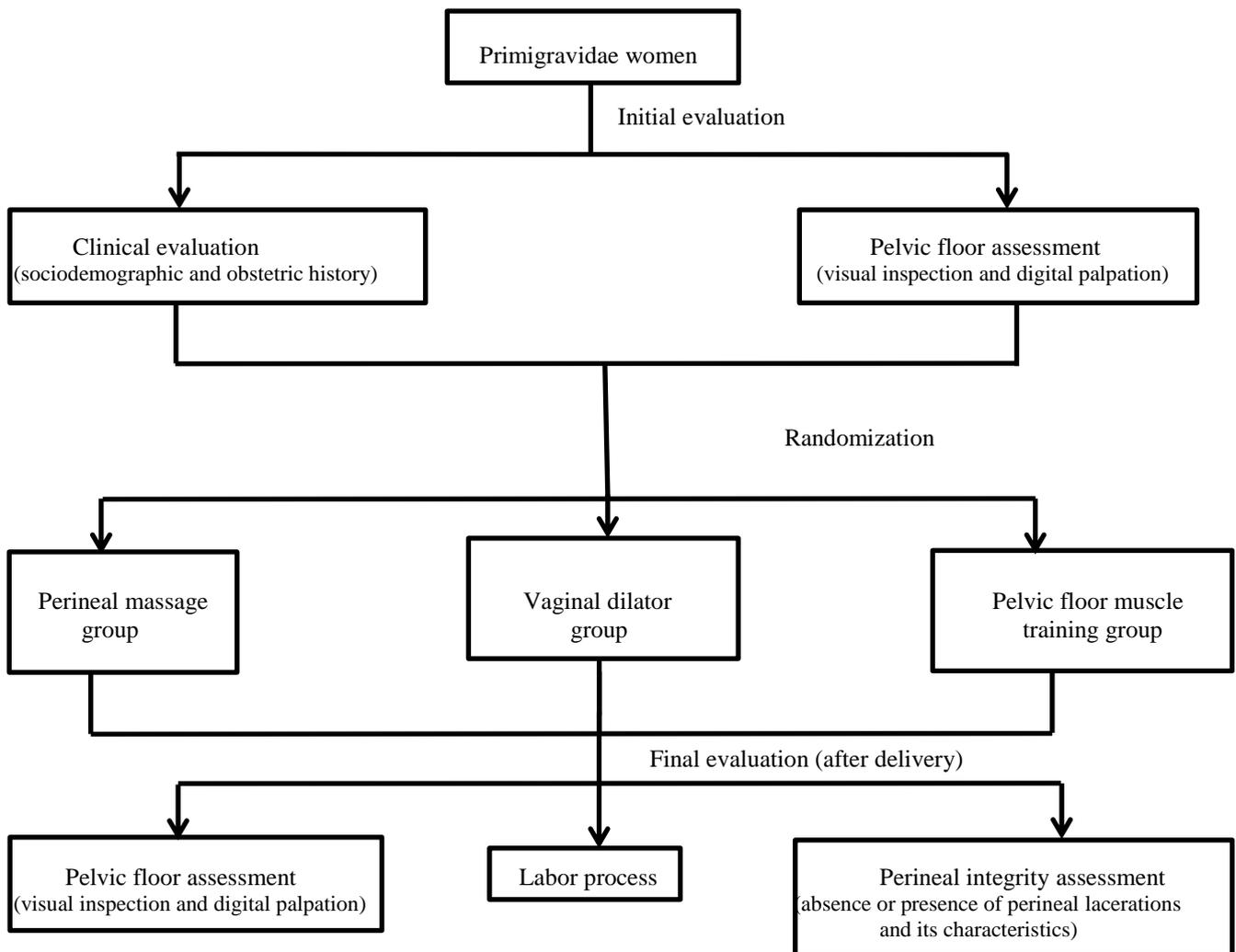
On physical examination, visual inspection and palpation to assess the overall condition of the pelvic floor will be made. On visual inspection it will be verified the color, changes in the skin and mucosa integrity, presence of tissue sagging, and in palpation, by finger touch, it will be observed the bilateral muscle tone, possible presence of trigger points and pelvic organ prolapse. Next, it will be the assessment of pelvic floor function by the PERFECT method which is a functional assessment of the pelvic floor muscles (PFM) allowing to analyze the muscle contraction and condition of the fibers.<sup>19</sup> The contraction of PFM will be requested during expiration.

**Intervention procedures**

After the evaluation processes, the participants will be randomized by a researcher who was not involved with the recruitment, evaluation and treatment of participants using a sequence generated by a computer program

(<http://www.randomization.com>). The participants will be randomly allocated into three groups: perineal massage group (PMG), vaginal dilator group (VDG) and pelvic floor muscles training group (PFMTG). All participants should practice the proposed technique from the 34th week of pregnancy until the beginning of labor. After delivery, the participants will be submitted to the following assessments: labor process, perineal integrity and pelvic floor assessments as shown in Figure 1.

The participants will receive voice guidance and an informative written booklet about how to perform the technique proposed. A practical demonstration of how to do the technique will be done by a trained physical therapist in order to become familiar with the procedure and to take away all possible doubts. All participants will be monitored weekly by a physiotherapist to make sure that the techniques are being performed properly as proposed.



**Figure 1: Flow diagram summarizing the initial and final assessments, and the allocation process of participants in the groups.**

**Table 1: TMAP protocol developed for the present study. The description refers to a series of training (a total of four series daily).**

Gestational Week	Position Adopted	Type of muscular contraction	Number of contractions	Contraction sustaining time	Muscle relaxation time after contraction
34 <sup>th</sup>	Left lateral decubitus	Slow	10	3 seconds	6 seconds
		Fast	3	1 second	-
35 <sup>th</sup>	Sitting in the chair - feet flat	Slow	10	4 seconds	8 seconds
		Fast	3	1 second	-
36 <sup>th</sup>	Sitting in the chair - feet flat	Slow	10	5 seconds	10 seconds
		Fast	3	1 second	-
37 <sup>th</sup>	Sitting (Buddha)	Slow	10	6 seconds	12 seconds
		Fast	3	1 seconds	-
38 <sup>th</sup>	Sitting (Buddha)	Slow	10	7 seconds	12 seconds
		Fast	3	1 second	-
39 <sup>th</sup>	Crouching	Slow	10	8 seconds	12 seconds
		Fast	3	1 second	-
40 <sup>th</sup>	Crouching	Slow	10	8 seconds	12 seconds
		Fast	3	1 second	-

***Perineal massage group (PMG)***

The participants of this group will be orientated to practice perineal massage once a day during approximately 10 minutes per practice, from the 34th week of gestation until the beginning of labor. Massage can be made by the pregnant woman herself or by someone else and should obey the following sequence: 1) after hand hygiene, the pregnant woman must be positioned comfortably (semi-sitting, crouching or standing with one leg resting on a step) and use intimate water based lubricant at her fingertips; 2) start the massage in the outdoor area of the vulva with circular movements of the skin and connective tissue around the vagina and at the central tendon of the perineum, clockwise, clitoris to clitoris; 3) introduce two thumb fingers or index and middle fingers into the vagina at a distance of approximately 4 centimeters; 4) perform internal massaging with laterally semicircles towards the anus for 20 to 30 seconds; 5) put pressure down towards the anus and to each side of the vagina until feeling a slight burning or stretching sensation and hold the position for 2 minutes; 6) massage the lower half of the vaginal introitus in a movement simulating the letter "U". All movements should be repeated four times.<sup>3</sup>

***Vaginal dilator group (VDG)***

Pregnant women of this group should use the vaginal dilator Epi-No® once a day for 15 minutes, from the 34th week of pregnancy until the beginning of labor. This device consists of a silicone balloon in an eight shape that, after inserted into the vagina, is inflated by manual pumping, promoting a stretching of the structures around it (hymenal edge, connective tissues and muscles perivaginal). The vaginal dilator should be coated with a condom and intimate water based lubricant and then be

inserted into the vaginal canal in such way that the balloon stays two centimeters away from the vaginal introitus. This position is to ensure the lengthening of the desirable structures and that it does not touch the uterine cervix during use.<sup>2,4</sup> Then, the device will be inflated by manual pumping until the tolerable woman's limit. The pregnant woman will be encouraged to daily inflate a greater volume of compressed air into the balloon so that the amount of air is greater than the quantity in the previous day, achieving, day after day, a greater stretching of perivaginal structures, always respecting the individual tolerance limit.<sup>2</sup> The amount of manual pumping imposed to inflate the balloon should be written in an Intervention Diary so that the next use, the pregnant woman will be sure that pumped the device more times than in the previous session. At the end of use, the balloon should be washed with water and mild soap and dried with a paper or cotton towel.

***Pelvic floor muscles training group (PFMTG)***

The participants allocated to this group will perform PFMT. In this study, it was decided to prepare a progressive protocol emphasizing conscious muscle relaxation, i.e., considering a resting time based on the contraction time. The resting time was double of the sustaining time of each contraction up to the 38th week of pregnancy, after remaining fixed this relaxation time up to the moment of delivery. This time was chosen because during the expulsive labor phase, there is a need for the PFM to consciously relax during a long period, in order to facilitate the descendants and rotational movements of the baby's head and consequently, its passage.<sup>5,20</sup> Thus, the PFMT protocol of this study does not aim only muscle strength but also contraction promotion, which aims body and perineal awareness, muscle tone, coordination and appropriate motor control to allow an

active muscle relaxation in the second labor stage. The progression of PFMT will occur gradually in view of the peculiarities that involve the pelvic floor in the gestational stage (mechanical and hormonal overload) and the ultimate goal is the promotion of an intact perineum after vaginal delivery. The exercises will obey a sequence, according to the gestation week, considering the following factors/parameters: exercise position, number and sustaining period of slow and fast contractions, and relaxation time between contractions as given in Table 1.<sup>21</sup>

All pregnant women should contract the PFM during the expiratory phase of breathing associated with an isometric contraction of the abdominal muscles and at the end of each series of contractions, perform a one minute interval between sets and in that time perform the diaphragmatic breathing exercise to promote overall relaxation. At that moment, the pregnant woman may adopt any comfortable and convenient position for her.<sup>21</sup> The participants will carry out the PFMT protocol proposed once a day, every day from the 34th week of gestation until the beginning of labor. Digital palpation will be used only to verify the correct PFM contraction in all weekly sessions of physiotherapy follow up.

### **Outcome measures**

#### *Primary outcome*

The primary outcome will be the perineal integrity assessed by the absence or presence of perineal lacerations as well as the description of its characteristics, according to the protocol described by Leite.<sup>22</sup> The characteristics to be evaluated are:

#### *Type*

Classified as single or multiple considering the anterior and posterior perineum region and vaginal wall.

#### *Location*

Classified according to the affected region. Being the anterior region of the perineum, involving the clitoris, left little lip, small right lip, left vestibular region and right vestibular region. The posterior perineum region will be considered when involving left, right and middle region. The vaginal wall will be considered when it presents anterior, back, left back and right back lacerations.<sup>22</sup>

#### *Degree of perineal laceration*

It will be evaluated as described by Cunningham et al.<sup>23</sup>

#### *Laceration form*

It will be considered solely for the lacerations affecting posterior perineal region and should be classified as linear, branched and "U" shaped.<sup>22</sup>

The data related to the technique and the material used for perineal suturing should be reported when performed, given its relationship with the healing quality of perineal repair and its implications with the appearance of painful disorders of pelvic floor.<sup>22,24-26</sup> All notes related to perineal outcomes will be recorded in a structured form that will be provided to professional that will lead the delivery. In this form, there will be a schematic drawing of the vulva and perineum to mark the exact location where the tear occurred.

#### *Secondary outcome*

The secondary outcome will be the function of the PFM evaluated by the PERFECT method between 45 and 60 days after delivery.<sup>19</sup>

#### *Statistical analysis*

Statistical analysis will be done by a blinded investigator who will not have knowledge of which treatment group the data belongs. The data will be tabulated on Excel software and statistically analyzed in Statistica 7.0 program. Data will be expressed in absolute and relative frequencies, mean and standard deviation. Independent variables will be the methods of intervention: perineal massage, vaginal dilator and TMAP. Dependent variables will be perineal integrity and MAP function.

Data normality will be confirmed by Shapiro-Wilk test. A logarithmic transformation will be used for the variables of asymmetric distribution. The presence or absence of laceration after delivery will be calculated using the chi-Square test. The effect of interventions (intra group) will be calculated using analysis of variance (ANOVA) and in significant cases will be used Tukey test to discriminate the difference.

The clinical relevance of the results will be confirmed by calculating the effect size of the significant differences found between the groups. The effects will be Considered: 0:00 to 0:49 small; Medium 0.50-0.79 and 0.80 above great.<sup>27</sup> A 5% significance level will be assumed.

### **DISCUSSION**

Although there is a well-established technique for the promotion of an intact perineum as the perineal massage, the emergence of new approaches are necessary. A study which compares the effects of this method with the vaginal dilator Epi-No® and a TMAP protocol is required. These methods take into consideration labor physiology and PFM participation, given their notorious involvement in clinical outcomes in women's health.

To facilitate the passage of the baby through the birth canal, it is required a greater compliance and flexibility of pelvic floor. The techniques involving tissue stretch as the perineal massage and Epi-No® vaginal dilator

promote greater distensibility of perineal and perivaginal tissues, including skin and muscles. The PFMT favors the control, coordination and muscle relaxation, making it more flexible and relaxed at the time of the baby's passage, providing the woman better control over her perineal muscles during childbirth, as well as a positive attitude to conduct a spontaneous delivery. During the second labor stage, the woman needs to contract the abdominal muscles and relax the perineal region muscles, promoting a muscular balance in this active process in order to allow the descendants and rotational movements of the fetal head and drive out the baby with lower perineal trauma risks.<sup>9-12,28</sup>

The stretching techniques promote a controlled deformation of the muscles, i.e., an elastic deformation (not permanent). The type of deformation is influenced by the strength and the duration of the deformation force. If the force is small, but applied for a long time, for instance during labor with a prolonged expulsive stage, this deformation may become plastic (permanent), resulting in tissue laxity. Therefore, well conducted stretching techniques for short periods and a controlled muscle strength previously trained by specific exercises, with more muscle awareness, coordination and flexibility, contribute to a lower likelihood of perineal injury.<sup>11-18,29</sup> Few studies have evaluated the effects of Epi-No® in perineal outcomes and on the role of PFM, and the existing results are still inconsistent due to lack of studies with methodological rigor and also directed to the Brazilian population.

Scientific research suggests that TMAP during pregnancy period can lead to obstruction of the vaginal canal due to hypertrophy and increased muscle tone, resulting in negative outcomes in delivery.<sup>16,30</sup> In addition, uncontrolled activation of MAP, with or without abdominal muscles training, can increase the PFM tension, resulting in a resistance of the delivery canal, representing an obstacle to the passage of the baby.<sup>28,30</sup> However, other studies claim that antenatal TMAP improves flexibility, strength and motor control, facilitating the passage of the baby during the second delivery stage, reducing the need for instrumental delivery and the risk of injury.<sup>11,18</sup>

Thus, knowing the effects of antenatal methods of pelvic floor preparation on the perineal integrity and function of the PFM as well as compare them will bring scientific knowledge to assist in the decision-making about which method is the best suited to clinical practice aiming the prevention of perineal trauma.

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