

# Antenatal perineal massage for trauma prevention: a pilot randomized clinical trial

Massagem perineal pré-natal para prevenção do trauma: piloto de ensaio clínico randomizado

Masaje perineal prenatal para la prevención del trauma: piloto de ensayo clínico aleatorizado

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## Descriptores

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## Abstract

**Objective:** To evaluate the adherence of pregnant women and companions to the performance of digital perineal massage during pregnancy and its effect on the prevention of perineal trauma during childbirth and on the reduction of associated morbidity at 45 and 90 days postpartum.

**Methods:** A pilot study of a randomized clinical trial with 153 normal risk pregnant women; 78 women in the intervention group underwent digital perineal massage and 75 women in the control group received usual care. For the analysis of the main outcome (perineal trauma) and secondary outcomes, 44 women who had vaginal delivery remained in each group. The intervention was performed daily by the pregnant woman or the companion of her choice from 34 weeks of gestation during 5-10 minutes.

**Results:** Perineal massage was a protective factor for edema in the first 10 days postpartum (RR 0.64 95%CI 0.41-0.99) and involuntary gas loss at 45 days postpartum (RR0.57 95%CI 0.38-0.86). The residual adjustment  $\geq 2$  observed in the analysis of perineal conditions postpartum showed a trend of women in the intervention group having an intact perineum. The women and companions who performed perineal massage accepted the practice well, recommended it and would do it again in a future pregnancy.

**Conclusion:** The digital perineal massage performed daily from 34 weeks of gestation was a practice well accepted by women of this study and their companions. Although not protecting women from perineal trauma, this practice reduced the risk of edema at 10 days postpartum and gas incontinence at 45 days postpartum.

Brazilian Clinical Trial Registry: RBR-4MSYDX

## Resumo

**Objetivo:** Avaliar a adesão de gestantes e acompanhantes à realização da massagem perineal digital durante a gestação e seu efeito na prevenção do trauma perineal no parto e na redução de morbidade associada nos 45 e 90 dias pós-parto.

**Métodos:** Estudo piloto de ensaio clínico randomizado com 153 gestantes de risco habitual, 78 mulheres no grupo de intervenção realizaram a massagem perineal digital e 75 mulheres do grupo controle receberam os cuidados habituais. Para a análise do desfecho principal (trauma perineal) e dos desfechos secundários, permaneceram em cada grupo 44 mulheres que tiveram parto vaginal. A intervenção foi realizada pela gestante ou acompanhante de sua escolha, diariamente, a partir de 34 semanas de gestação, por 5 a 10 minutos.

**Resultados:** A massagem perineal foi fator de proteção para edema nos primeiros 10 dias pós-parto (RR 0,64 IC95%0,41-0,99) e perda involuntária de gases nos 45 dias pós-parto (RR0,57 IC95%0,38-0,86). O ajuste residual  $\geq 2$  observado na análise das condições do períneo pós-parto mostrou uma tendência das mulheres

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do grupo intervenção terem períneo íntegro. As mulheres e os acompanhantes que realizaram a massagem perineal aceitaram bem a prática, recomendariam e fariam novamente em futura gestação.

**Conclusão:** A massagem perineal digital realizada diariamente, a partir de 34 semanas de gestação, foi uma prática bem aceita pelas mulheres e acompanhantes deste estudo. Apesar de não proteger a mulher de trauma perineal, esta prática reduziu o risco de edema 10 dias pós-parto e incontinência de gases 45 dias pós-parto.

## Resumen

**Objetivo:** Evaluar la participación de mujeres embarazadas y acompañantes en la realización del masaje digital perineal durante el embarazo y su efecto en la prevención del trauma perineal durante el parto y en la reducción de la morbilidad asociada con los 45 y 90 días post parto.

**Métodos:** Estudio piloto de ensayo clínico aleatorizado con 153 mujeres embarazadas con riesgo normal, 78 mujeres en el grupo de intervención realizaron el masaje digital perineal y 75 mujeres del grupo control recibieron los cuidados habituales. Para el análisis del desenlace principal (trauma perineal) y de los desenlaces secundarios, permanecieron en cada grupo 44 mujeres que tuvieron parto vaginal. La intervención la realizó la mujer embarazada o el acompañante por ella elegido, diariamente, a partir de las 34 semanas de embarazo, por 5 a 10 minutos.

**Resultados:** El masaje perineal fue factor de protección para el edema en los primeros 10 días postparto (RR 0,64 IC95%0,41-0,99) y la pérdida involuntaria de gases en los 45 días post parto (RR0,57 IC95%0,38-0,86). El ajuste residual  $\geq 2$  observado en el análisis de las condiciones del perineo postparto mostró una tendencia en las mujeres del grupo intervención a que tengan el perineo íntegro. Las mujeres y los acompañantes que realizaron el masaje perineal recibieron bien la práctica, la recomendarían y la harían nuevamente en un futuro embarazo.

**Conclusión:** El masaje digital perineal realizado diariamente, a partir de las 34 semanas de embarazo, fue una práctica bien recibida por las mujeres y acompañantes de este estudio. Pese a que no protege a la mujer de un trauma perineal, esta práctica redujo el riesgo de edema a los 10 días post parto y la incontinencia de gases 45 días post parto.

## Introduction

Most vaginal births are associated with some perineal trauma as a result of spontaneous lacerations or as a consequence of episiotomy. A study conducted in the United Kingdom showed that only 9.6% of nulliparous women and 31.2% of multiparous women had an intact perineum after a vaginal birth.<sup>(1)</sup> In Brazil, the results of care provided at a Natural Birth Center showed that minor traumas - intact perineum and first-degree lacerations – accounted for 75.6% of women treated, with 10.3% of second-degree lacerations and 14.1% of episiotomy.<sup>(2)</sup>

The occurrence of perineal trauma can be influenced by several factors such as maternal age, gestational age at birth, baby's weight at birth,<sup>(3)</sup> maternal position<sup>(4)</sup> and professional assisting the birth.<sup>(5)</sup> Perineal pain and dyspareunia are frequent postpartum morbidities, and recovery from perineal trauma is among the main factors that affect the resumption of sexual activity during this period.<sup>(6)</sup>

Despite the negative impact on women's daily activities, the discomfort caused by trauma is often neglected by health professionals or not reported by women for being considered normal in the postpartum period.<sup>(7,8)</sup> During vaginal delivery care, different interventions are being used to stretch the perineum slowly, favoring physiology and avoiding

perineal injury. Among the techniques performed in the second stage of labor are the use of warm compresses, intrapartum perineal massage<sup>(9)</sup> and perineal injection of hyaluronidase.<sup>(10)</sup> Some interventions used to prevent perineal trauma during pregnancy are being investigated such as Epi-no,<sup>(11-13)</sup> antenatal digital perineal massage<sup>(14)</sup> and pelvic floor training programs.<sup>(15)</sup>

In a systematic review on the performance of digital perineal massage from 34 weeks of pregnancy onwards, were indicated benefits as a general reduction in the incidence of trauma that requires suturing, less propensity for episiotomy in primiparous women and a significant reduction in the incidence of pain in the first three months after childbirth among multipara women.<sup>(14)</sup> Regarding adherence, most women assess the practice as physically and psychologically acceptable, also when performed by a partner of their choice.<sup>(16)</sup>

Although digital perineal massage is a low-cost practice that can be performed by the pregnant woman herself and/or her partner, and the available evidence indicate considerable benefits, there is no knowledge about the feasibility and effectiveness of this intervention in the Brazilian reality. In this context, the aim of this study was to evaluate the adherence of pregnant women and their companions to the performance of digital perineal massage

during pregnancy and its effect on the prevention of perineal trauma during childbirth and on the reduction of associated morbidity at 45 and 90 days postpartum.

## Methods

Pilot study of a randomized clinical trial (RCT) developed as part of a mixed-method study thesis on the topic of antenatal perineal massage for the prevention of perineal trauma in the Brazilian reality. Pilot studies address a variety of methodological and practical issues that allow testing the feasibility of a complete RCT and assessing the acceptability of an intervention.<sup>(17)</sup>

The study subjects were pregnant women who intended to give birth in one of the three public maternity hospitals (A, B and C) in Greater Florianópolis in the state of Santa Catarina, Brazil. Inclusion criteria were: single, normal risk pregnancy, regardless of maternal age, gestational age  $\leq 35$  weeks at randomization, decision for vaginal delivery at the end of pregnancy. Exclusion criteria were fetal death, fetus with estimated weight  $\geq 4,000$ g or any evidence of cephalopelvic disproportion, indication for elective cesarean, allergy to almond oil and already undergoing perineal massage.

For pregnant women and, when present, for companions available to perform the intervention, the following inclusion criteria were also included: availability to perform perineal digital massage daily for 5-10 minutes; ability to understand, read and speak Portuguese and understand massage instructions.

The pilot study was conducted because Brazilian studies about the intervention have not been identified and there is need to assess its feasibility in the Brazilian reality. The sample was based on Kelsey's formula<sup>(18)</sup> for RCTs using data from a Canadian study,<sup>(19)</sup> and 289 pregnant women were estimated for each group (5% significance level and 80% test power), which is an unattainable sample for this project. As a result, the sample size of the pilot study was determined by the time available, from March 2016 to December 2017, for the collection

and analysis of data on the perineal outcome soon after birth, as well as at 45 and 90 days postpartum.

Women in the intervention group (IG) underwent digital perineal massage (self-massage) or received it from a companion of their choice. The practice of digital massage consists of introducing one or two fingers three to four centimeters deep into the entrance of the vagina, first applying and maintaining downward pressure for two minutes and then for another two minutes on each side.<sup>(19)</sup> Women in the control group (CG) performed the usual antenatal care.

Pregnant women were invited to participate in the waiting room of local health units before or after the antenatal consultation, in group meetings of pregnant women, or during a visit offered by one of the institutions to get to know the maternity. After recruiting eligible subjects, data collection was systematized in four steps.

The first step consisted of an individual meeting for randomization, orientation session on the intervention and collection of sociodemographic (age, marital status, years of education and skin color) and obstetric (gestational age at randomization, antenatal care location and having had childbirth, episiotomy or previous laceration) data. At the randomization meeting scheduled before the draw, women received written and oral information about the most recent evidence about episiotomy and spontaneous laceration. A sequence of random numbers was computer generated for the randomization, the numbers were inserted into individualized, opaque and sealed envelopes. The participants chose an envelope and after opening, the number was checked for IG or CG in the generated list of random numbers.

All participants were instructed not to reveal to professionals in antenatal care and the maternity about the study in order to reduce the possibility of bias in the care and recording of perineal conditions after birth.<sup>(20)</sup>

In the orientation session, information was given to IG participants and companions about how to massage the pelvic floor muscles daily for 5-10 minutes from 34 weeks of pregnancy until the day of delivery. The guidelines included the use of vid-

eo and explanatory folder, provision of almond oil to help with vaginal lubrication during the massage and a diary to record the number of days the massage was performed, if it was performed by the pregnant woman or companion, and average completion time.

In the second step, data on childbirth care were collected through an interview with the puerperal woman in the maternity hospital (use of Kristeller maneuver and Valsalva maneuver) and from the medical record (use of analgesia, professional who attended the birth, induction of labor, use of oxytocin, position of delivery, newborn's weight and perineal condition after delivery).

The third and fourth steps comprised telephone interviews at 45 and 90 days postpartum with collection of data on symptoms observed in the first 10 days, as well as at 45 and 90 days postpartum.

Data of the interview with mothers and companions (if they were able to perform the massage as instructed, if they would do it again in a future pregnancy and if they would recommend the practice) and of the diary records (number of days when the pregnant woman and/or companion performed the massage and the average time in minutes for the perineal massage) were collected for analysis of the main outcome, i.e. the adherence of women and companions to the perineal massage during pregnancy. The positive answer to these questions, added to the performance of perineal massage for at least 5 minutes in each session, for at least 10 days corresponded to good adherence to the guided practice.

Data on the perineal condition after delivery (intact perineum, first-degree laceration without and with suture, second-degree laceration or episiotomy) were collected from medical records. The other secondary outcomes were all reported by women using the Visual Analog Scale ranging from 0 to 10 (0 = no pain; 5 = moderate pain; and 10 = the worst pain) for the outcome: perineal region pain and dyspareunia soon after delivery and at 45 and 90 days; the report of yes or no for the outcomes pain, redness, hematoma and edema in the perineal region in the first 10 days postpartum; the occurrence of urinary, gas and bowel incontinence

at 45 and 90 days postpartum; and the number of days for resumption of sexual activity.

Data were analyzed in the IBM SPSS Statistical package. In the descriptive analysis, the absolute and relative frequency (categorical variables) and measures of position and dispersion of data (numerical variables) were verified. The normal distribution of data was verified by the Kolmogorov-Smirnov or Shapiro Wilk test, according to sample size.

The comparison of numerical variables between the IG and CG was performed using the independent t test or the Mann-Whitney U test, according to data distribution. For the association of categorical variables with groups (IG and CG), the Pearson's Chi-Square or Fisher's Exact test was performed, with presentation of the gross analysis of the respective Relative Risks (RR) and confidence interval. It was not possible to perform the adjusted analysis of RR by control variables due to the sample size of the study.

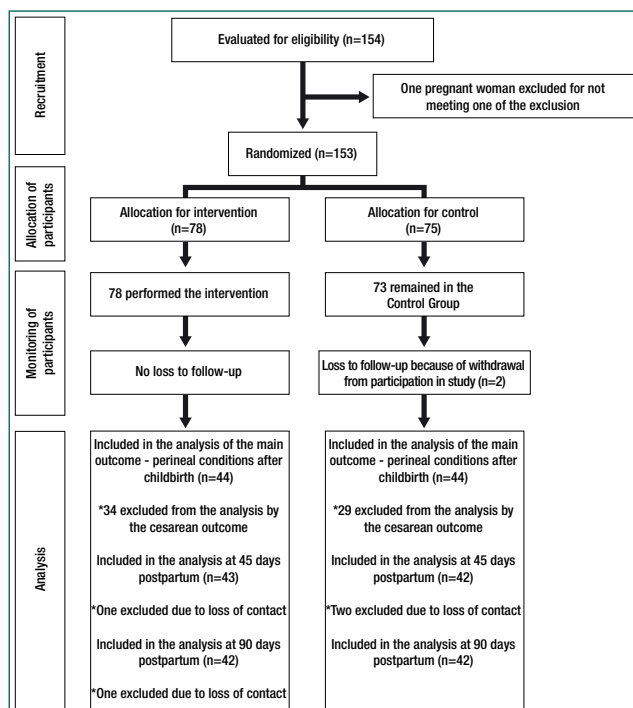
For participants in the IG, the variables related to perineal massage were compared between the absence/presence of the main outcome and secondary outcomes. For variables that showed a difference in the number of days of massage with the outcome, the ROC curve analysis was performed, which takes into account the sensitivity and specificity values to obtain the accuracy, area under the curve and discriminate the best cutoff point. The confidence interval adopted was 95% and the significance level was 5%.

The research protocol was approved by the Research Ethics Committee under CAAE 53239416.8.0000.0121 and by the Municipal Health Department of Florianópolis under opinion number 1.470.848. All participants signed the Informed Consent Form. The ECR was registered on the virtual platform - Brazilian Clinical Trials Registry (ReBEC): RBR-4MSYDX.

## Results

A total of 153 women participated in the study, 78 in the IG and 75 in the CG (Figure 1).<sup>(21)</sup> The 88 women who had vaginal delivery were included in

the analysis of the main and secondary outcomes and could assess the influence of the digital perineal massage performed in the antenatal period in perineal trauma during childbirth, being 44 in the IG and 44 in the CG. Given the loss of contact with some women, in the analysis at 45 days postpartum, the IG had 43 women and the CG had 42 women; and in the analysis at 90 days postpartum, each group had 42 women.



Source: Schulz KF, Altman DG, Moher D. CONSORT 2010 Statement: updated guidelines for reporting parallel group randomised trials. *BMJ*. 2010; 340(27):698-702.<sup>(21)</sup>

**Figure 1.** Flowchart of randomized clinical trial for non-pharmacological treatments

As for adherence to perineal massage, almost all women (93%) in the IG (n=44) reported being able to perform as instructed and that they would adopt the practice again in a future pregnancy (97.6%). All would recommend it to friends or family. Twenty-four companions performed the perineal massage at the request of pregnant women and all of them would do it again and recommend the practice. Most (83.3%) reported being able to perform the practice as instructed. The mean period between perineal massage orientation sessions and delivery was 39.1 days (sd=10.4). The average

number of days the massage was performed was of 22.5 days (sd=12.8); pregnant women performed the practice on 12.8 days (sd = 13.4) on average, while companions did it on 10.5 days (sd=12.7). The average time to perform each session was 7.5 minutes (sd=2.3). Table 1 presents the baseline of women's sociodemographic, obstetric and childbirth care characteristics. The groups were homogeneous, with no statistically significant difference between them. The mean interval between delivery and postpartum interview (in the maternity ward) was 34.9 hours (sd=13.0) in the IG and 31.5 hours (sd=14.5) in the CG. Only one parturient woman received analgesia, and she was in the CG. Almost all parturient women were assisted by a medical professional at the time of delivery and three by a nurse, and these were in the IG.

Regarding primary and secondary outcomes, table 2 shows that although the frequency of perineal trauma requiring sutures was higher in the group of women who did not undergo the intervention (IG = 22 versus CG = 31), there was no statistically significant difference between having had antenatal digital perineal massage and the occurrence of perineal trauma at birth. However, the residual adjustment showed a tendency of women in IG presenting an intact perineum. There were also no significant differences in the mean scores attributed by women to perineal pain or dyspareunia between the two groups.

Table 3 shows that the occurrence of edema in the first 10 days after childbirth reported by women was significantly lower in women in the IG than in the CG (RR 0.64 95% CI 0.41-0.99). Likewise, the involuntary loss of gas reported by women in the interview at 45 days postpartum was significantly lower in women in the IG than in the CG (RR 0.57, 95% CI 0.38-0.86). In the other outcomes, no significant differences were observed between the groups.

Through the accuracy analysis, it was possible to find that the best cutoff point for the non-occurrence of edema in the first 10 days after childbirth was to perform the massage for 16 days (area under the curve - AUC = 0.74; sensitivity=81.8%; specificity=70.6%). For the non-occurrence of involuntary gas loss at 45

**Table 1.** Sociodemographic, obstetric and childbirth care characteristics of women according to the allocation group (n = 88)

Characteristics	Intervention group (n = 44) n (%)	Control group (n = 44) n (%)	p-value
<b>Sociodemographic</b>			
Age - Mean (sd)	29.5(5.5)	31.1(6.1)	0.202
Years of study - Mean (sd)	15.8(5.2)	16.50(4.3)	0.504
<b>Marital status</b>			
Single	7(15.9)	5(11.4)	0.803
Married	19(43.2)	19(43.2)	
Domestic partnership	18(40.9)	20(45.4)	
<b>Skin color</b>			
White	27(61.4)	32(72.7)	0.257
Non-white	17(38.6)	12(27.3)	
<b>Obstetrical</b>			
Gestational age US week. at randomization - Mean (sd)	33.47(1.3)	33.50(1.5)	0.679*
<b>Previous births</b>			
No	35(79.5)	35(79.5)	1.000
Yes (only one)	9(20.5)	9(20.5)	
<b>Previous episiotomy (n= 9)</b>			
No	6(66.7)	2(22.2)	0.153
Yes	3(33.3)	7(77.8)	
<b>Laceration with prior suture (n= 9)</b>			
No	4(44.4)	7(77.8)	0.335
Yes	5(55.6)	2(22.2)	
<b>Antenatal care</b>			
Public service	29(65.9)	29(65.9)	1.000
Private service	15(34.1)	15(34.1)	
<b>Childbirth care</b>			
<b>Place</b>			
Maternity A	30(68.2)	32(72.7)	0.432
Maternity B	3(6.8)	6(13.6)	
Maternity C	5(11.4)	2(4.5)	
Another institution	6(13.6)	4(9.2)	
<b>Labor induction*</b>			
No	33(75.0)	32(72.7)	0.808
Yes	11(25.0)	12(27.3)	
<b>Use of oxytocin*</b>			
No	31(72.1)	28(65.1)	0.486
Yes	12(27.9)	15(34.9)	
<b>Kristeller maneuver</b>			
No	42(95.5)	41(95.3)	1.000
Yes	2(4.5)	2(4.7)	
<b>Position of birth*</b>			
Horizontal	6(13.6)	5(11.4)	0.352
Vertical	38(86.4)	39(88.6)	
<b>Valsalva maneuver</b>			
No	17(38.6)	18(40.9)	0.828
Yes	27(61.4)	26(59.1)	
Newborn Weight* – Mean(sd)	3310.2(520.1)	3179.4(445.7)	0.499

\*Data collected from puerperal women's medical records

days postpartum, the significant difference was found in the number of days between the first day of massage and delivery, and the best cutoff point was to have started the massage 36.5 days in advance (AUC = 0.77; sensitivity=71.9% and specificity=85.7%).

**Table 2.** Perineal conditions after delivery according to allocation groups (n=88)

Variables	Intervention group (n = 44) n(%)	Control group (n = 44) n(%)	p-value
<b>Perineal conditions</b>			
Intact perineum	15(34.9) <sup>†</sup>	7(15.9)	0.292
1 <sup>st</sup> degree laceration without suture	6(14.0)	6(13.6)	
1 <sup>st</sup> degree laceration with suture	9(20.9)	10(22.7)	
2 <sup>nd</sup> degree laceration	12(27.9)	20(45.5) <sup>†</sup>	
Episiotomy	1(2.3)	1(2.3)	
	<b>Mean (Standard deviation)</b>	<b>Mean (Standard deviation)</b>	
Perineal pain score right after delivery	3.0(2.9)	4.1(2.9)	0.085 <sup>†</sup>
Return to sexual activity (days)	34.9(8.3)	36.1(15.3)	0.767
Pain score 45 days postpartum	1.4(2.1)	1.7(2.5)	0.642
Dyspareunia score 45 days postpartum	2.3(2.2)	3.1(2.8)	0.432
Pain score 90 days postpartum	0.3(1.0)	0.3(0.9)	0.789
Dyspareunia score 90 days postpartum	1.3(1.8)	2.0(2.5)	0.242

\* Residual adjustment ≥2,0; <sup>†</sup> Mann-Whitney U test (non-parametric)

**Table 3.** Effects of intervention on perineal outcomes according to groups (n = 85)

Variables	Intervention group (n = 43) n(%)	Control group (n = 42) n(%)	RR (95% CI)	p-value
<b>Perineal conditions</b>				
No trauma*	21(48.8)	13(29.5)	0.73 (0.51-1.03)	0.065
With trauma	22(51.2)	31(70.5)		
<b>Pain in the first 10 days</b>				
No	19(48.7)	20(51.3)	1.07 (0.72-1.58)	0.751
Yes	24(52.2)	22(47.8)		
<b>Redness in the first 10 days</b>				
No	39(90.7)	35(83.3)	0.56 (0.18-1.77)	0.351
Yes	4(9.3)	7(16.7)		
<b>Hematoma in the first 10 days</b>				
No	42(97.7)	40(95.2)	0.49 (0.05-5.19)	0.616
Yes	1(2.3)	2(4.8)		
<b>Edema in the first 10 days</b>				
No	26(60.5) <sup>†</sup>	16(38.1)	0.64 (0.41-0.99)	0.032
Yes	17(39.5)	26(61.9) <sup>†</sup>		
<b>Urinary incontinence 45 days</b>				
No	30(69.8)	25(59.5)	0.75 (0.41-1.34)	0.323
Yes	13(30.2)	17(40.5)		
<b>Bowel incontinence 45 days</b>				
No	39(90.7)	39(92.9)	1.30 (0.31-5.47)	1.000
Yes	4(9.3)	3(7.1)		
<b>Involuntary gas loss 45 days</b>				
No	34(79.1)	22(52.4)	0.57 (0.38-0.86)	0.009
Yes	9(20.9)	20(47.6)		
<b>Urinary incontinence 90 days (n=42)</b>				
No	32(76.2)	34(81.0)	1.25 (0.55-2.85)	0.595
Yes	10(23.8)	8(19.0)		
<b>Bowel incontinence 90 days (n=42)</b>				
No	42(100.0)	40(95.2)	- (-)	-
Yes	- (-)	2(4.8)		
<b>Involuntary gas loss 90 days (n=42)</b>				
No	33(78.6)	27(64.3)	0.60 (0.30-1.22)	0.147
Yes	9(21.4)	15(35.7)		

\* Intact perineum or 1<sup>st</sup> degree laceration without suture

## Discussion

The results showed a good adherence of participants to the massage, which was performed for 22.5 days on average, during an average time of 7.5 minutes per session, which corresponded to the instructions given (5-10 minutes). Most women were able to perform the intervention according to the instructions, stated they would do it again in a future pregnancy and would recommend it to friends or family, corroborating other studies.<sup>(16,22)</sup>

A qualitative study of 25 women and 10 companions who participated in this pilot showed that digital perineal massage was well accepted, highlighting the practice as an opportunity for self-knowledge and intimacy of the couple, regardless of the type of delivery or the perineal result after the vaginal delivery.<sup>(23)</sup> A quantitative study evaluated the acceptability of daily perineal massage by 113 primigravid women by means of a questionnaire. For 61.4% of respondents, the practice was acceptable and only 25.7% reported that the practice was embarrassing, while 56.7% of participants were happy that their husband/partner agreed to massage them.<sup>(24)</sup>

Partners' participation in performing the massage can be an opportunity to include them in the care aimed at preparing for childbirth. When this is the pregnant woman's desire, having a perineal massage performed by the partner, in addition to facilitating the practice, can provide a moment that favors bonding with the partner and the baby who is about to arrive. Recent studies demonstrate that despite the changes in society, the participation of men during antenatal care, childbirth, postpartum and baby care is still little encouraged and many of them still do not understand the need and importance of their presence in this period.<sup>(25,26)</sup>

Although this is a pilot study, it showed that perineal massage was a protective factor for two secondary outcomes reported by women, edema in the first 10 days postpartum and gas incontinence at 45 days postpartum.

Perineal edema is closely related to postpartum pain, and was significantly less present in the reports of women in IG. In a study that evaluated the treatment of perineal pain in the postpartum

period after vaginal delivery of 56 women with perineal pain, 42.9% had perineal changes, highlighting the occurrence of edema in 37.5%, hyperemia in 5.4% and ecchymosis in 3.6% of participants. These women characterized perineal pain as throbbing, squeezing, hot, burning, painful, boring, uncomfortable, catching and tense, limiting activities of daily living, such as sitting, lying down and walking.<sup>(7)</sup> As perineal massage during pregnancy reduces puerperal edema, this practice can indirectly contribute to reduce the pain and recovery time after childbirth.

Gas incontinence can be included in the definition of bowel incontinence, that is, when there is involuntary loss of fecal content through the anus. Even if isolated, the involuntary gas loss can significantly affect the person's quality of life.<sup>(27)</sup> Anal incontinence is among the main acute complications of episiotomy,<sup>(28)</sup> can cause embarrassing situations and great discomfort for women. Although the association between gas loss and perineal trauma was not evaluated or the association with involuntary gas loss was not maintained at 90 days, in the present study, the results showed aspects related to the quality of life of women who underwent the digital perineal massage at 45 days postpartum.

As this is a pilot study, the results on edema reduction in the first 10 days postpartum and gas incontinence reported at 45 days postpartum point to possible benefits of this massage. In addition, the residual adjustment  $\geq 2$  observed in the analysis of perineal conditions after delivery by allocation groups shows the trend of women in IG having a greater chance of an intact perineum after delivery. This analysis shows that the effectiveness of digital perineal massage for the prevention of perineal trauma needs to be evaluated in other experimental studies.

As limitations of this study, we highlight the evaluation of secondary outcomes based on women's perception of perineal symptoms and the impossibility of definitive conclusions because of the small sample size.

While conducting this pilot clinical trial study, there were no difficulties in the adherence of pregnant women and their companions to the perfor-

mance of digital perineal massage for the prevention of perineal trauma. The difficulties in reaching the sample size resulted from the difficulty in recruiting participants and the high rates of cesarean section. The first was impaired because it was not possible to obtain the telephone contact from pregnant women who underwent antenatal care during the data collection period. The second is related to the high rates of cesarean section, 43.6% in the IG and 39.7% in the CG, which led to the exclusion of study participants.

These limitations are likely to be reduced in other experimental studies. We suggest the use of measurement instruments to assess secondary outcomes, the establishment of partnerships with institutions that make up primary health care for the recruitment of participants and the possibility to conduct RCTs in institutions with alternative care models and lower intervention rates.<sup>(29)</sup>

## Conclusion

Based on the results of this pilot study, we assessed that digital perineal massage during pregnancy is a feasible practice in the Brazilian reality, since pregnant women and companions demonstrated good adherence to the intervention and followed the instructions on how to perform it. Despite not reducing perineal trauma in the studied population, the perineal massage showed an association with the reduction of edema in the first 10 days postpartum and of gas incontinence at 45 days postpartum, as reported by participants. We recommend the development of RCTs in Brazil for assessment of the effectiveness of perineal massage on perineal trauma during childbirth and the inclusion of this practice in antenatal guidelines, so that pregnant women can benefit from the results found in this study.

## Collaborations

Monguilhott JJC, Brüggemann OM, Velho MB, Knobel R and Costa R contributed to the study design, data analysis and interpretation, article

writing, relevant critical review of the intellectual content and approval of the final version to be published.

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