Fisioterapia & Saúde Funcional

Systematic Review

Pelvic floor interventions during pregnancy: a systematic review and critical analysis of protocols

Intervenções no assoalho pélvico durante a gestação: revisão sistemática e análise crítica de protocolos

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ABSTRACT

Background: Interventions performed during pregnancy to prevent perineal trauma have been widely studied; however, there is a need to reflect on the protocols used. **Objective:** To analyze the protocols for pelvic floor muscle training (PFMT), antenatal perineal massage (APM), and the Epi-no® device used during pregnancy to prevent perineal trauma. **Methods:** We conducted a systematic review of the literature using the PubMed, Embase, and PEDro databases, employing the keywords: antenatal perineal massage, antenatal pelvic floor muscle training (or exercise), and instrument-assisted perineal stretching and expulsive training (Epi-no device). The PICOS strategy was applied to select intervention studies. **Results:** Fourteen PFMT, 17 APM, and eight Epi-no® device protocols were included. The protocols varied greatly in terms of frequency, duration, and professional supervision. We observed a pattern regarding the gestational age at which these interventions begin: PFMT starts after the first trimester, APM is introduced at the end of the third trimester, and the Epi-no® device is used from the 37th week of gestation. **Conclusions:** APM is the most studied intervention for the prevention of perineal trauma, with well-established protocols and good effectiveness. PFMT has been investigated for the prevention and/or treatment of urinary incontinence, but the results are still limited regarding its role in perineal trauma. Studies involving Epi-no are controversial concerning protocols and effectiveness; therefore, it should be used with caution until more research is conducted.

Key-words: Pelvic Floor; Prenatal Care; Physical Therapy Specialty.

RESUMO

Introdução: As intervenções realizadas durante a gravidez para prevenção de traumas perineais têm sido amplamente estudadas, mas há necessidade de reflexão sobre os protocolos utilizados. **Objetivo:** Analisar os protocolos de treinamento da musculatura do assoalho pélvico (TMAP), massagem perineal (MP) e uso do dispositivo Epi-no® utilizados na gestação para a prevenção de traumas perineais. **Métodos:** Foi realizada uma revisão sistemática da literatura nas bases de dados PubMed, Embase e PEDro usando as palavras-chave: antenatal perineal massage, antenatal pelvic floor muscle training (or exercise), and instrument-assisted perineal stretching and expulsive training (Epi-no device). Aplicamos a estratégia PICOS para selecionar estudos de intervenção. **Resultados:** Foram incluídos 14 protocolos de TMAP, 17 de MP e oito protocolos de uso do dispositivo Epi-no®. Os protocolos variaram muito em termos de frequência, duração e supervisão profissional. Observamos um padrão quanto ao início da idade gestacional onde o TMAP inicia após o primeiro semestre, a MP no final do terceiro trimestre e o uso do Epi-no® a partir da 37ª semana gestacional. **Conclusão:** A MP é a intervenção mais estudada para a prevenção de trauma perineal, com protocolos bem estabelecidos e boa efetividade. O TMAP tem sido investigado na prevenção e/ou tratamento da incontinência urinária, mas os resultados ainda são limitados em relação ao seu papel no trauma perineal. Os estudos com Epi-no são controversos em relação aos protocolos e à efetividade; por isso, deve ser utilizado com cautela até que mais pesquisas sejam realizadas.

Palavras-chave: Assoalho Pélvico; Pré-natal; Fisioterapia.

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INTRODUCTION

The pelvic floor (PF) structure comprising muscles, ligaments, and fascias have important functions include avoiding urinary incontinence (UI) and fecal incontinence (FI), supporting pelvic organs, and enabling sexual life, not to mention its important role during delivery [1]. During the gestational period, an overload occurs in this structure mainly due to increased uterine volume and fetal weight. Moreover, hormonal actions of relaxin and progesterone contribute to muscle relaxation, which causes the opening of the pelvis and, consequently, the stretching of the PF, leading to pelvic floor dysfunctions (PFD). Although pregnancy is the most important and independent risk factor related to PFD, vaginal childbirth also represents a significant risk factor [2].

The second stage of labor is critical for the PF once it suffers considerable distension due to fetal passage. It is estimated the fetal head is four times bigger than the diameter of the urogenital hiatus, thus overstretching can also lead to PFD [2]. During that expulsive phase, perineal trauma may occur, whether perineal lacerations or episiotomy.

Perineal lacerations (or tears) occur naturally and vary from first to fourth degrees according to the severity of the affected tissues, whose extension can go from the skin to the anal epithelium [3-4]. From 53% to 79% of the women that go through vaginal childbirth experience some form of minor perineal laceration, predominantly first or second-degree. Severe lacerations, i.e., third or four degrees, are also known as obstetric anal sphincter injuries and occur less frequently [5]. Episiotomy is a surgical incision that corresponds to second-degree perineal laceration as it can reach muscle fibers. In Brazil, episiotomy rates achieved 56% in vaginal childbirth and 74.6% in primiparous [6]. The more severe the injuries, the more likely they can cause PFD and perineal pain. Notably, unraveling the specific role of vaginal childbirth, pregnancy, and perineal tears in PFD represents a challenge since women can have other risk factors associated [3-4].

To prevent PFD and perineal trauma, physiotherapists has employed three main interventions to prepare the PFM during pregnancy: 1) pelvic floor muscle training (PFMT); 2) antenatal perineal massage (APM), and 3) instrument-assisted perineal stretching and expulsive training (Epi-no device)[7].

Previous systematic reviews assessed the efficacy of these interventions during pregnancy. Woodley et al (2020) showed that carrying out PFMT can prevent UI in the final pregnancy phase and after delivery [8]. Beckman and Stock (2013) concluded that the use of APM in the last pregnancy weeks avoids perineal trauma, especially episiotomy, and perineal pain after delivery [9] and Abdelhakim et al (2020) that APM is associated with a lower risk of severe perineal trauma and postpartum complication [10]. Brito, Ferreira, and Marcolin (2015) mentioned that the Epi-no® device use does not reduce the incidence of episiotomy or perineal tears [11].

This work targets to analyze the intervention protocols of PFMT, APM, and the use of the Epi-No device on the pelvic floor during pregnancy to prevent birth-related perineal injuries. In particular, this work seeks to bridge the gap regarding recommendations on the preparation of the pelvic floor during pregnancy.

METHODOLOGY

This is a literature systematic review conducted in the PubMed, Embase, and PEDro databases. The review was performed according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA).

We followed standard search strategies for each database by combining the following terms using the AND and OR boolean operators: pelvic floor muscle training, pelvic floor muscle exercise, pelvic floor exercise, perineal exercise, antenatal perineal massage, perineal massage, epi-no, epi-no device, birth trainer, birth trainer device, instrument-assisted stretching device, inflatable birth canal dilator associated with the terms pregnancy, gestation, pregnant woman. In the supplementary table, we present the search strategies for each intervention in each database (Table S1).

Based on the PICOS (Population, Intervention, Comparison, Outcome, Study design) framework, the inclusion criteria comprised the population (P) of pregnant women; intervention (I) studies that employed either PFMT, APM, Epi-no® device use, or any combination of these procedures. Regarding comparison (C), studies with a control group without intervention, a control group under minimal intervention, or a comparison between resources were considered. The outcome (O) should include results related to childbirth (perineal tear, episiotomy, or perineal pain in the postpartum period). The study design type (S) was randomized or quasi-randomized clinical trials (RCT).

Studies in any other language than English, Spanish, or Portuguese, literature review studies, expert opinion, and abstracts in conference proceedings were excluded. Also, studies that evaluate perineal massage during labor and postpartum; and studies that did not report the intervention protocol were not eligible.

The database searches were performed between June and July 2023. Three independent researchers (EJLG, LRR and MHOS) carried out the initial selection of studies, considering the inclusion/exclusion criteria, and a third researcher (SLN) solved the discrepancies. The initial assessment only considered the title, which allowed us to identify studies lying outside the

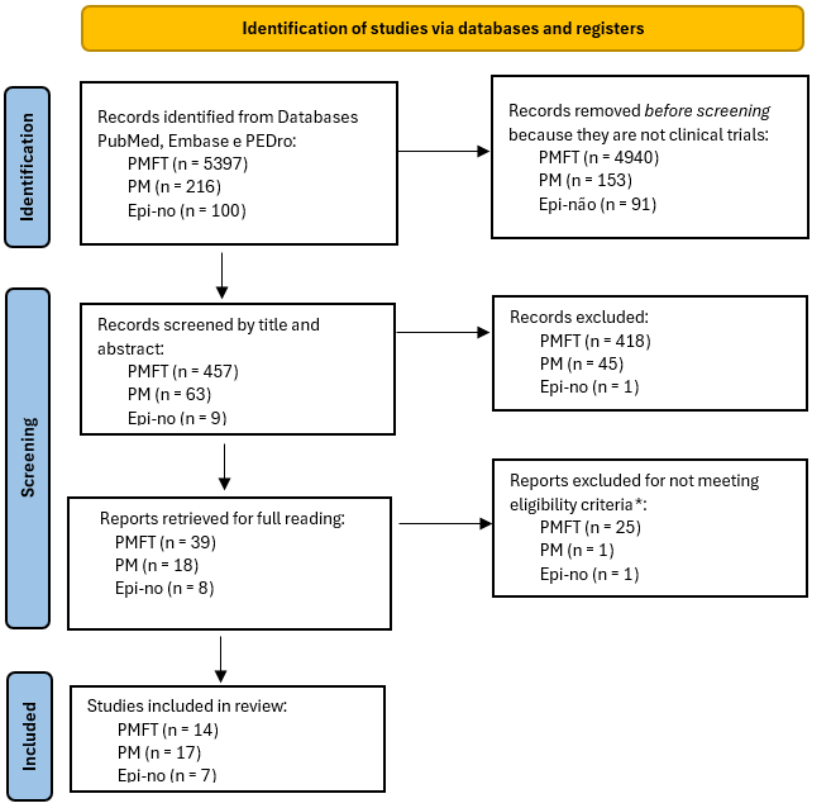
scope quickly. Then, all selected articles had their abstracts analyzed to ensure adherence to the inclusion criteria. To reach a final decision, the full text of potentially relevant articles went through assessment by a senior researcher with significant experience in systematic reviews and the research theme.

The analyses of these articles enable us to gather information on the objectives, study type, sample size, population, and intervention protocols (such as gestational age at onset, frequency, duration, timing, professional supervision, and other specificities of each protocol), as well as results pertaining to perineal tissue.

RESULTS

The initial search resulted in a total of 5713 articles. After deleting duplicates and unrelated articles, we ended up with 38 full papers (Figure 1). The data from intervention protocols are summarized in Tables, where Table 1 refers to PFMT (fourteen protocols); Table 2 considers APM (seventeen protocols); and Table 3 reports instrument-assisted perineal stretching and expulsive training - Epi-no® device (eight protocols). Two articles carried out an association between APM and PFMT [12-13]; and two article associated APM with Epi-no® device [14-15].

Figure 1. PRISMA 2020 flow diagram for new systematic reviews that included searches of databases and registers Only.



Legend: *Elegibility criteria: interventions during pregnancy that present outcomes related to perineal tissue; and full texts available.

Table 1. PFMT intervention protocols during pregnancy, Fortaleza – CE, Brazil, 2023.

Authors/ Year	Population/ Sample	Gestational age at onset	Supervision frequency	Individual or group	Exercise protocol	Exercise frequency	Findings
Salvesen; Morkved, 2004	301 Nulliparous women (148 in EG[a] and 153 in CG[b]).	Between 20 and 36 weeks	Once a week for a period of 12 weeks	Not informed	Trained with a physiotherapist for 60 min once per week for 12 weeks, to perform near maximal PFM contractions 6–8 sec, with 3 or 4 fast contractions the end of each contraction. Resting 6 seconds. It was performed in lying, sitting, kneeling, and standing positions with legs apart. Women were encouraged to perform 8 to 12 intensive PFM contractions at home, in their preferred position.	Twice daily	EG had fewer episiotomies (51% vs. 64%; OR 0.59, 95% CI: 0.35 to 1.00; NNT = 7).
Agur et al.,2008	268 Primigravidae (139 in EG[a] and 129 in CG[b]).	20 weeks	Once a month	Not informed	Three sets of 8 PFM contractions each held for 6 sec with 2 min rest between sets. At 34 weeks gestation, increase to 12 contractions per set.	Twice daily	No significant difference between the EG and CG on episiotomy rate (30.9% vs 31%; p=0.41) or degree of perineal trauma (46.8% vs 56.9%; p=0.21).
Mason et al., 2010	288 Nulliparous (141 in EG[a] and 145 in CG[b]).	Between 11–14 weeks (not clear)	Once a month	Group	Under supervision, perform near-maximal PFM contractions for 6–8 seconds, followed by 3 or 4 fast contractions at the end of each contraction. Repeat in lying, sitting, kneeling, and standing positions with legs apart. At home, perform 8–12 maximal PFM contractions.	Twice daily	No differences between EG and CG in perineal trauma (no damage: 42.2% vs. 40.5%; episiotomy: 23.7 vs 27.5).
Dias et al., 2011	42 Nulliparous (21 in EG[a] and 21 in CG[b]).	20 weeks	Once a week	Individual	Four sets of 10 PFM contractions for 6 – 8 sec, 6-sec of interval, 3 fast contractions at the end of the 10 contraction. A 30-sec rest was defined between each set.	Twice daily	All perineal lacerations were 1st degree in both groups with no between-group differences (p=0.66). Episiotomy occurred in 38% of the EG and 24% of the CG.
Ko et al., 2011	300 Nulliparous. 300 (150 in EG[a] and 150 in CG[b]).	16 to 24 weeks	Once a week	Group	Three sets of 8 contractions held for 6 sec, 2-min rest between sets.	Twice daily	No significant differences between the EG and CG for episiotomy (p = 0.87) or severe perineal lacerations (p = 0.63).
Wang et al., 2014	106 Nulliparous (51 in EG[a] and 55 in CG[b]).	16 - 32 weeks	Not informed	Not informed	Any time of day in a standing, supine, or sitting position. 2 PFM contractions hold for at least 3 sec, followed by 5 fast	Two to three times a day	No significant differences between the EG and CG on laceration rates

					contractions; to repeat for 10 - 15 min, two or three times a day; or to perform 150 - 200 contractions per day.		(p = 0.351) or episiotomy rates (p = 0.982).
Okido et al., 2015	59 Primigravidae (26 in EG[a] and 33 in CG[b])	Between 20 and 36 weeks	Once a week	Group	Ten sets of maximum PFM contractions held for 6–8 sec followed by 3 fast contractions; repeated in left lateral decubitus, sitting, four arm supports, and standing.	Daily	Episiotomy rates in the EG and CG were 35.3% and 28.3%; laceration rates were 22.5% and 15.4% (p = 0.66).
Fritel et al., 2015	282 Nulliparous, (140 in EG[a] and 142 in CG[b]).	Between 20 and 28 weeks	Once a week	Not informed	Standing contractions (5 min), lying contractions (10 min), and learning to start a PFM contraction just before exerting intra-abdominal pressure (knack exercise).	Daily	No significant differences between the EG and CG for third-degree lacerations (0.0% vs. 2.2%).
Leon-Larios et al., 2017	466 Primiparous (254 in EG[a] and 212 in CG[b]).	32 weeks	Not informed	Not informed	Ten to fifteen PFM contractions held for 5 seconds, resting after each. And contract the muscles, gradually increasing intensity as if the muscles were a lift going up floor by floor. Perform twice a day for 10–15 minutes.	10 - 15 minutes twice a day	EG showed a 31.63% reduction in episiotomy rates (50.56% vs. 82.19%, p < 0.001), a higher likelihood of an intact perineum (17.61% vs. 6.85%, p < 0.003), fewer third-degree tears (5.18% vs. 13.12%, p < 0.001), fewer fourth-degree tears (0.52% vs. 2.5%, p < 0.001), less postpartum perineal pain (24.57% vs. 36.30%, p < 0.001), and less request for postnatal analgesia (21.14% vs. 30.82%, p < 0.001).
Shamy; Fatah, 2018	20 Pregnant women (10 in EG[a] and 10 in CG[b]).	20 weeks	Not clear	Not clear	Three sets of 8 PFM contractions hold for 6 sec, 6-sec rest after each, 2 min rest between sets. Performed in the left lateral decubitus position, sitting and standing. At 36 weeks, increase to 12 contractions per set.	Twice daily, three sessions per week.	In the EG, 90% of women had spontaneous vaginal delivery compared to 0% in the CG; 10% in the EG had vaginal deliveries with episiotomy compared to 50% in the CG; and cesarean sections were 0% in the EG and 50% in the CG (p < 0.05).
Wang et al., 2020	108 Nulliparous (54 in EG[a] and 54 in CG[b]).	30 - 32 weeks	Not informed	Not informed	Under app guidance (audio), 15 minutes of PFM contractions held for at least 3 seconds, followed by 2–6 seconds of rest, in standing, sitting, and lying positions, twice a day. Or 150	Twice a day	In the EG and CG, the rates of lateral episiotomy were 24% vs. 29.6%, midline episiotomy were 18% vs. 14.8%, first-degree

					contractions per day. For at least 3 months.		laceration were 30% vs. 27.8%, and no damage were 24% vs. 20.4%.
Dieb et al., 2020	400 Pregnant women (200 in EG[a] and 200 in CG[b]).	35 weeks	Not informed	Not informed	Three sets of 8 to 12 PFM contractions per day, held for 8 seconds with 8 seconds of rest, in lying down and sitting positions. If that was not possible, she held them for as long as she could.	Daily	EG had fewer perineal tears (13.5% vs. 21.5%; p = 0.034), fewer episiotomies (29.5% vs. 38.5%; p = 0.045), less pain in the first 24 hours after delivery (p = 0.001) and after 15 days (p = 0.013), and a reduced need for postpartum analgesia (p < 0.001).
Silva- José et al., 2021	98 Pregnant women (48 in EG[a] and 50 in CG[b]).	8 - 10 weeks	3 weekly sessions (virtual)	One weekly session Individual and two groups weekly	Two or three sets of 6–8 PFM contractions, for 8 to 10-sec each, and fast contractions (1–2 sets of 6–8 contractions, and 14–18 contractions of 2 to 3 sec each) of the different structures of the PFM (vaginal and anal contractions).	3 times per week	EG had 73% of perineal tears, while CG had 52% (p = 0.033). No differences in first-degree tears, but second- and third-degree tears were more frequent in the CG (p = 0.006). Episiotomy rates were 38% in the CG and 12% in the EG (p = 0.031), with no significant differences in non-instrumental deliveries (p = 0.256). For instrumental deliveries, there were no significant differences in perineal tears (p > 0.05), but episiotomy rates were significantly higher in the CG (p = 0.028).
Sobhgol et al., 2022	164 Nulliparous (83 in EG[a] and 81 in CG[b]).	20 weeks	Fortnightly	Individual	Eight PFM contractions for 8 - 10 sec, rest for 8 - 10 sec, and 5 fast contractions; sitting or standing with legs apart. Contract PFM before coughing, sneezing, lifting, or bending.	3 times a day	No significant differences between EG and CG in the rates of any degree of perineal laceration or episiotomy.

Legend: [a] Experimental group;[b] Control group.

Table 2. APM intervention protocols, Fortaleza – CE, Brazil, 2023.

Authors/ Year	Population/Sample	Gestational age at onset	Performed by	Instruction format	Frequency	Time	Lubrification	Digital insertion depth	Findings
Avery; Van Arsdale, 1987	55 Nulliparous (29 in EG[a] and 26 in CG[b]).	Last 6 weeks of pregnancy	The participant herself or her partner	Not clear (seems written)	Daily	5 - 10 minutes	Natural oil (wheat germ, olive, or plain salad oil)	About 2 inches	In the EG, 52% had an intact perineum or a first-degree laceration, while 48% had an episiotomy or second, third, or fourth-degree lacerations. In the CG, the respective percentages were 24% and 76% ($p < 0.05$). Excluding second-degree lacerations, the episiotomy rates were 38% in the EG and 65% in the. Third and fourth-degree lacerations occurred only where an episiotomy was performed.
Mynaugh, 1991	83 Primiparous (45 in EG[a] and 38 in CG[b]).	25 to 36 weeks	The participant herself or her partner	Video instruction tape and written handout	Not informed	5 minutes	Vitamin E, vegetable oil, or water-soluble jelly	Up to the vagina's second knuckle	No significant differences between the EG and the CG in the episiotomy rates or any type of perineal laceration.
Labrecque et al., 1994	46 Nulliparous (22 in EG[a] and 24 in CG[b]).	32 to 34 week	The participant herself or her partner	Verbal and written (leaflet)	Daily	5 to 10 minutes	Sweet almond oil	3-4 cm	Among who had a vaginal delivery, the groups were similar in the proportion of episiotomies: 61.1% (n = 11) in one group and 55.5% (n = 10) in the other. Three women in each group experienced a second-degree tear without an episiotomy.
Shipman et al., 1997	861 Nulliparous (332 in EG[a] and 350 in CG[b]).	29 to 32 weeks	The participant herself or her partner	Written information and verbal instruction	Three to four times a week	4 minutes	Sweet almond oil	About 2 inches	The rate of perineal tears was 69% in the EG and 75.1% in the CG. After adjusting for the mother's age and the infant's birth weight, these differences achieved statistical significance ($p = 0.024$).

Labrecque et al., 1999	1034 Primiparous (519 in EG[a] and 515 in CG[b]) and 493 with ≥1 previous vaginal birth (246 in EG[a] and 247 in CG[b])	34 to 35 weeks	The participant herself or her partner	Written information	Daily	10 minutes	Sweet almond oil	3-4 cm	The incidence of an intact perineum was 19.3% in the EG and 12.3% in the CG (p = 0.002). Among women without a previous vaginal birth, was 61% higher in the EG (p = 0.001).
Labrecque et al., 2000	Pregnant women 377 with (187 in EG[a] and 190 in CG[b]) or 579 without (283 in EG[a] and 289 in CG[b]) a previous vaginal birth.	34 to 35 weeks	The participant herself	Not informed	Daily	5 to 10 minutes	Not informed	Not informed	Among women without a previous vaginal birth, the rates of an intact perineum were 24.5% (EG) and 15.1% (CG); of episiotomy were 25.3% and 28%, and of third or fourth-degree lacerations at 8.7% and 12.6%, respectively. For women with a previous vaginal birth, the rates of an intact perineum were 34.8% (EG) and 31.7% (CG), of episiotomy 14.9% (EG) and 16.7% (CG), and no occurrences of third or fourth-degree lacerations in the EG compared to 0.5% in the CG.
Bodner-Adler et al., 2002	531 Primiparous (121 in EG[a] and 410 in CG[b])	Not informed	The participant herself	Verbal instruction	3 - 4 times a week	5 - 10 minutes	Almond oil	3 - 4 cm	No significant differences between EG and CG in the rates of perineal tears or episiotomy.
Mei-dan et al., 2008	234 Nulliparous (128 in EG[a] and 106 in CG[b])	30 - 34 weeks	The participant	Verbal and written information	Daily	10 minutes	Calendula oil with added Vitamin E	2–3 cm	No significant differences between EG and CG in the rates of intact perineum, episiotomy, or any degree of laceration.
Takeuchi; Horiuchi, 2016	161 Primiparous (81 in EG[a] and 80 in CG[b])	30 - 33 weeks	The participant	smartphone website and textbooks	3 - 4 times per week	5 - 10 minutes	Not informed	Not informed	No significant differences between EG and CG in the rates of intact perineum, episiotomy, or any degree of laceration.
Leon-Larios et al., 2017	466 Primiparous (254 in EG[a] and 212 in CG[b]).	32 weeks	The participant herself or her partner	Written and diagrammatic instructions	Every week until birth	8 minutes	Olive Oil	3 - 4 cm	EG showed a 31.63% reduction in episiotomy rates (50.56% vs. 82.19%, p < 0.001), a higher likelihood of having an intact

									perineum (17.61% vs. 6.85%, p < 0.003), fewer third-degree tears (5.18% vs. 13.12%, p < 0.001), and fewer fourth-degree tears (0.52% vs. 2.5%, p < 0.001), less postpartum perineal pain (24.57% vs. 36.30%, p < 0.001) and required less analgesia in the postnatal period (21.14% vs. 30.82%, p < 0.001).
Ugwu et al., 2018	108 Pregnant women (53 in EG[a] and 55 in CG[b]).	34 - 36 weeks	The participant herself or her husband	Verbal instructions	Daily	10 minutes	KY jelly	3 - 5 cm	EG was significantly more likely to have an intact perineum (50.9% vs. 29.1%; p = 0.02). The incidence of episiotomy was lower in the EG (37.7% vs. 58.2%; p = 0.03).
Freitas et al., 2019	27 Primigravidae women (14 in perineal massage group and 13 in instrument-assisted stretching group).	33 weeks	Physiotherapist with experience in gynecology	Not informed	Two sessions per week for 4 weeks (8 sessions)	10 minutes	Coconut oil	4 cm	No significant differences between the perineal massage group and the instrument-assisted stretching group regarding perineal lacerations of any type.
Cueva-Reguera et al., 2020	49 Secundigravida women (30 in EG[a] - conventional treatment plus APM and 19 in CG[b] - conventional treatment plus MLD[c]).	25 weeks	The participant herself	Not informed	One day per week	20 minutes	Jelly lubrication	5 cm	No significant differences between EG and CG regarding perineal lacerations or episiotomy.

Dieb et al., 2020	400 Pregnant patients (200 in EG[a] and 200 in CG[b]).	35 weeks	The participant herself or her partner	Not informed	Three times weekly	5 minutes	Hypoallergenic lubricant (olive oil or KY jelly).	3 - 5 cm	EG had fewer perineal tears (13.5% vs. 21.5%; p = 0.034), fewer episiotomies (29.5% vs. 38.5%; p = 0.045), less pain in the first 24 hours after delivery (p = 0.001) and after 15 days (p = 0.013), and a reduced need for postpartum analgesia (p < 0.001).
Cabral et al., 2022	116 Pregnant women (96 PnM[d] group: 24, IStrLS[e] group: 24, PnM + IStrLS group: 24, PnM + IStrSR[f] group: 24)	33 weeks	The physiotherapist	Not informed	Twice weekly	10 minutes	Coconut oil	4 cm	No significant differences among the four groups in terms of intact perineum or any degree of laceration.
Álvarez-González et al., 2022	322 Pregnant women (87 Massage group: 29, Self-massage group: 27, Control group: 29)	34 weeks	The participant herself and physiotherapist	Verbal instruction	twice a week (on alternate days)	10 minutes	water-based lubricant	Not informed	The episiotomy rates were 70.4% in the CG, 51.9% in the self-massage group, and 7.4% in the massage group (p < 0.001). There were no significant differences between the groups regarding perineal tears.
Kiremitli et al., 2022	173 Nulliparous pregnant women (55 antenatal groups, 59 intrapartum groups, 59 control groups)	34 weeks	The first perineal massage was taught to the patient by the midwife or doctor	Verbal instruction	Daily	10 minutes	olive oil	3 - 4 cm	In the antenatal group, 25.5% of participants delivered without an episiotomy, compared to 18.6% in the intrapartum group and 8.6% in the CG (p = 0.04). The intact perineum rate was significantly higher in the antenatal group (p = 0.03). Third-degree lacerations were less common in both the antenatal and intrapartum groups compared to the CG, with a significant difference only between the antenatal group and the CG (p = 0.04).

Legend: [a] Experimental group;[b] Control group; [c] Manual drainage lymphatic; [d] Perineal massage; [e] Instrument-assisted perineal group with a long static protocol; [f] Instrument-assisted perineal group with a short-repeated protocol.

Table 3. Epi-no® device intervention protocols during pregnancy, Fortaleza – CE, Brazil, 2023.

Authors/ Year	Population/Sample	Gestational age at onset	Performed by	Frequency	Time	Exercise	Device vaginal insertion depth	Findings
Kovacs; Heath; Heather, 2004	287 Primigravidae (39 in EG[a] and 248 in CG[b]).	37 weeks	The participant herself	Once daily for 14 days	15 minutes	Expulsive phase training	Not informed	The rate of an intact perineum was higher in the EG (46% vs. 17%; $p < 0.05$), and perineal tears were less common in the EG (28% vs. 49%; $p < 0.05$). However, no significant differences between the groups in terms of episiotomy rates.
Kok et al., 2004	31 primiparous	37 weeks	The participant herself	Once daily for 14 days	15 minutes	Expulsive phase training	Until only 2 cm of the balloon are still visible	The perineal trauma rate was slightly but not significantly lower in the EG (90.0% vs. 96.6%, $p = 0.24$). The episiotomy rate was significantly lower in the EG (50.0% vs. 93.3%; $p < 0.0001$), and the extent of perineal trauma appeared to be less severe in the EG.
Ruckhãberle et al., 2009	272 nulliparous (135 in EG[a] and 137 in CG[b]).	37 weeks	The participant herself	Once daily	15 minutes	Strength and expulsive phase training	Until only 2 cm of the balloon are still visible	Higher incidence of intact perineum (37.4% vs. 25.7%; $P = 0.05$) and a trend toward lower episiotomy rates (41.9% vs. 50.5%; $P = 0.11$) in the EG. No significant differences were found between the two groups regarding the incidence of perineal tears.
Shek et al., 2011	200 nulliparous (104 in EG[a] and 96 in CG[b]).	37 weeks	The participant herself	Up to two sessions per day	20 minutes	Expulsive phase training	Two-thirds of the balloon	No significant differences between the EG and CG in episiotomy rates (33% vs. 29%), any perineal tear (36% vs. 44%), or major perineal tear (3% vs. 5%).
Atan et al., 2016	660 nulliparous (335 in EG[a] and 325 in CG[b]).	37 weeks	The participant herself	Up to two sessions per day	20 minutes, (5-minute cycles)	Expulsive phase training	Two-thirds of the balloon	No significant differences between EG and CG in the episiotomy rates (26.7% vs 27%), of any perineal tear (50% vs. 50%) or of major perineal tear (7% vs. 5%).
Freitas et al., 2019	27 Primigravidae women (14 in PnM[c] group and 13 in instrument-assisted stretching group).	33 weeks	A trained physiotherapist with experience in gynecology	Two sessions per week for 4 weeks	15 minutes	Expulsive phase training	Until only 2 cm of the balloon are still visible	No significant differences between groups regarding perineal lacerations of any type.

Kubotani et al., 2020	18 Nulliparous (09 in EG[a] and 09 in CG[b])	27 -34 weeks	Physiotherapist	Once a week	10 minutes	Stretching and expulsive phase training	Not informed	EG showed improved perineal distensibility, which was evidenced by the increase in sagittal diameter at rest ($p<0.01$). In T3DUS[d], EG showed a significant increase in the sagittal measurement ($p=0.02$), hiatal circumference at rest ($p=0.03$), and epinometry values (diameter of the balloon; $p<0.01$). The increase in epinometry values was directly correlated ($p=0.02$) with the number of physical therapy sessions.
Cabral et al., 2022	96 Pregnant women (PnM[c] group: 24, IStrLS[e] group: 24, PnM + IStrLS group: 24, PnM + IStrSR[f] group: 24)	34 weeks	Physiotherapist	Twice weekly for 4 weeks	15 minutes	Stretching and expulsive phase training	Approximately 2 cm of the balloon was visible	No differences in the perineal laceration degree between groups.

Legend: [a] Experimental group;[b] Control group;[c] Perineal massage;[d] Transperineal 3D ultrasound;[e] Instrument-assisted perineal group with a long static protocol; [f]Instrument-assisted perineal group with a short-repeated protocol.

Regarding the PFMT interventions in the studies, it is possible to observe that most of them consider primigravidae [12,16-17] and nulliparas [18-25]; other works comprise all pregnant women [13,26-27], such that multiparas are not contemplated in a grouped way. Seven works started intervention from the 20th week of gestational age [16-18,20,23,25-26] others earlier [19,21-22,27], and others closer to the end of pregnancy [12-13,24]. Five works did not report supervision details [12-13,22,24,26], in five works, the supervision occurred once a week [17-18,20-21,23], in two studies, it happened once a month [16,19], in one study, individual virtual supervision occurred once a week and group supervision twice a week [27], and in one study the supervision occurred fortnightly [25]. In the analyzed studies, we observed that most protocols include exercises twice a day [12,16,18-21,24]. Four studies organized the exercises by time [12,17,22-23], the others by sets and repetitions. The number of sets and repetitions was quite variable.

In the Antenatal PM studies, most studies included nulliparous, primiparous or primigravidae.; four included pregnant women in general [13,15,28-29], and one included secundigravida [30], two studies separated groups of pregnant women with and without previous vaginal birth [31,32]. Six articles started the intervention from the 34th week [28-29,31-34], the earliest gestational age in the protocols was 25 weeks [30,35] and the tardiest 35 weeks [13]. The recommendation to perform APM daily was seen in 7 studies [28,31-34,36-37], the others ranged from one to four times a week.

Regarding Epi-no® device, only one study was carried out with pregnant women, regardless of the number of previous deliveries [15], all others were with nulliparous, primiparous or primigravidae. Most protocols started at the 37th week of pregnancy [38-42]. Four studies recommended training once a day [38-40,43]; two recommended twice a day [41-42]; and two others performed twice a week [14-15]. The studies instructed training for 15 or 20 minutes. There was no consensus on how much the balloon should be introduced in the patient. All studies included expulsive training, two studies have included stretching [15,43] and only one include PFM contractions, according to guidance from the device's designers [40].

DISCUSSION

Pelvic floor muscle training (PFMT)

PFMT consists of performing exercises to gain strength, endurance, power, relaxation, or a combination of these parameters. The precursor of what we now understand by PFMT was Arnold Kegel, an American gynecologist, who thought about performing PFMT contractions or exercises to prevent or treat pelvic floor disorders [44-45].

Notably, PFMT is indicated to treat stress, urgency, or mixed UI, reduce symptoms of urogenital prolapse and prevent or delay the deterioration of anterior urogenital prolapse [46]. PFMT has been used primarily to prevent or treat UI in pregnancy and postpartum [8]. Performing PFMT during pregnancy in primiparous women reduces the occurrence of UI at the end of pregnancy and up to 6 months after childbirth; available scientific evidence supports its use; however, some studies point out that positive results may not be maintained in the long term. The probability of reporting UI is also lower for women who undergo PFMT during pregnancy. Women who have persistent UI three months postpartum and perform PFMT are less likely to report UI symptoms 12 months after childbirth[8,16,21,47-48].

The perinatal results are not affected by the PFMT procedure during pregnancy, resulting thus in a safe practice. Also, PFMT does not impact outcomes related to the newborn (e.g., gestational age, weight, size, and Apgar index) nor the pregnant (epidural request, episiotomy/laceration rates, number of cesareans or instrumental delivery, duration of the second labor stage, and total labor duration) [16-17,20].

Antenatal PFMT can shorten the first and second stages of labor in primigravidae, but it does not prevent perineal trauma [49]. Nevertheless, further research where outcomes comprise perineal injuries is needed since most studies only consider pelvic floor dysfunctions, mainly UI [49].

Leon-Larios et al (2017) found that women to performed PFMT and APM showed a 31.63% reduction in episiotomy (50.56% versus 82.19%, $p < 0.001$), a higher likelihood of having intact perineum (17.61% versus 6.85%, $p < 0.003$), fewer third (5.18% versus13.12%, $p < 0.001$) and fourth degree-tears (0.52% versus 2.5%, $p < 0.001$), less postpartum perineal pain (24.57% versus 36.30%, $p < 0.001$) and required less analgesia in the postnatal period (21.14% versus 30.82%, $p < 0.001$) [12].

The main references cited in the studied protocols were the works of Bo et al (1995) [50], the 2nd International Consultation on Incontinence [51] and Morkved et al (2003) [52]. Silva-José et al (2021) [27] included PFMT in a program of several exercises, as proposed in the Barakat model [53]. But this model does not detail the PFMT protocol. Sobhgol et al (2022) [25] inform that their protocol was based on the Knack method [54], in addition to other studies. This method refers to the skill of intentionally contracting the pelvic floor muscles just before and throughout the intra-abdominal pressure rise associated with a stressful activity such as a cough, to prevent urine loss [54].

To perform the PMFT, it is necessary that a physiotherapist previously assess the muscular function of the PF regarding some aspects, such as reflexes, sensibility, strength, tone and endurance, motor control, and motor coordination. This assessment is critical since it allows the elaboration of an individualized therapeutic protocol according to the woman's needs. Furthermore, the physiotherapist aims to teach how to perform the PFM adequately, which directly influences the PFMT benefits [11,40]. The PFMT success depends on the capability of the PMF identification and the perineal region integrity in the corporal scheme, correct contraction awareness, and adherence to the exercise protocol [18]. The training supervision, either individually or group, is a very crucial aspect to achieve good results [28].

Based on the included studies, it was observed that there is no consensus regarding the adopted protocols. Thus, rigorous investigations to compare them are needed to better assess the outcomes. Nonetheless, as PFMT during gestation has been recognized as a safe practice with demonstrated benefits, it must be encouraged and incorporated in obstetric care.

Antenatal perineal massage (APM)

APM is a technique that aims to enhance flexibility, reduce resistance to PFM and increase vasodilation of blood vessels, specifically in the perineal region, and can be performed by a professional, the pregnant woman herself, or her partner [9-10]. The technique can be easily taught, does not cause significant discomfort, and is usually well-accepted among women. Given the benefits of this procedure and the absence of harmful impact on perineal results, APM should be encouraged [10,12].

Remarkably, the APM may increase the chances of perineum integrity, reduce perineal injuries, especially the third and fourth-degree ones, and episiotomy; it may also reduce the perineum pain during the postpartum period and help in the healing process. Overall, APM does not demonstrate adverse effects on perinatal results [9-10].

Most of the protocols included in this review started MPA at 34 weeks, but Abdelhakim et al (2020) suggest conducting studies that assess their benefits if performed before 34 weeks of gestation [10]. The APM and PFMT association might help

pregnant women since the APM benefits on the perineum remain, and PFMT may contribute to the prevention and treatment of UI in gestation and postpartum [8,12-13].

To apply AMP, women or her partner must wash the hands properly and have the nails trimmed; if a health professional is in charge, it is necessary to use procedure gloves. The location must be a private place, where the woman can feel relaxed and adopt a comfortable position. The fingers and the perineal tissues must be lubricated with vegetable oils (e.g., coconut or almond oils), water-based lubricant gel, or the natural vagina's lubrication. Firstly, an external massage must be applied, with circular or sliding moves around the vagina and on the perineal tendon center for 20 to 30 seconds. For self-massage, the woman must insert the thumbs; if performed by another person, the middle and ring fingers must be inserted about 3 to 4 cm inside the vagina. It can be initiated with semicircles from one side to the other, passing over the anal area for about 20 to 30 seconds. Then, pressure must be applied downwards (towards the anus) and to the sides until a light burning sensation can be felt (it must not generate pain or harsh burning sensation) to provide some stretch. The position must be sustained for 1 to 2 minutes. Next, the semicircular movements are performed again, followed by "U" shaped movements in the lower half of the vaginal introitus [55].

Among the seventeen articles, two studies [36,56] were based their work by Avery and Van Arsdale (1987) [33]. This study suggests that the perineal massage be carried out daily in the last 6 weeks of the gestational period, for 5 to 10 minutes, using essential oils, through digital insertion about 2 inches (about 5 cm) into the vagina, maintaining the stretch for 30 to 60 seconds [33]. Cabral et al (2022) [15] and Freitas et al (2019) [14] were based on the Beckman and Stock review [9]; and Cueva-Reguera et al (2020) [30] was based on the work of Ugwu et al (2018) [28]. There was no consensus regarding the frequency and whether the digital must be superficial or a little deeper. Beckman et al. (2013) demonstrated that the perineal massage execution once or twice a week is more beneficial than more than two times [9].

APM is a preventive intervention that requires motivation, adequate information, support, and specific knowledge by the professional who will assist. Orientation, demonstration, and supervised execution play a significant role in motor learning. The physiotherapist already applies perineal massage to treat other conditions related to the pelvic floor. Therefore, executing this intervention supervised by a specialized physiotherapist, considering the professional's knowledge about PFM, provides a better experience in the execution, and, therefore, better results are obtained. APM practice does not require high technologies, allowing it to be self-administered by the pregnant woman when well directed. Considering its possible benefits, the professionals in obstetric care should encourage the practice.

Instrument-assisted perineal stretching and expulsive phase training

The EPI-NO® device is a vaginal dilator consisting of an inflatable silicone balloon coupled with a manometer and a manual pump. The device was inspired by African women, who performed perineal stretching with gourds of progressive diameters. The purpose of the device is to simulate the expulsive period of labor, to stretch, and to strengthen the PFM to favor perineal integrity [42,57].

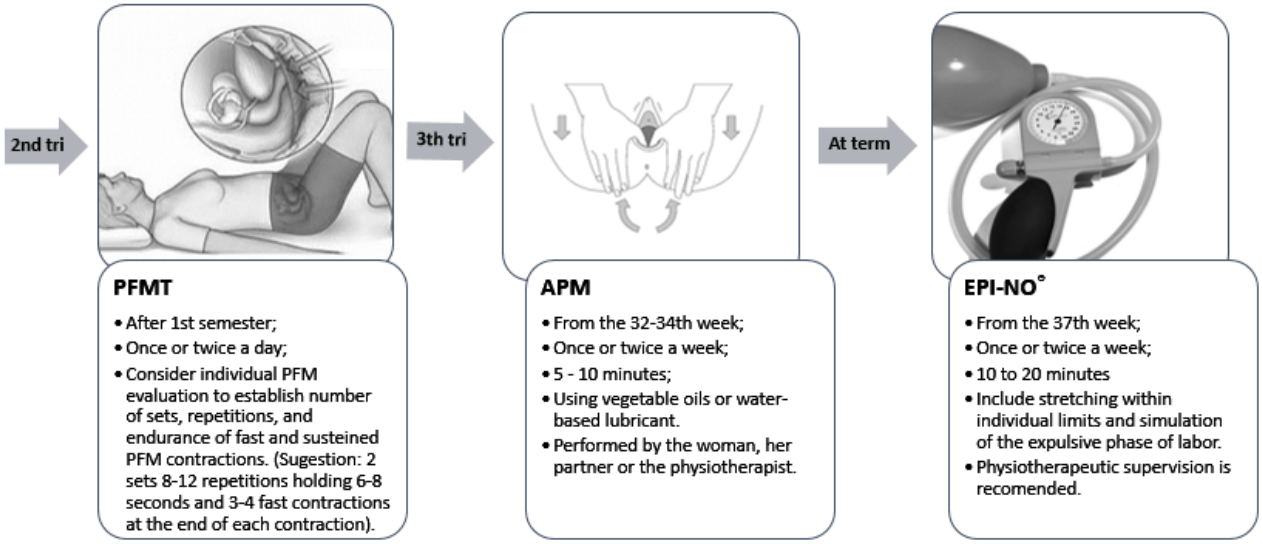
Some studies have found beneficial effects of using the device, such as reducing episiotomy rates, levator ani injuries, and increasing the likelihood of perineal integrity. However, most results are not significant [38-41,58]. Other studies and systematic reviews have not observed a drop in episiotomy rates, reduction in the second stage of labor, and increased perineal integrity. Moreover, such studies found no evidence concerning the reduction of perineal injuries, the incidence of levator ani avulsion, irreversible Hiatal overdistension, and the clinical trauma of the anal sphincter. Therefore, regarding the prevention of perineal injuries, levator ani avulsion, and anal sphincter injury, the device does not have scientific evidence for these outcomes. However, it is necessary to carry out well-designed studies in various obstetric settings on its use so that more concrete conclusions can be established [7,11].

Regarding its usage, the manufacturer's recommendation is to insert two-thirds of the balloon into the vagina. For improved strength, there is no need to inflate the balloon but simply move it, sustaining the contraction for 10 seconds upwards and relaxing for 10 seconds. For stretching, the balloon must be gradually inflated until it causes a comfortable stretching sensation, remaining inflated for about 10 minutes. With the progression of the sessions, the balloon can reach larger diameters. With the balloon inflated, training for the expulsive period can be performed. According to the producers, optimal training is achieved when the balloon reaches a diameter of 8-10 cm (3-4 inches) and can be slid out while inflated after about two weeks of training [57]. In the literature, there are no different recommendations on its use; only two studies included in this review present references to support the proposals of their protocols.

The manufacturers claim that the device can be self-administered by the woman; nonetheless, considering that the population's knowledge about the PF and its functions is limited, we consider the supervised practice may be safer and more adequate. There is a need for investigations on the realization of supervised practice to evaluate its effects on PFM more rigorously.

In figure 2 we include a summary with the main information and suggestions for possible protocols. A careful assessment of the muscle function of the PF is necessary for the formulation of a well-directed and supervised therapeutic protocol. In this regard, physical therapists have the competencies required to accomplish such assessment, therefore contributing to the health of pregnant women.

Figure 2. Protocols suggested for perineal preparation during pregnancy.



Legend: PFMT – Pelvic floor muscle training; PFM – Pelvic floor muscles; APM – Antenatal Perineal Massage.

This systematic review aims to fill a gap regarding recommendations for the preparation of the pelvic floor during pregnancy, enabling professionals to have easy access to high-quality information. In doing so, RCT intervention protocols or quasi-randomized studies were analyzed and summarized. We built upon reliable databases and conducted a detailed review process. Since we focus on assessing protocols, we note that analyzing the effectiveness of the methods is outside the scope of this study as well as we did not conduct a methodological quality analysis of the included studies, a relevant limitation of this review.

CONCLUSION

AMP is the most studied intervention for the prevention of perineal trauma, with well-established protocols and good effectiveness, and it is recommended for preventing perineal trauma and postpartum perineal pain. According to the analyzed protocols, can be started from the 34th-35th week of gestation, for about 5-10 minutes, with vegetable oils or water-based lubricants, 1-2 times a week. We believe that APM's individualized guidance and supervision at some frequency would also be interesting to a better effectiveness and security of this intervention.

PFMT has been investigated in the prevention and/or treatment of urinary incontinence, but results are still limited regarding its role in perineal trauma. PFMT usually starts after first trimester or from the 20th gestational week, including 1-4 sets with 8-12 contractions over 6-8 seconds (considering the sustaining period during evaluation) and 3-4 short contractions after each sustained one (or after each set), once or twice a day. Individualized assessment should be considered when prescribing the PFMT, and supervision at some frequency can help ensure that the woman is performing the exercises correctly.

Studies involving Epi-no are controversial regarding protocols and effectiveness; therefore, it should be used with caution until more research is conducted. It is crucial to explain to the woman that the current scientific evidence does not support its effectiveness on the PFM trauma prevention. Considering the integration of the professional's experience with the patient's preferences and values and the best scientific evidence available, bases for clinical decision-making, its use should be discussed individually. If used, the recommendation is to apply it from the 37th week of gestational age, following the protocol proposed by the manufacturer, including stretching within individual limits, training of the pelvic floor muscles, and simulation of the expulsive stage of childbirth. We believe that the most prudent thing would be to use it only with physiotherapeutic supervision.

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