



FACULDADE DE MEDICINA DE RIBEIRÃO PRETO-USP
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LABORATÓRIO DE AVALIAÇÃO FUNCIONAL DOS MÚSCULOS DO ASSOALHO PÉLVICO

PHD PROJECT

Physiotherapeutic protocol compared to usual care in the treatment of postpartum primiparas after perineal trauma: a type 1 hybrid effectiveness-implementation randomized controlled trial with economic evaluation

Ribeirão Preto – SP

July 11, 2025

The intervention group will receive the following interventions

During hospitalization:

1. **Information:** on physiotherapy in women's health, pelvic floor muscles (PFM) and their dysfunctions, using educational materials and images, as well as guidance on the care to be taken during hospitalization (guidance on postures to be adopted or avoided, breathing control, load management, and intimate hygiene).
2. **Contraction of the Pelvic Floor Muscles (PFMC):** PFMC will be carried out during hospitalization with the aim of observing the participant's ability to contract and advising on the correct way to contract according to visual feedback. The participant will be asked to perform 10 light contractions of the pelvic floor muscles at the limit of her pain tolerance in the supine position, with her knees bent and her feet on the bed, without palpation. Phrases such as "hold your pee", "close your vagina with the strength of your pelvic floor muscles" and "don't contract any other muscles or hold your breath" will be used to explain the movement to be performed.
3. **Cryotherapy:** 1 session of 20 minutes of application of an ice pack prepared by the researcher responsible for the intervention. The ice pack will consist of a 15 cm plastic bag with 150g of crushed ice, weighed on a scale in order to adapt it to the female genital anatomy. The ice pack will be wrapped in a thin cotton cloth to avoid direct contact with the skin. After positioning the ice, the participant will be asked to put her underwear back on, keeping the bag in the appropriate position. The temperature of the perineal region will be measured during the application in three time periods: immediately before cryotherapy, ten minutes after the start of cryotherapy and at the end of cryotherapy. The thermometer used will be a Minipa brand, which is portable, has a laser sight and does not come into direct contact with the participant's skin, thus avoiding contamination.

After hospitalization: at home

1. **Pelvic Floor Muscle Training (PFMT):** PFMT at home will consist of a total of 12 weekly online sessions and will be divided into two time periods: up to 40 days after childbirth, which will be carried out with the aim of controlling inflammation; after 40 days after childbirth, which will be carried out with the aim of strengthening the muscles. Therefore, with the participant in the supine position, knees bent and feet on the bed, she will be asked to perform, under supervision:

- Up to 40 days after childbirth (7 sessions): 3 sets of 10 quick, light contractions of the pelvic floor muscles at the limit of pain tolerance, with 2-minute rest intervals between sets;
- From 40 days after delivery (5 sessions): 3 sets of 10 maximum contractions sustained for 6 seconds followed by 10 rapid maximum contractions; 2-minute rest intervals between sets.

Guidance will also be provided to carry out the training daily at home, with the same protocol and without supervision. The frequency of PFMT at home will be monitored by a researcher not involved in the training or evaluation, and will be recorded.

2. **Cryotherapy:** Participants will be instructed to apply ice packs for pain relief. The number of applications and pain before and after (NRS) will be recorded.

The control group will receive the usual care provided by the maternity ward at Hospital das Clínicas de Ribeirão Preto, which consists of suturing the injury and administering oral analgesics.

TIDieR evaluation

Item number	Item	Physiotherapy Protocol	Control
	SUMMARY NAME		
1.	Provide a name or a phrase that describes the intervention	Combined pelvic floor muscle training (PFMT) protocol associated with cryotherapy, guidance and information	Usual maternity care
	WHY		
2.	Describe any justification, theory or objective of the essential elements of the intervention.	Cryotherapy can relieve pain, and TMAP is able to minimize sexual dysfunction and the functional consequences of perineal trauma	The usual maternity care includes analgesic medication to help relieve pain
	WHAT		
3.	Materials: Describe all physical or informational materials used in the intervention, including those provided to participants or used in the execution of the intervention or in the training of those responsible for the intervention. Provide information on where the materials can be accessed (e.g. online appendix, URL).	Ice pack, which will consist of a 15 cm plastic bag containing 150 g of crushed ice, wrapped in a fine cotton mesh and informative images about the anatomy and function of the pelvic floor muscles.	Not applicable
4.	Procedures: Describe each of the procedures, activities and/or processes used in the intervention, including any enabling or supporting activities.	During hospitalization: the participants will receive information on physiotherapy in women's health, PFM and its dysfunctions, as well as guidance on the care to be taken; contraction of the pelvic floor muscles with the aim of observing the participant's ability to contract and providing guidance on the correct way to contract according to visual feedback. The participant will be asked to perform 10 light contractions of the pelvic floor muscles at the limit of pain tolerance in the supine position, with her knees bent and feet on the bed, without palpation; 20 minutes of ice pack application which will be wrapped in a thin cotton cloth to avoid direct contact with the skin. After placing the ice, the participant will be asked to put her underwear back on, keeping the bag in the appropriate position. The temperature of the perineal region will be measured during the application in three time periods: immediately before cryotherapy, ten minutes after the start of cryotherapy and at the end of cryotherapy After hospitalization (at home): 12 weekly online sessions and will be	During hospitalization, women will receive individual doses of analgesic medication (e.g. Dipyrone) when they complain of pain in the perineal region. After discharge, these patients will be advised to use the same medication, with the doses indicated by the maternity doctors, in cases of pain in the perineal region.

		<p>divided into two time periods: up to 40 days after delivery, which will be carried out with the aim of controlling inflammation; after 40 days after delivery, which will be carried out with the aim of strengthening the muscles. Therefore, with the participant in the supine position, knees bent and feet on the bed, she will be asked to perform, under supervision:</p> <p>Up to 40 days after childbirth (7 sessions): 3 sets of 10 quick, light contractions of the pelvic floor muscles at the limit of pain tolerance, with 2-minute rest intervals between sets;</p> <p>From 40 days after delivery (5 sessions): 3 sets of 10 maximum contractions sustained for 6 seconds followed by 10 rapid maximum contractions; 2-minute rest intervals between sets.</p> <p>Guidance will also be provided to carry out the training daily at home, with the same protocol and without supervision. The frequency of TMAP at home will be monitored by a researcher not involved in the training or evaluation, and will be recorded.</p> <p>The participants will be instructed to apply ice packs for pain relief. The number of applications and pain before and after will be recorded.</p>	
	WHO SUPPLIED		
5.	For each category of professional responsible for the intervention (e.g. psychologist, nursing assistant), describe their skills, background and the specific training they have received.	A physiotherapist with around 2 years' experience in women's health physiotherapy	Doctor hired by the maternity ward of the Hospital das Clínicas de Ribeirão Preto (HC-FMRP)
	HOW		
6.	Describe how the intervention was carried out (e.g. face-to-face or via other means such as the Internet or telephone) and whether it was carried out individually or in groups.	An individual face-to-face session supervised during hospitalization. After hospitalization, TMAP will be carried out through weekly online sessions and the application of the ice pack will be unsupervised.	Face-to-face and individually supervised during hospitalization. After hospitalization, the use of medication will be unsupervised.
	WHERE		
7.	Describe the type(s) of site(s) where the intervention took place, including any necessary infrastructure or relevant features.	During hospitalization at HCFMRP and after hospitalization at home, the latter requiring internet access and a device with internet access, such as a cell phone or computer.	During hospitalization at HCFMRP and after hospitalization at home.
	WHEN and HOW MUCH		

8.	Describe the number of times the intervention was carried out and over what period of time, including the number of sessions, the schedule, the duration, the intensity or the dose.	<p>The participants will receive 1 physiotherapy session during hospitalization, with 20 minutes of cryotherapy and MAP contraction training.</p> <p>After hospitalization, the participants will receive 12 weekly TMAP sessions and will apply ice packs as needed (the number of applications will be recorded).</p>	According to the participant's needs and complaints
	ADAPTATION		
9.	If the intervention was planned to be personalized, regulated or adapted, describe what, why, when and how.	<p>Some aspects of the intervention will be personalized for each participant, such as the number of ice pack applications at home.</p> <p>This will be determined by the participant's pain. The application of ice packs at home will be advised to the participants as a non-pharmacological method for the relief of perineal pain.</p>	The use of analgesic medication will be personalized according to the participant's pain complaints, during hospitalization and at home.
	MODIFICATIONS		
10.	If the intervention was modified during the study, describe the changes (what, why, when and how).	No changes are planned during the protocol, however, if the patient does not feel comfortable or wishes to stop applying ice or muscle contractions, as well as TMAP during the online sessions, her wishes will be respected and the changes will be recorded	Not applicable
	QUALITY		
11.	Expected: If adherence or fidelity to the intervention was evaluated, describe how and by whom, and if strategies were used to maintain or improve fidelity, describe them.	Acceptability, suitability, feasibility, adherence and satisfaction with the proposed protocol will be assessed by the investigator in charge of the evaluations	Adherence and compliance will be assessed using a medication diary
12.	Current: If adherence or fidelity to the intervention was assessed, describe the extent to which the intervention was carried out as planned.	Not applicable	Not applicable