FACULDADE DE MEDICINA DE RIBEIRÃO PRETO-USP
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LAFAP

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

You are being invited to take part in this study which will evaluate the possible benefit of physiotherapy in relieving pain in women who have suffered a perineal laceration, i.e. an injury to the area between the vagina and the anus during the baby's exit during vaginal delivery. This is an important study because many Brazilian women suffer some degree of perineal laceration (injury) during childbirth, which has immediate and delayed consequences, including perineal pain (between the vagina and anus), urinary incontinence (involuntary loss of pee) and pain during sexual intercourse, which directly affects their quality of life, causing great discomfort and annoyance.

The aim of the research is to assess whether pelvic floor muscle exercises, also known as pelvic floor muscle training or female intimate muscle training, started during the hospitalization phase after childbirth and associated with the use of ice on the site where the injury occurred (perineal trauma), can relieve pain and speed up recovery in this region.

If you agree to take part, you will be drawn to be part of a control group that will be assessed and receive only the guidance and care normally offered in the maternity ward (Group 1) or a group that will receive physiotherapy sessions for 12 weeks (Group 2). If you are in Group 2, during your hospitalization you will be instructed by a physiotherapist to contract and relax your pelvic floor muscles and you will be given ice for 20 minutes on the site of the perineal trauma (injury). If you experience any discomfort, you can ask for the treatment to be stopped at any time. When you return home, you will continue to receive remote physiotherapy sessions (cell phone or computer app) once a week lasting approximately 40 minutes each session for 12 weeks.

All participants (Group 1 and Group 2) will be assessed at the beginning of the study before the draw, which will be made using a table with computer-generated numbers. The draw is made to ensure that all participants will have the same chance of being part of the two study groups and there will be no interference from the participants themselves or the researcher in charge, i.e. you will not be able to choose which group to be in.

All study participants will be asked about their use of analgesic medication, such as type of medication, amount taken and time, as well as perineal pain before and after use. Adherence to and satisfaction with the protocol will also be assessed. Throughout the study period, all participants will be properly monitored and assisted through weekly remote meetings conducted by a physical therapist. In addition, the research team will periodically contact participants by phone to conduct assessments and follow-ups.

Participants may also contact the team at any time by phone if they have questions or concerns related to the intervention..

If you agree to take part, regardless of which group you are in, you will answer a questionnaire to assess your pain, which you will have to answer twice during your hospital stay, 40 minutes apart, in the case of the

Group 1 or before and after the first physiotherapy session in the case of Group 2 participants, once a week for one month after childbirth, every two weeks in the second month, at the end of treatment (3 months after childbirth) and 6 months after childbirth. The face-to-face assessments will be carried out at 2 points: during hospitalization and 3 months after delivery. The other assessments will be carried out by telephone/whatsapp 6-8 weeks after delivery, 3 months and 6 months after delivery.

The face-to-face assessments take place as follows: The first assessment (during hospitalization) begins with an interview in which you will be questioned about personal data, income (salary), schooling (how much you studied), obstetric and urinary history and personal background. Some data, such as date of delivery, degree of perineal trauma (injury between the vagina and anus) and medical records will be retrieved from the hospital system.

The second part will be a physical assessment, which will evaluate your intimate muscles (pelvic floor) and whether they are able to close your vagina (contract). First, an ultrasound scan will be carried out in the area between the anus and the vagina. This examination will also make it possible to visualize the injury and its recovery. After each assessment, questionnaires will be administered to assess the level of perineal pain, sexual function (if you are having sex and how you are feeling), urinary function (if you accidentally lose pee), intestinal function (if you accidentally lose feces), your functionality (if you have difficulties moving around after giving birth), your quality of life, gender-based violence (if you have ever suffered any kind of physical, sexual or psychological violence) and genital self-image (how satisfied you are with the appearance of your intimate region). In the second face-to-face assessment, in addition to these questionnaires, a vaginal palpation test will also be carried out to assess the force of contraction in your intimate area. For this assessment, the physiotherapist will insert one or two fingers into your vagina and ask you to contract as if you were holding in your pee. The ultrasound test is non-invasive (the probe is not inserted into the anus, urethra or vagina) and both the ultrasound and palpation tests are not usually painful, but if you have any discomfort you can ask for it to be stopped at any time.

Participant check: _____

Researcher check:_____

The discomforts and risks to which the participant will be exposed are those expected when carrying out the assessment and physiotherapy treatment for the pelvic floor, such as possible embarrassment, and no additional risks or discomforts will be added. You are free to ask any questions related to the research before, during and after your participation in the research, and you will be able to access the results of the research after it has been completed. You are also free to withdraw your consent and stop taking part in the study at any time, without this causing any harm to the continuity of your treatment. If you do not want to take part in the research, this refusal will not affect your treatment at this service in any way. You may request reimbursement for your transportation during the research. Confidentiality will be respected by assuring the participants that they will not be identified, and the confidentiality of the information related to their privacy will be maintained. Should any damage occur as a result of your participation in the research, you will be entitled to compensation in accordance with the laws in force in your country. This Free and Informed Consent Form has been prepared in two copies: after being duly signed, one will be given to the research participant and the other will be filed by the researcher responsible

There are no direct benefits from your participation in the research project, but you will contribute to finding out whether the treatment being researched works, which could benefit many women. You will also receive information about the pelvic floor and the function of the intimate muscles that are able to close the anus, urethra and vagina. Regardless of which group you are in, we will teach you how to contract these muscles correctly and after you have taken part in the study, you will receive a booklet and guidance on how to prevent and treat related problems (e.g. loss of urine and faeces without your will, descent of organs such as the bladder and uterus and impaired sexual function).

A Research Ethics Committee (REC) is made up of a group of people who are responsible for supervising research on human beings that is carried out at the institution and has the function of protecting and guaranteeing the rights, safety and well-being of all research participants who volunteer to take part in it.

The CEP of the Hospital das Clínicas e da Faculdade de Medicina de Ribeirão Preto is located in the basement of the hospital and is open from Monday to Friday, from 8:00 am to 5:00 pm. The contact telephone number is (016) 3602-2228 and is available for any ethical questions about the research. Contact details of the researchers involved: Caroline Soares de Paula (+5519996307633; carolinesoarespaula@gmail.com) and Dr. Cristine Homsi Jorge (+551633150741).

Participant's name: _____
Participant's signature :_____
Date:_____

Researcher's name: _____
Researcher signature: _____
Date:_____