

FEDERAL UNIVERSITY OF RIO GRANDE DO SUL
SCHOOL OF MEDICINE
GRADUATE PROGRAM IN HEALTH SCIENCES:
GYNECOLOGY AND OBSTETRICS

**PERINEAL MASSAGE DURING LABOR FOR THE PREVENTION OF
PERINEAL TRAUMA: A RANDOMIZED CLINICAL TRIAL**

Project Number in CAAE: 77121923.5.0000.5327

PORTE ALEGRE
2024

INFORMED CONSENT FORM

Project Number in CAAE: 77121923.5.0000.5327

Project Title: Perineal massage during labor for the prevention of perineal trauma: a randomized clinical trial.

You are being invited to participate in a research study aimed at evaluating the effectiveness of a technique to prevent perineal trauma (laceration and episiotomy) during the second stage of labor. This research is being conducted by the Master's Program in Health Sciences – Gynecology and Obstetrics at the Hospital de Clínicas de Porto Alegre/RS (HCPA).

If you accept this invitation, your participation will involve: granting access to relevant medical data from your records, receiving perineal massage, and answering questions about your perception of the technique used.

Perineal massage consists of relaxing and stretching the muscles of the perineum during labor, with the aim of preparing the birth canal and facilitating the passage of the fetus. The researcher will insert one or two fingers into the vaginal canal and perform side-to-side movements with light downward pressure toward the rectum, according to your tolerance.

No risks related to participation in this research are known, considering that perineal massage is low risk and is not associated with an increase in perineal trauma. However, some physical discomfort may occur during the application of the technique.

If proven effective, you may benefit from prevention of lacerations and/or episiotomy, especially the more severe ones, as well as a faster postpartum recovery. If effectiveness is not proven, the technique will not cause any harm.

Your participation in this study is completely voluntary, meaning it is not mandatory. You have the right to refuse to continue participating at any time. Should you decide not to participate or to withdraw your consent, there will be no penalty or loss of benefits to the care you currently receive or may receive at the institution.

No payment is planned for your participation, and you will not incur any costs related to the procedures involved.

If any adverse event or harm occurs as a result of your participation, you will receive all necessary medical care at no personal cost.

The data collected during the study will be kept confidential. Results will be presented collectively without identifying participants, meaning your name will not appear in any publication of the results.

If you have any questions, you may contact the principal investigator, Gabriela Plentz Stein, at (51) 99771-0248, or the Research Ethics Committee of the Hospital de Clínicas de Porto Alegre (HCPA) at (51) 3359-6246, email cep@hcpa.edu.br, or visit the 5th floor, Block C of HCPA, Monday to Friday, from 8 a.m. to 5 p.m.

This form is signed in two copies, one for the participant and one for the researchers.

Name of Research Participant

Signature

Name of Researcher Obtaining Consent

Signature

Place and date: Porto Alegre, ___/___/___