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

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PORTO ALEGRE

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Study Protocol

1. Background and Rationale

Perineal trauma during childbirth, particularly episiotomy and spontaneous lacerations, is associated with pain, prolonged recovery, and complications during the puerperium. Evidence from prior meta-analyses (e.g., Aasheim et al., Cochrane 2017) suggests potential benefits of perineal massage in reducing these outcomes. This study aims to contribute robust evidence through a properly randomized, controlled design conducted in a high-volume public hospital.

2. Objectives

Primary Objective: To evaluate whether perineal massage reduces the incidence of intact perineum (absence of episiotomy or laceration) compared to standard care.

Secondary Objectives: To assess differences between groups in the degree of lacerations, need for sutures, incidence of episiotomy, neonatal APGAR scores, and second stage labor duration.

3. Study Design

Type: Interventional, Randomized Controlled Trial
Model: Parallel Assignment
Allocation: 1:1 (Massage vs. Control)
Estimated enrollment: 466 participants
Location: Hospital de Clínicas de Porto Alegre (HCPA), Brazil

4. Eligibility Criteria

Inclusion:
- Women ≥18 years old
- Gestational age: 37-42 weeks
- Cephalic presentation
- First stage of labor
- No history of perineal massage in prenatal period

Exclusion:
- Cesarean delivery
- Diagnosis of HELLP syndrome
- Unstable maternal or fetal vital signs

Statistical Analysis Plan (SAP)

1. Overview

The SAP describes the statistical methods that will be used to analyze the data from the trial and to address each primary and secondary objective.

2. Sample Size Calculation

Based on Cochrane meta-analysis by Aasheim et al. (2017), a reduction in episiotomy rate from 22% to 12% (RR = 0.55)
Power: 80%
Sample size: 466 participants (233 per arm)

3. Population for Analysis

Full Analysis Set (FAS): all randomized participants, analyzed by original assignment (intention-to-treat)
Per Protocol (PP): participants who adhered to the assigned intervention

4. Statistical Methods

Descriptive Statistics:
- Continuous variables: mean ± SD or median (IQR), depending on normality
- Categorical variables: frequency and percentage

Test of Normality:
- Shapiro-Wilk test

Between-Group Comparisons:
- Normal distribution: independent samples t-test
- Non-normal distribution: Mann-Whitney U test
- Categorical variables: Pearson Chi-square, Fisher’s exact test, or Yates' correction

Within-Subject Comparisons (Pre/Post if applicable):
- Normal distribution: paired t-test
- Non-normal distribution: Wilcoxon signed-rank test
- Dichotomous categorical variables: McNemar test

Significance Threshold:
- Two-sided p-value ≤ 0.05 will be considered statistically significant.

Missing Data:
- Assessed for patterns and handled using complete-case analysis or imputation if necessary.

5. Software

Statistical analysis will be conducted using SPSS for Windows, version 18.0.