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Antenatal ThREe Steps Perineal mASSage in reducing perineal trauma and post-partum morbidities: TRESPASS clinical study

PROTOCOL SYNOPSIS

Title	Antenatal ThREe Steps Perineal mASSage in reducing perineal trauma and post-partum morbidities: TRESPASS clinical study
Sponsor	Azienda Sanitaria Universitaria Friuli Centrale (ASUFC)
Principal investigator	Dott.ssa Martina Arcieri
Study collaborators	Dott. G. Baccarini, Dott.ssa E. Barbui, Dott.ssa A. Citossi, Dott. S. Floris, Dr.ssa C. Giorgiutti, Dott. S. Restaino, Dr.ssa V. Tius, Prof. G. Vizzielli,
Rationale	Perineal trauma from delivery correlates with an increased incidence of perineal pain and discomfort, dyspareunia and sexual dysfunction, as well as urinary and anal incontinence and therefore have a significant impact on women's physical and mental health. Prepartum perineal massage has been shown to reduce the incidence of spontaneous vagino-perineal tears and promote better anatomo-functional recovery of the perineum in the postpartum period. To date, there are no guidelines on the best modes of perineal massage, and there is a lack of true standardization of the process in the literature. Investigating the relationship between prepartum perineal massage and perineal tears (and related short- and long-term morbidity) could lead to improvement in obstetric clinical practice by giving the right guidance to the pregnant woman in pelvic floor education.
Endpoint	The authors developed, on the basis of the evidence available at the present time, a peculiar type of perineal massage, embedded in a standardized clinical process including training and follow-up of the patient. Thus, the primary endpoint of the present study is to assess the difference in incidence in the two study groups of the absence of vagino-perineal tears (intact perineum). Secondary endpoints to be assessed are the superiority of perineal massage on the duration of the second stage of labor, on incidence of operative delivery and episiotomies, and on perineal pain and dyspareunia in postpartum.
Type	Prospective randomized superiority trial.
Participating centers	ASUFC - Clinic of Obstetrics-Gynecology, Santa Maria della Misericordia Hospital of Udine
Study duration	2 years
Period of observation	2024-2026
Sample size	154 patients (77 for each arm).
Statistical analysis	Quantitative variables will be described with mean and standard deviation; qualitative variables will be summarized in percentages and frequency indices. Continuous and categorical data will be compared with Student's t test and Fisher's exact test, respectively. Relationships between the data will be expressed using Relative Risk with confidence intervals. A p-value < 0.05 will be considered statistically significant.
Population and data sources	Pregnant women referred to the Udine Obstetrics Clinic who meet the inclusion criteria. Data are collected from the patient history and clinical interview, medical records and partograms, data collection form and written questionnaires; they will be entered into a computerized database in which the patient's name will be replaced by a progressively increasing number to preserve anonymity.
Inclusion criteria	- Single pregnancy - Part presented cephalic - Age between 18 and 40 years - Pregravid body mass index (BMI) between 18 and 29.9 - Understanding of the Italian language - Estimated Fetal Weight in range (3rdcentile to 97thcentile according to Intergrowth)
Study design	All pregnant patients who meet the inclusion criteria will be selected and offered participation in the study by delivering the information brochure at the 2nd trimester obstetrical visit. If at the 3rd trimester obstetrical visit the patient expresses willingness to participate in the study, consent will be signed and enrollment and randomization to the study will be performed. The patient will then be notified of the date of the training meeting

	held by the investigator and/or co-authors; at this meeting, a brief lecture on aspects of primary pelvic floor prevention will be offered to patients in group A, who will also be educated on the perineal massage proposed by the Authors. Group B patients will equally be offered a short lecture on aspects of primary prevention, leaving the patient free choice in pelvic floor education in pregnancy. Group A patients will perform the learned perineal massage at home, reporting their adherence to the study in a diary. After delivery, at the time of discharge, a data collection form regarding postpartum perineal pain will be given to the patient and the date of the 45-day follow-up visit will be communicated.
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Notes	Version 1.4 of 20.02.2024

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Principal investigator,

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