Official Title: Pelvic Floor Training Combined with Perineal Massage Reduces Episiotomy to 5.7%: A Four Arm Randomized Controlled Trial

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1. PROTOCOL TITLE AND IDENTIFICATION

Title: Pelvic Floor Training Combined with Perineal Massage Reduces Episiotomy to 5.7%: A Four Ar m Randomized Controlled Trial

Short Title / Running Title: Pelvic Floor Training and Perineal Massage Reduce Episiotomy

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Study Sites:
Batman Training and Research Hospital, Obstetrics and Gynecology Clinics, Batman, Turkey.

Ethics Approval:
Approved by the Publication Ethics Committee of Batman University, Faculty of Social and Human Sci ences, Natural and Engineering Sciences.
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Decision Number: 2026/01
Institutional permission obtained from Batman Provincial Health Directorate.

Protocol Version: Final Version, dated January 8, 2026.

2. BACKGROUND AND RATIONALE

Episiotomy rates remain high despite global recommendations for restrictive use (<10%). Antenatal pe lvic floor muscle training (PFMT) and perineal massage are individually effective, yet their combined ef

fect compared to other non-pharmacological modalities (e.g., Swiss ball) has not been adequately ass essed. Additionally, isolated intensive PFMT without perineal relaxation training may theoretically incre ase pelvic floor hypertonicity, paradoxically raising episiotomy risk. This study aims to fill these knowle dge gaps by comparing four interventions in a four-arm, double-blind, randomized controlled design.

3. STUDY OBJECTIVES

Primary Objective:
To compare episiotomy rates among low-risk pregnant women receiving standard care, pelvic floor mu scle training (PFMT) alone, PFMT combined with Swiss ball exercises, or PFMT combined with perine al massage.

Hypothesis:
The addition of perineal massage to PFMT will yield the lowest episiotomy rate. Isolated PFMT without perineal preparation may not reduce, and might even increase, the need for episiotomy compared to st andard care.

4. STUDY DESIGN

This is a randomized, double-blind, controlled experimental trial with four parallel arms, designed and r eported in accordance with CONSORT guidelines. The study was conducted at the Obstetrics and Gy necology Clinics of Batman Training and Research Hospital.

5. STUDY POPULATION AND ELIGIBILITY CRITERIA

Participants: Pregnant women presenting to the study facility.

Inclusion Criteria
- Age ≥ 18 years
- Gestational age between 20 and 36 weeks at time of enrollment
- No prior exposure to any of the study interventions
- No history of previous episiotomy
- Estimated fetal weight between 3,000 and 4,000 grams
- No labor induction
- Absence of any systemic disease complicating the current pregnancy
- No regular use of medications or supplements other than multivitamins
- Pre-pregnancy body mass index (BMI) within the range of 18–25 kg/m²

Exclusion Criteria
- Failure to meet any of the inclusion criteria
- Declining to provide written informed consent

6. SAMPLE SIZE DETERMINATION

A formal a priori power analysis using G*Power (version 3.1) for one-way ANOVA (four groups) assum ed a medium effect size f=0.25, α=0.05, and 80% power. The minimum required sample was 52 partici pants per group (total 208). To accommodate potential attrition, the target was inflated by 20%, yieldin g a planned enrollment of 429 pregnant women. The final randomized sample consisted of 431 partici pants.

7. RANDOMIZATION AND BLINDING

Eligible participants were randomly assigned to one of four groups using simple randomization with the sealed envelope method (bag technique) to ensure allocation concealment.
Group Allocation:
- Control Group (standard antenatal care, n=153)
- PFMT + Perineal Massage Group (n=88)
- PFMT + Swiss Ball Group (n=58)
- PFMT Alone Group (n=132)

Double-blind Design: Participants were blinded to their group assignment. The researchers collecting clinical outcome data and performing statistical analyses were also blinded. Birth attendants could not be fully blinded due to the nature of the interventions, but all decisions regarding episiotomy were mad e according to routine clinical practice, and the outcome assessors and data analysts were masked.

8. INTERVENTIONS

All intervention groups received nurse-led pelvic floor education sessions at least once per week until delivery. Sessions covered pelvic floor anatomy, identification of correct muscle contraction, performan ce of Kegel exercises, and diaphragmatic breathing.

Group-specific interventions:
- Control Group: Received standard antenatal care with no additional intervention.
- PFMT + Perineal Massage Group: In addition to weekly PFMT sessions, participants were taught digi tal perineal massage and instructed to perform it at least once daily starting from the 34th gestational week until delivery.
- PFMT + Swiss Ball Group: In addition to weekly PFMT sessions, participants performed active pelvic movements on a Swiss ball during labor (pelvic anteversion, retroversion, lateral tilts, and circular hip movements), as clinically appropriate.
- PFMT Alone Group: Received pelvic floor muscle exercises administered by a nurse at least once a week for at least one hour, starting from week 34 onward, without any additional perineal preparation o r Swiss ball use.

9. OUTCOME MEASURES

Primary Outcome Measure:
Episiotomy rate (percentage of vaginal deliveries in which episiotomy was performed). The presence o r absence of episiotomy was recorded immediately postpartum.

Secondary Outcome Measures (recorded on a clinical follow-up form):
- Degree of perineal laceration (1st–4th degree) when no episiotomy
- Duration of labor (first and second stages)
- Neonatal birth weight
- APGAR scores at 1 and 5 minutes

Sociodemographic and obstetric characteristics (age, education, occupation, gestational week, gravidit y, parity, previous mode of delivery, pre-pregnancy BMI) were collected via a structured Personal Infor mation Form.

10. DATA COLLECTION AND MANAGEMENT

Data were collected using standardized paper forms and subsequently entered into a secure electroni c database. All participant records were de-identified. Access to data was restricted to authorized rese arch personnel. The datasets used and/or analyzed during the study are available from the correspon ding author upon reasonable request, subject to institutional ethical approval.

11. STATISTICAL ANALYSIS PLAN

All analyses were performed using IBM SPSS Statistics version 26. Descriptive statistics (frequencies, percentages, means, standard deviations, medians, min–max) summarized baseline characteristics. N ormality was assessed with the Kolmogorov–Smirnov test.
- Between-group comparisons of continuous variables: Independent-samples t-test (normal distribution) or Mann–Whitney U test (non-normal).
- Three or more group comparisons: One-way ANOVA (parametric) or Kruskal–Wallis test (non-param etric). Post-hoc comparisons with Bonferroni correction were used for significant omnibus tests.
- Categorical variables: Chi-square or Fisher’s exact test.
- Associations between two continuous variables: Pearson or Spearman correlation coefficients.
A two-tailed p-value <0.05 defined statistical significance.

Primary analysis compared episiotomy rates across the four groups using Chi-square test; pairwise po st-hoc comparisons were conducted.

12. ETHICAL CONSIDERATIONS

The study was conducted in accordance with the Declaration of Helsinki. Ethical approval was obtaine d from Batman University Publication Ethics Committee (Date: January 8, 2026; Decision No: 2026/01

). Institutional permission was granted by the Batman Provincial Health Directorate. All participants pro vided written informed consent after being informed about the purpose, voluntary nature, confidentialit y protocols, and the right to withdraw at any time.

13. DATA SHARING STATEMENT

Individual participant data will not be publicly shared due to the absence of explicit informed consent fo r broad data sharing. De-identified datasets may be made available from the corresponding author up on reasonable request, subject to institutional ethics committee review and a data sharing agreement.

14. FUNDING AND CONFLICTS OF INTEREST

No external funding was received. The authors declare no conflicts of interest.

15. REFERENCES (Key studies cited in protocol)

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