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The Effects Of Mother-Friendly Practices On Maternal And Fetal Outcomes: A Multicenter Study

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Author Statement

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STUDY PROTOCOL

This study was designed as a prospective, multicenter, randomized controlled trial to evaluate the effects of mother-friendly practices on maternal and fetal outcomes. The study was conducted between February 2025 and June 2025 in two tertiary care hospitals with different models of obstetric care. Sakarya Training and Research Hospital, designated as a mother-friendly hospital, provided care based on a model emphasizing minimal intervention, continuous support, and improved physical conditions, whereas Ümraniye Training and Research Hospital provided standard obstetric care.

A total of 281 primiparous women with singleton term pregnancies (≥37 weeks) were enrolled. Participants were randomly assigned in a 1:1 ratio to either the mother-friendly care group or the standard care group using a sequentially numbered, sealed-envelope method to ensure allocation concealment. Due to the nature of the intervention, blinding of participants and healthcare providers was not feasible.

In the intervention group, participants received care in single-occupancy labor rooms, were allowed continuous companion support, and were encouraged to use non-pharmacological pain relief methods such as massage, warm compresses, music therapy, and aromatherapy, along with minimal medical intervention. In the control group, participants received routine obstetric care, including standard monitoring and conventional labor management practices.

Data were prospectively collected by attending midwives and physicians using standardized forms. Recorded variables included maternal age, education level, gestational week at admission, cervical dilation, childbirth education status, labor interventions (e.g., enema, episiotomy, vacuum, forceps), and use of non-pharmacological methods. Maternal outcomes included mode of delivery, postpartum hemorrhage, duration of labor, and pain scores measured using the Visual Analog Scale (VAS) during latent and active labor phases. Neonatal outcomes included birth weight, Apgar scores, and NICU admission. Maternal satisfaction was assessed using the validated Scale for Measuring Maternal Satisfaction in Birth within the first postpartum hour.

The primary outcome of the study was a composite maternal and neonatal outcome, including cesarean delivery, postpartum hemorrhage, low Apgar score (<7 at 5 minutes), and NICU admission. Secondary outcomes included mode of delivery, duration of labor, episiotomy rate, instrumental delivery, pain scores, and maternal satisfaction.

The study was conducted in accordance with the principles of the Declaration of Helsinki and approved by the Sakarya University Clinical Research Ethics Committee. Written informed consent was obtained from all participants prior to enrollment.

STATISTICAL ANALYSIS PLAN

Statistical analyses were performed using SPSS version 22. Descriptive statistics were presented as mean ± standard deviation for continuous variables and as frequencies and percentages for categorical variables. The normality of continuous variables was assessed using the Kolmogorov–Smirnov test.

For comparisons between the two groups, the independent samples t-test was used for normally distributed variables, while the Mann–Whitney U test was applied for non-normally distributed variables. Categorical variables were compared using Pearson's chi-square test. For comparisons involving more than two groups, the Kruskal–Wallis test was used.

Correlation analyses between continuous variables were performed using Spearman's rank correlation coefficient. A two-tailed p-value of <0.05 was considered statistically significant.

To further strengthen the analysis, multivariate regression models were planned to adjust for potential confounding variables, including maternal age, education level, and labor-related factors. The results of regression analyses were reported as odds ratios (ORs) with 95% confidence intervals (CIs).

Missing data were handled using complete-case analysis. Sensitivity analyses were considered to evaluate the robustness of the findings.

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INFORMED CONSENT STATEMENT

Participants were informed in detail about the purpose and procedures of the study conducted by Dr. Merve Keskin Paker at the Department of Obstetrics and Gynecology of Sakarya Training and Research Hospital. Following this explanation, eligible individuals were invited to participate as study subjects.

All participants were assured that their personal and medical information would be treated with strict confidentiality and respect, and that all data obtained during the study would be used solely for scientific and educational purposes. Adequate assurance was provided regarding the protection of personal data.

Participants were informed that they could withdraw from the study at any time without providing any reason, and that their decision to participate or not would not affect their medical care or their relationship with healthcare providers. Additionally, participants could be excluded from the study by the researchers if deemed necessary, provided that no harm would occur to their medical condition.

No financial burden was imposed on participants for study-related procedures, and no financial compensation was provided. Participants were also informed that, in the event of any health problems arising directly or indirectly from the study, all necessary medical care would be provided without any cost.

Contact information of the principal investigator was provided, allowing participants to reach the research team at any time in case of questions or health concerns during the study.

All participants confirmed that they had received both written and verbal information, had sufficient time to consider participation, fully understood the study, and voluntarily agreed to participate without any coercion. A signed copy of the informed consent form was provided to each participant.