# Study Protocol

Study Title: The Effect of Emotional Freedom Technique Applied to High-Risk Pregnant Women on Anxiety and Postpartum Depression: A Randomized Controlled Trial

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## Study Design

This study aims to evaluate the effect of the Emotional Freedom Technique (EFT) applied in the preoperative period on anxiety and postpartum depression (PPD) in high-risk pregnant women scheduled for cesarean section.

The study was conducted between March and September 2024 at a City Hospital and followed a single-blind randomized controlled design.

## Participants

The sample consisted of high-risk pregnant women according to the Ministry of Health Risk Assessment Form who met the inclusion criteria. Inclusion criteria included: women scheduled for C-section surgery, gestational age over 36 weeks, a State-Trait Anxiety Scale (STAI-S) mean score of 37 or higher, and voluntary consent to participate. The sample size was calculated using pilot study data. Based on the analysis using the (STAI-S) mean scores, it was assumed that a statistically significant difference of at least 5 points would occur between groups post-intervention. The study was planned with a 95% confidence level ($\alpha$=0.05) and 80% statistical power (1-$\beta$=0.80), requiring at least 18 participants per group. To meet parametric test assumptions, 30 participants were assigned to each group.

## Randomization and Blinding

Randomization was performed by a researcher not involved in the intervention using an online randomization tool (randomizer.org). Group assignments were sealed in opaque envelopes and delivered to the intervening researcher to ensure confidentiality. The study was conducted in a single-blind design, with participants unaware of their group assignments.

## Data Collection Instruments

1. Introductory Information Form: Focuses on socio-demographic and obstetric characteristics.
2. STAI-S: Developed by Spielberger et al. (1970) and adapted to Turkish by Öner and Le Compte (1983). It consists of 20 items scored on a 4-point Likert-type scale (range 20–80). Higher scores indicate greater anxiety. Cronbach's alpha = 0.80.
3. Edinburgh Postnatal Depression Scale (EPDS): Developed by Cox et al. (1987) and

adapted to Turkish by Aydın et al. (2004). It consists of 10 items scored from 0–3, with scores ≥13 indicating risk of PPD. Cronbach's alpha = 0.88.
4. Subjective Units of Emotion (SUE) Scale: Assesses emotional intensity after EFT sessions (−10 to +10).

## Intervention

Participants were randomized into two groups: EFT Group and Standard Care Group.

EFT Group: Pregnant women meeting inclusion criteria were informed about the study and gave written consent. The introductory form and SUE scale were administered. EFT points were demonstrated, and trial applications were conducted. Sessions continued until participants reached +7 on the SUE scale. STAI-S was re-administered one hour before surgery. Postpartum, women were instructed to use EFT independently, and the EPDS was administered via telephone on postpartum day 21.

EFT Application Stages:
a) Symptom Severity: Initial SUE scale assessment.
b) Engagement with the Problem: Focus on emotion and problem.
c) Breathing and Acceptance: Deep breathing with an acceptance statement ("Even though I feel fear, I completely accept myself.").
d) Tapping: Light tapping on 14 acupressure points while repeating the acceptance statement.
e) Interim Evaluation: SUE re-applied; repeat sessions if necessary.
f) Affirmation: When SUE reaches 0, positive affirmations are added ("I am releasing my worry; I am safe; I am peacefully welcoming my baby.").
g) Termination: Process ends when positive energy reaches +7.

Standard Care Group: Pregnant women in the control group received standard preoperative care. STAI-S was re-administered in the last hour before C-section, and EPDS was applied via telephone on postpartum day 21.

## Statistical Analysis

Data were analyzed using statistical software. The Shapiro–Wilk test and skewness–kurtosis were used to assess distribution normality. Normally distributed data were analyzed with Independent Samples T-test. One-Way ANOVA tested three or more variables, with Bonferroni and Tukey post hoc tests for pairwise comparisons. Paired Samples T-test was used to compare pre- and post-test data within groups. Pearson correlation analyzed relationships between continuous variables. Significance level was set at $p < 0.05$, and Bonferroni-adjusted significance at $p < 0.01$.

## Ethical Considerations

Ethical approval was obtained from the university ethics committee (Approval No: 2024/299). Participants were informed about the purpose of the study, and written informed consent was obtained from all who voluntarily agreed to participate.