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Effect of Skin-to-Skin Contact on Father–Infant Bonding: A Randomized Controlled Tri

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1. Synopsis

- Design: Interventional, randomized, parallel-group, three-arm study conducted in maternity units.
- Arms: (A) Early one-time skin-to-skin contact; (B) Frequent skin-to-skin contact; (C) Standard care comparator.
- Primary Endpoint: Paternal–Infant Attachment Scale (PIAS) total score at approximately 3 months postpartum (points; higher scores indicate stronger bonding).
- Secondary Endpoints: PIAS subscale scores; frequency (days/week) and daily minutes of skin-to-skin contact; selected caregiving behaviors.
- Population: Adult fathers of healthy term singleton newborns.
- Setting: University and state hospital obstetrics units in Türkiye.
- Duration per participant: Baseline assessment soon after birth and a follow-up assessment around 3 months postpartum.

2. Background and Rationale

Skin-to-skin contact between caregivers and newborns is a simple, low-cost practice that may foster early bonding. Experimental evidence focusing on fathers is comparatively limited in Türkiye. This study evaluates whether structured father–infant skin-to-skin contact schedules enhance bonding versus standard care.

3. Objectives

Primary Objective. To determine whether father–infant skin-to-skin contact improves paternal–infant bonding compared with standard care.

Secondary Objectives. To compare subscale scores of bonding, describe skin-to-skin frequency and duration, and explore associations with selected caregiving behaviors and sociodemographic factors.

4. Endpoints

Primary Endpoint. PIAS total score at 3 months postpartum.

Secondary Endpoints. PIAS subscale scores; frequency of skin-to-skin (days/week); daily minutes of skin-to-skin; indicators of paternal involvement.

5. Trial Design

Randomized, parallel assignment with three arms and approximately equal allocation. The early one-time arm includes a single skin-to-skin session soon after birth. The frequent arm includes repeated sessions (e.g., at least 15 minutes per session on most days). The comparator arm receives routine postnatal care without a structured schedule.

6. Study Setting

The study is conducted in obstetrics units of a university research hospital and a state hospital in Türkiye.

7. Eligibility Criteria

Inclusion Criteria:

- Fathers aged 18 years or older.
- First-time fathers residing with the mother and infant.
- Able to provide skin-to-skin contact (e.g., sessions of approximately 15 minutes) within a defined post-birth window.
- At least primary school education.
- Infant: healthy, term (≈38–42 weeks' gestation), singleton, with birth weight within an acceptable range per protocol.

Exclusion Criteria:

- Significant communication barriers or conditions limiting informed consent.
- Infants requiring special care or with major congenital anomalies/serious illness.
- Sustained separation from the infant (e.g., prolonged hospitalization or travel) that precludes scheduled follow-up.

8. Interventions

Early One-Time Skin-to-Skin: A single supervised session of skin-to-skin contact shortly after delivery, following unit procedures.

Frequent Skin-to-Skin: Repeated sessions encouraged at home and/or during postnatal stays (e.g., on most days of the week), each lasting approximately 15 minutes, as feasible for the family.

Standard Care: Routine postnatal care without a structured skin-to-skin schedule; families may practice contact ad libitum per usual care.

9. Assessments and Schedule

Assessments include a baseline questionnaire administered soon after birth and a follow-up evaluation at approximately 3 months postpartum, which includes the PIAS. Additional questionnaires capture frequency (days/week) and daily minutes of skin-to-skin, and caregiving behaviors. All assessments are performed with standardized instructions.

10. Safety Considerations

This is a minimal-risk behavioral study. No investigational drugs or devices are used. Adverse events are not anticipated beyond transient discomfort from holding position. Any unexpected concerns reported by participants will be documented and managed according to institutional policies.

11. Ethics and Oversight

The study was reviewed and approved by an institutional ethics committee. Written informed consent is obtained from all participating fathers prior to enrollment. The protocol adheres to the principles of the Declaration of Helsinki and relevant national regulations.

12. Data Management and Confidentiality

Data are recorded on de-identified forms and stored securely. Access to identifiable information is restricted to authorized personnel. Results will be disseminated in aggregate form without personal identifiers.

Statistical Analysis Plan (SAP)

This SAP outlines analyses for the primary and secondary endpoints, populations for analysis, handling of missing data, and statistical thresholds. Analyses use a two-sided alpha of 0.05 unless otherwise noted.

13. Analysis Populations

Intent-to-Treat (ITT): All randomized participants with at least one post-baseline assessment. Per-Protocol (PP): Subset without major protocol deviations.

14. Descriptive Statistics

Continuous variables: mean, standard deviation, median, minimum, and maximum. Categorical variables: counts and percentages.

15. Primary Endpoint Analysis

Group comparisons of PIAS total scores at 3 months postpartum will be performed using a nonparametric omnibus test (e.g., Kruskal–Wallis). If the omnibus test is significant, post-hoc pairwise comparisons will be conducted with appropriate adjustments for multiplicity.

16. Secondary Analyses

Subscale scores will be analyzed analogously to the primary endpoint. Exploratory analyses may assess associations between bonding outcomes and selected caregiving behaviors or demographic variables using correlation and regression models, with model assumptions checked and documented.

17. Covariates and Sensitivity Analyses

Potential covariates (e.g., education level, partner’s employment, caregiving involvement) may be considered in adjusted models. Sensitivity analyses may exclude participants with major deviations or missing key assessments.

18. Missing Data Handling

Extent and patterns of missing data will be summarized. Analyses will primarily use available cases; if necessary, sensitivity analyses such as multiple imputation may be considered consistent with the nonparametric framework.

19. Multiplicity and Software

Multiplicity adjustments will be applied to control type I error for multiple pairwise tests when applicable. Analyses will be performed using standard statistical software (e.g., SPSS, R, or Python).

20. Administrative Information

Sponsor/Institution: Çanakkale Onsekiz Mart University (ÇOMÜ). Study officials and investigators are listed in the trial record. This document is intended for public posting on ClinicalTrials.gov and does not include participant names or other personally identifiable information.

Any deviations from this plan will be documented in the results section when outcomes are reported.