**TR Istanbul University-Cerrahpaşa ID: İstanbulUCEdu**

# Statistical Analysis Plan : June 1, 2023
# The effect of two different bathing methods on vital parameters and stress levels in preterm babies.

Clinical Trial Number: NCT06166485

## BIOSTATISTICS PRELIMINARY ASSESSMENT

The thesis summary and research hypotheses of the thesis titled " The effect of bathing applied in two different orders on the stress level and physiological parameters in term babies" were examined in detail. For this purpose, mothers who applied to the gynecology clinic of Istanbul Şişli Hamidiye Etfal Training and Research Hospital, whose weight was between 2.5 and 4 kg, whose Apgar score was over 7 points, who did not have any health problems, who were healthy term babies, and who voluntarily agreed to participate in the study. and their children will be included. As a data collection tool;

- Personal information form,
- Processing time (time to get the bath done),
- Babies' calm down time,
- newborn stress scale,
- Physiological parameters (body temperature, pulse, respiration, O2 saturation ) will be used.

Data from IBM SPSS Statistics Standard Concurrent User V 26 (IBM Corp. , Armonk , New York, USA) will be evaluated in the statistical package program. Descriptive statistics will be given as number of units ( *n* ), percentage ( *%* ), mean ± standard deviation ( *Mean±SD* ), median ( *M* ), minimum ( *min* ) and maximum ( *max* ) values. Shapiro-Wilk normality test will be used to ensure that numerical variables comply with normal distribution. The appropriate hypothesis testing method planned to be used in the study was determined as "Mixed Pattern Variance Analysis" if parametric test assumptions were met. In cases where the parametric test assumptions regarding the relevant test are not met, whether there is a difference between the groups in terms of quantitative variables will be evaluated with the " Student t test " if the parametric test assumptions are met, and with the "Mann-Whitney test" if the parametric test assumptions are not met. In examining whether the quantitative variables change according to the pre-test and post-test measurement time, they will be examined with the " Paired t test" if the test assumptions are met, and with the "Wilcoxon test" if they are not met. In all hypothesis tests, the probability of Type I error will be taken as $\alpha=0.05$ and a value of $p<0.05$ will be considered statistically significant.

Mohamed et al. (2018)** in their study, they investigated whether bathing applied in two different orders in term babies had an effect on stress level and physiological parameters. Differences between and within groups were calculated for body temperature (°C), heart rate (beats/ min ) and oxygen saturation (%). Minimal significant change was observed in the study While the average heart rate (beats/ min ) was 145 ± 16.44 points in the training group as a result of the first measurements, it was found to be 138 ± 12.12 points in the last measurement. In the control group, the first measurement was 140 ± 14.22 points and the last measurement was 139 ± 10.88 points. As a result, it was determined that there should be 86 observations in the sample with a statistical power level of 80.4% and a significance level of 5% for the calculated (f=0.128)* effect size. Considering sample loss (10%) such as dropping out of the study, **it will be sufficient to work with at least 94 patients** . The study was planned to include 47 people in each group.

* *COHEN, J. , "Statistical Power Analysis for the Behavioral Sciences ( Revised ed.)", 1977.*

*** Mohamed , SSA, Faheim , SS, Farg , DSS, & Hassan, HE (2018). the relation between trunk-to-head bathing oath the traditional head-to-trunk bathing on newborns ' outcome . pussy Res J Nurs , 4(1), 1-12.*

**F tests –** ANOVA: Repeated measures , within-between interaction

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| **Analysis:** | A priori : Compute required sample size | |
| **Input :** | Effect size f=0.1275153 | |
| | α err prob | =0.05 |
| | Power (1-β err prob ) | =0.80 |
| | Number of groups | =2 |
| | Number of measurements | =4 |
| | corr among rap measures | =0.5 |
| | Nonsphericity correction ϵ | =1 |
| **Output :** | Noncentrality parameter λ | =11.1869844 |
| | Critical F=2.6404222 | |
| | numerator df | = 3.0000000 |
| | denominator df | = 252 |
| | **Total sample size** | **=86** |
| | **Actual power** | **=0.8044596** |