Impact, Feasibility, and Acceptability of a Digital Health Intervention for Healthy Children With Pediatric Lower Urinary Tract Symptoms (pLUTS)

Statistical Analysis Plan

NCT05852353

July 14, 2025

Planned sample size was 100 enrolled parent-child dyads. The final sample included 70 parent-child dyads.

Feasibility metrics, secondary outcomes, and sociodemographic data were analyzed descriptively. For both the overall group and sub-groups, the following statistics will be calculated: count, percentage, mean scores, standard deviation (SD), median scores, interquartile range (IQR), minimum and maximum scores.

Paired t-tests were used for normally distributed variables, while non-parametric tests were used (Wilcoxon and Sign) for non-normally distributed variables to compare pre- and post- intervention scores. McNemar's test was used for categorical variables to evaluate changes in proportions from baseline to post-intervention.

Missing data was addressed using complete-case analysis; participants were only included if they completed the surveys specific to each post-intervention timepoint.

Statistical significance was set at $p < 0.05$, and analyses were conducted using R.

The reliability of the survey measuring acceptability and education design was assessed using Cronbach's alpha with an $\alpha \geq 0.6$ and ≤ 0.8 considered acceptable internal consistency. Bar charts were generated to visualize the distribution of Likert scale responses, offering further insight into response patterns and helping to further explain the reliability test results.

A hybrid process combining inductive and deductive thematic analysis, guided by the theoretical framework of acceptability, was performed by two research team members to analyze open-ended feedback on families' experiences and perceptions of Bladder Basics. SPSS and Dedoose were used for statistical and thematic analyses, respectively.