Statistical Analysis Plan:

All quantitative variables will be assessed for the normality by Shapiro-Wilk's test. If they follow Gaussian distribution, then they will be expressed as mean ± SD. Continuous or quantitative variables which wouldn't follow normal distribution, will be transformed into logarithms or square root. Again, normality will be assessed by Shapiro-Wilk's test. Those variables which will not be following normal distribution after transformation will be represented by median (Interquartile range). Qualitative variables will be expressed as counts and percentages. Analysis will be carried out for the Intention to treat population as well per protocol population. Missing observations will be handled with imputation techniques. Comparison of quantitative data between the intervention group and control group will be done by independent sample 't' test, if they follow normal distribution. Non-normally distributed quantitative variables will be compared by Mann-Whitney U test. Comparison of categorical variables between groups was done by either Chi-square test or Fisher's Exact test based on the number of observations available. ANOVA will be used to compare the mean of normally distributed continuous variable across more than two categories. Equivalent non-parametric test viz, Kruskal Wallis H test will be used to compare non normally distributed continuous variables. Paired 't' test or Wilcoxon Signed Rank test will be used to compare pre and post continuous variables within the groups based on their normality. Exploring the possibilities of doing regression models with covariates. Data capturing and automation will be taken care by Tableau Software. Microsoft Excel will be used to cross validate the data collected. Data validation and analysis will be carried out by IBM SPSS Statistics for Windows Ver 28.0; Armonk; NY; IBM Corporation. For statistical significance, two tailed p values <0.05 will be considered.