

## **STATISTICAL ANALYSIS PLAN**

A descriptive analysis will be conducted to assess the baseline sociodemographic and clinical characteristics of the pregnant women under study, using measures of central tendency and dispersion for quantitative variables and frequency distribution for qualitative variables.

A comparison between the intervention and control arms will be carried out to determine if there is any imbalanced sociodemographic or clinical variable, using the Chi-square test with continuity correction, or Fisher's exact test in cases where expected values are less than 5.

To determine pre-post intervention differences in the main outcome variables (overall SF-36 assessment and by subscales), respective generalized linear models for repeated measures will be constructed, including the study arm as an intra-subject factor, and the imbalanced variables as covariates.

In the different analyses, the outcome variables will be evaluated on an intention-to-treat basis and the threshold for statistical significance will be set at  $p < 0.05$  (two-tailed). An interim analysis will be conducted at a previously set follow-up point to assess the need for early study termination due to benefit, determining a statistical significance for the main outcome variable at  $p < 0.01$ .

The statistical program SPSS 26.0 for Windows (SPSS: an IBM Company, Armonk, NY) will be used.