Statistical plan:

A sample size of 15 patients/group was calculated based on WES score at 12-month follow-up (T12). An alpha risk of 0.05 and a beta risk of 0.20 (power 0.8) in a bilateral contrast was accepted to detect a minimum difference of 1.4 between two groups, assuming that there were 3 groups and a standard deviation of 1.11. [24] including a potential 10% loss of participants available at follow up meetings.

The statistical analysis was performed using the Jamovi statistical software (v.2.3.21)[*]. Descriptive statistics were performed using mean and median as measures of central tendency and standard deviation and 25%-75% values as measures of dispersion. To study the differences between 0 and 12 months, within the same group, the paired t-test was used when the assumptions of normality (Shapiro Wilk test) and homoscedasticity (Levene's test) were met and the Wilcoxon test when they were not.

To determine the difference between the groups, one way ANOVA test plus Tukey's test were used when the variables were continuous quantitative and met the assumptions of normality and homoscedasticity. When they did not or the variables were discrete quantitative variables, the Kruskal Wallis test and Tukey's test were used instead. To determine the differences between the groups for the modified success criteria, Fisher's exact test was performed on contingency tables. A value of p<0.05 was considered significant.