

**Project title:** Mediterranean diet adherence, testicular function and fertility: MedFertyl

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## **Statistical Analysis Plan**

### Sample size:

Sample size computation was based on sperm progressive motility (SPM), a main outcome of a previous Spanish cohort (Led-Fertyl) on 200 healthy young men, in which a mean (SD) SPM of 43.5% (17.4%) was found (PMID:38283622). Based on the distribution of semen examination results in 2020 (PMID:33528873) and two well-designed dietary intervention RCT (PMID:30475967, PMID:33579652), we expected an improvement of at least 22% in SPM in individuals following the MedDiet intervention compared with the control group. A sample size of 52 men per group is estimated, with an 80% power and a 0.05 level of confidence. Allowing for a possible 20% of abandonment, we decided to include 126 participants: 63 men/arm.

### Statistical analysis:

Population characteristics will be described with means(SD), medians(IQR), or percentages(number). Intent-to-treat analyses will be performed. Differences between groups post-intervention will be analyzed using ANCOVA and controlling for baseline. Analyses will be verified using per-protocol approaches. Subgroup analyses of the primary results will be conducted within strata of age and BMI, among others. Mediation analysis will be designed a-posteriori. Statistical analyses will be performed using SAS/STATA/R software, and a two-tailed P-value<0.05 will be deemed statistically significant.