Effect of a single nutritional intervention previous to a critical period of fat gain in university students with overweight and obesity. A randomized controlled trial

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Study Protocol and Statistical Analysis Plan

The normality of the data distribution was tested using Shapiro Wilk's test. Continuous variables are presented as mean and standard deviation (SD). A t-test was performed to compare differences between groups before beginning the intervention (Table 1). ANOVA analysis was used to determine the interaction between intervention*sex and intervention*age. Repeated measures ANOVA were used to compare the different evaluation times (T1, T2, and T3) per intervention group (CG and IG). Bonferroni post-hoc was used to establish differences among groups per each time.

A t-test was used for independent samples to compare differences between deltas (post – pre-values of FM, physical activity, and feeding questionnaires) by groups, and Wilcoxon test for paired samples when normality was violated. Also, Chi-square and Fisher's exact tests were used to compare variation on nutritional questionnaires and set of dietary recommendations. Hedges' g, which includes a correction for small sample bias, was used to estimate the effect size, complementing the p-value from t-tests. Hedges' g was interpreted as no effect (< 0.2), small (0.2 to < 0.5), medium (0.5 to < 0.8), and large (≥ 0.8) [25]. The significance level was set at $p<0.05$.