ISRCTN44687723

Title: "Childhood overweight and obesity intervention: Effectiveness of a programme based on parents as agents of change"

Study center: Faculty of Psychology and Education Sciences of the University of Porto (Portugal)

PI and Co-PI: Orlanda Cruz (PI; orlanda@fpce.up.pt) and Ana Catarina Canário (Co-PI; anacanario@fpce.up.pt)

Statistical analytic plan

We will run a descriptive analysis of the participants' demographic and outcome variables at the baseline for participants' characterization. We will then compare the participants' demographic descriptives and outcome variables across conditions (through Chi-square tests for associations and independent sample t-tests) for characterization purposes and to identify whether the randomized allocation procedures provided samples with similar characteristics at baseline.

To evaluate the effects of the intervention, we will use repeated measures multivariate analysis of variance (MANOVA), with the outcome variables at the three assessment time points as the within-subjects factor and the condition (intervention vs control) as the between-subjects factor. If necessary, the models may be adjusted for possible covariates.

Following the intention-to-treat principles, all the available data from the participants will be analyzed in the conditions they were allocated regardless of whether they completed all the assessment time points or whether those in the intervention condition completed the Group LifeStyle Triple P intervention.

We will assess the data distribution at each assessment time point. In case the data reveals non-normal distribution, we will apply robust methods. The missing data in the dataset will be dealt with appropriately according to the missingness pattern identified. The imputation strategy may include multiple imputations (MI) or full imputation maximum likelihood estimation (FIML) if the missingness pattern suggests the data are missing at random (MAR). Other strategies to address missing data may be selected if the missingness pattern is better addressed through different strategies. We will then do a sensitivity analysis, comparing the dataset where we used strategies to handle missing data to the dataset with data from the participants who completed the assessment time points.

We will evaluate the dropout rates throughout the trial. We will compare the demographic and outcome variables at baseline between those who complete and those who drop out through Chi-square tests for associations and independent sample t-tests. Using the same statistical procedures, we will also compare whether the participants in the control and intervention conditions are still equivalent on demographic characteristics and baseline outcome variables after attrition.

Results will be reported considering p<.05 as the statistically significant threshold, and the effect size for each outcome will also be reported. In case any further analyses or deviations from the proposed statistical analysis plan are needed to characterize the effects of the Group Lifestyle Triple P, we will describe them in the manuscript reporting the trial outcomes, presenting the reasons that justify our choices.