Statistical Analysis Plan

Study title: Enhancement of Learning and Memory Following Supplementation With Juice PLUS+®
OMEGA in an Adolescent Population

Acronym: AdCog-O

Date: 15/08/2023

This study utilises a 2-arm, parallel, placebo controlled design to assess the beneficial effect of an omega-3 supplement on memory and learning compared to a matched placebo. Omega-3 index, as assessed using Dried Blood Spots, and all cognitive outcomes are measured at baseline and following 16 weeks of intervention. Additionally, a subset of participants will complete EEG measurements during an N-back task and resting state at baseline and post-intervention.

In order to compare performance between treatment groups (omega-3 or placebo) at each visit (baseline and post-intervention), as well as assess change between visits within each treatment group, all cognitive, EEG and biomarker data will be analysed in R studio using two-way mixed ANOVAs to identify main effects of treatment condition (between subject, 2 levels) and visit (within subject, 2 levels), as well as any potential interaction. Where the main effect of treatment or visit is significant, Bonferroni corrected pairwise comparisons will be explored at the level of interaction, even if the interaction itself is not significant (Howell., 2010; Huck., 2015; Wilcox., 1987). Extreme outliers will be identified and excluded using box plots, and subjects with missing data will be excluded from analysis.