Statistical Analysis Plan

Official Title: Transduction of Psychological Stress into Systematic Inflammation by Mitochondrial DNA Signaling

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Statistical Plan and Power

Power: For the primary analysis, because we are utilizing a "matched" design (in which each subject serves as his/her own control), we based our power calculations on a simple paired t-test since power formulas are not available for complex models such as the ones we propose to apply to our data. We determined that with the sample size n = 60, we would have 80% power to detect a normalized difference (in terms of Cohen's d) as small as 0.38. Combined effects sizes from a meta-analysis of the literature [1] yield normalized effect sizes for IL-6 and TNF-α at 0.35 and 0.28, respectively. For ccf-mtDNA, our pilot data gave an estimated effect size of 1.13. Thus, with a sample of N=60, we were sufficiently powered to detect stress-induced changes. In fact, the collection and modelling of multiple measurements over time. With multiple observations, accounting for the correlation structure among repeated observations, we would increase the power of the analysis to detect a change.

Univariate and descriptive analysis will be performed on all dependent variables and, if necessary, normalizing and/or variance stabilizing transformations will be applied to the data before inferential analyses are undertaken. All hypothesis testing will involve two-sided alternative hypotheses with the α level set to 0.05. The analytic strategy for addressing the laboratory stress session will involve fitting linear mixed models, which allow flexible covariance structures to account for correlation of repeated measures data. Specifically, subject and day (nested within subject) will be the random effects, and condition (stress/control) will be the fixed effects. We will also include time and time^2 (when indicated) as fixed effects to allow for a nonlinear response. The outcome variables will be the various physiological and psychological responses: IL-6, TNFα, ccf-mtDNA, cortisol, epinephrine, norepinephrine HR, BP, momentary negative affect, and HRV.