Statistical Analysis Plan: Emotion-Diet Interactions in Pregnancy (PREDIP)

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STATISTICAL DESIGN AND POWER ANALYSIS

Statistical Design: The statistical approach for each of the Specific Aims will be performed as follows:

Aim 1a: A cross-over study design will test the hypothesis that experimental exposure to a standardized psychosocial stress task will potentiate the postprandial metabolic response to the standardized meal. Each subject will represent her own control within the assigned meal group (low or high GI). A paired-samples t-test will be employed, using the model: $E[Y_i] = \Delta AUC_i = (AUC_i)v1 - (AUC_i)v2$

where Y_i denotes the outcome measurement (change in $AUC_{glu/ins}$ or AUC_{FFA}) on maternal i, and AUC_i denotes the AUC for either metabolic outcome at a given laboratory visit; v1 or v2. As such, a test of the hypothesis that the above equations equals 0, represents a test that the effect of acute psychosocial stress exposure does not moderate the postprandial response to a standardized meal. A sensitivity analysis to estimate the difference in response by randomization sequence will ensure that the order of protocols does not confound the results.

Aim 1b: To explore the difference in the postprandial metabolic response following acute psychosocial stress exposure across meal types (low *vs* high GI), an independent sample t-test will be employed to compare the mean $AUC_{glucose/insulin}$ between the high GI and low GI groups.

Aim 2: To determine whether individual variation in biological stress reactivity (*i.e.,* $AUC_{cortisol}$ and AUC_{HRV}) moderates the effect of acute psychosocial stress on the metabolic response to the standardized meal, a general linear model accounting for within subject correlation will be employed, according to the model:

$$E[Y_{ij}] = \beta_0 + \beta_1 STRESS_{ij} + \beta_2 REACT_{ij}$$

where Y_{ij} denotes the outcome change in the AUC_i on maternal i, STRESS denotes the condition of exposure (stress vs no stress) to mother i on laboratory visit j, and REACT denotes stress reactivity, measured by $AUC_{cortisol}$ or AUC_{HRV}. A test of H_0: $\beta_1 = 0$ will test the hypothesis that mean AUC_i ($AUC_{gluc/ins}$ and AUC_{FFA}) differs by stress condition after adjustment for stress reactivity. An exchangeable correlation matrix will be assumed in the model.

Power Analysis: The primary outcome of the proposed research is the difference in the postprandial glucose/insulin response to a standardized meal (of either low or high GI) between the stress and non-stress conditions. Utilizing a cohort of 40 women in each meal group, it is estimated that the proposed study will have approximately 80% power to detect a 0.44 standard deviation difference in the mean within subject change in postprandial metabolic response ($AUC_{glu/ins}$ and AUC_{FFA}), associated with the introduction of the stress paradigm.