

Project 4: Interim Analysis

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Summary/Goals Aim 1

- **Research Hypothesis:**
 - ↑ baseline inflammatory levels = ↓ memory abilities and cortical thickness
 - ↑ baseline inflammatory levels over time = ↓ memory abilities and cortical thickness over time
- **Outcome:** Change in Cognitive Test and Cortical Thickness
- **Covariates:** inflammatory marker levels (~6), Age, Sex, Dementia status, other cofounders
- **Analysis Plan:** Linear Regression, controlling for baseline outcome measurements and all other covariates.
- **Power Analysis Needs:**
 - Primary covariate (primary inflammatory marker)?
 - Estimate of relationship between outcome and primary covariate, the correlation between the two, and standard deviation for both

Summary/Goals Aim 2

- **Research Hypothesis:**
 1. Association between amyloid deposition and inflammatory markers. Association between cortical thickness and inflammatory markers
 2. Change in Memory is associated with amyloid, cortical thickness, and inflammatory markers. There is an interaction between inflammatory markers and the other two (amyloid and cortical)
- **Outcome:** Cortical Thickness and Amyloid Deposition for (1) and Change in Memory for (2)
- **Covariates:** Age, Sex, Dementia status, confounders for both. Inflammatory for (1), Amyloid, cortical thickness, and inflammatory markers for (2)
- **Analysis Plan:** Linear Regression, controlling for baseline outcome measurements and all other covariates.
- **Power Analysis Needs:**
 - Primary covariate for each hypothesis?
 - Estimate of relationship between outcome and primary covariate, the correlation between the two, and standard deviation

Questions for Investigator

- Accounting for multiple comparisons was mentioned in the grant due to the high number of inflammatory markers that are of interest
 - Do you want to run individual models for each cytokine or can these all be in one model?
- Is PET imaging only done at baseline?
 - If it is measured at both timelines: For the first hypothesis in Aim 2, are you interested in looking at this association at baseline or year 1 or both?
- Is there a primary covariate for each of the hypothesis?
 - For example, in Aim 1, do you have a primary cytokine of interest from the six mentioned in the grant?