

1 NUSI Statistical Analysis Plan

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3 Initial analyses will be undertaken to inspect data for errors, inconsistencies, and incomplete
4 information. This will include examining the data with simple frequency tables and dot plots for
5 univariate data, and scatter plots and multi-way dot plots with bivariate and multivariate data. Data
6 anomalies and outliers will be examined and corrected if necessary.
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8 Analyses will include descriptive statistics at baseline and for each follow-up visit for all outcome and
9 exposure variables of interest. Statistics will be calculated for the overall study cohort and each
10 treatment arm separately. Descriptive statistics will include histograms, means, medians, and standard
11 deviations for continuous variables. Frequencies will be calculated for categorical variables. Differences
12 between treatment arms at baseline will be compared using two-sample t-tests, Wilcoxon rank-sum
13 tests, and chi-square tests, when applicable. For reporting inferential statistics, such as differences in
14 means, 95 percent confidence intervals will be used.
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16 The primary outcome is change in MRI PDFF from baseline to 8 weeks in the intervention group
17 compared to the standard of care group. Repeated measures analysis of variance will be used to test for
18 decreases in MRI PDFF from baseline at 4 and 8 weeks. Models will include baseline measurements as
19 covariates to adjust for potential differences between treatment groups at baseline. Model assumptions
20 will be verified prior to analysis.
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22 All analyses will follow the intention to treat principle, using all randomized participants in the analysis.
23 Statistical significance will be assessed at a significance level of 0.05. Analyses will be conducted using
24 SAS version 9.4 for Windows (Cary, NC, USA). An independent statistician will repeat the main analysis
25 to ensure statistical methods were performed correctly.