Statistical Analysis Plan

Effects of a Modified Hospital Elder Life Program in Abdominal Surgery Patients

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Sample Size and Power Calculation

The effect of NTU-HELP in preventing functional decline will be evaluated by the following mixed effects models:

\[ g(y_{it}) = \alpha + a_i + \beta_1*(studied-ward\ indicators)_i + b_i*(studied-ward\ indicators)_i + \beta_2*time_i + \beta_3*time^2_i + c_i*time_i + \beta_4*(confounders)_i + \beta_5*(treatment\ group)_i + \epsilon_{it} \]

where \( y_{it} \) is the “continuous” outcome measurement (with transformation \( g(.) \) whenever is needed), \( a_i \) is a random intercept (with mean 0) designating a different baseline outcome value for a patient, \( b_i \) is a random slope (with mean 0) indicating different studied-ward effects for different patients, \( c_i \) is another random slope indicating different tendencies to decline (or recover) over time for different patients, and \( \epsilon_{it} \) is the random error. The fixed regression coefficient \( \beta_1 \) is the overall studied-ward effect. The fixed regression coefficients \( \beta_2 \) and \( \beta_3 \) describe the overall pattern of the outcome measures across time. The fixed regression coefficient \( \beta_4 \) describes the effects of confounding variables. The fixed regression coefficient \( \beta_5 \) is our major interest and indicates the effect of the HELP intervention.

The sample size projections are constructed for testing the significance of the treatment effect \( \beta_5 \) in the proposed mixed effects model (i.e., \( H_0: \beta_5 = 0 \) versus \( H_1: \beta_5 \neq 0 \)). For simplicity, we assume there is no studied-ward multi-level effect for the sample size calculation (i.e., \( b_i = 0 \)). We use the “Optimal Design” Software Version 1.77 for the calculation (https://sites.google.com/site/optimaldesignsoftware/home). This software provides sample size and power estimation for developing an optimal
design for multi-level and longitudinal research. When implementing the OD software, we need to set up (1) the standardized effect size $\delta$ (the estimated treatment effect divided by the standard error of the outcome), (2) the within-patient variance $\sigma^2$, (3) the between-patient variance $\tau$, (4) the number of repeated measurements per patient $M$, and (5) the significance level $\alpha$. We use the standardized effect size $\delta=0.35$, which is considered “worth detecting” according to Cohen’s rules, $\sigma^2=1$, $\tau=1$, $M=5$ and $\alpha=0.05$. The plot of power versus the estimated patient numbers is shown in the following. From the plot, it will require 170 patients if for 60% power, 215 patients if for 70% power, 270 patients if for 80% power, and 360 patients if for 90% power. Considering the attrition and the future need for more complicated model building (i.e., more covariates into the mixed effects model, more complicated mixed effects model, approaches for categorical outcome measurements), we propose to recruit 350 patients to achieve above 80% power.