Statistical Analysis Plan

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

Study Hospital: National Taiwan University Hospital, Taiwan, Taiwan

Principal Investigator: Cheryl Chia-Hui Chen, RN, DNSc

Co-Investigator & Collaborator:

Guan-Hua Huang, PhD
Jin-Tung Liang, MD, PhD
Rue Lai, MD, PhD
Been-Ren Lin, MD, PhD
John Huang, MD
Ching-Yao Yang, MD, PhD
Yu-Wen Tien, MD, PhD,
Chiung-Nien Chen, MD, PhD
Ming-Tsan Lin, MD, PhD
Yi-Ting Yang, RN, MSN, graduate student
Hsiu-Ching Li, RN, MSN, PhD student
Jerry Dwi Trijoyo Purnomo MS, PhD student
Sharon K. Inouye, MD, MPH

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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:

$$g(y_{it}) = \beta + a_i + \beta_1*(\text{studied-ward indicators})_i + b_i*(\text{studied-ward indicators})_i + \beta_2*\text{time}_t + \beta_3*\text{time}_t^2 + c_i*\text{time}_t + \beta_4*(\text{confounders})_{it} + \beta_5*(\text{treatment group})_i + \varepsilon_t$$

i=1,…,n (# of patients); t=1,…,5 (time points),

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 ε_t is the random error. The fixed regression coefficient β_1 is the overall studied-ward effect. The fixed regression coefficients β_2 and β_3 describe the overall pattern of the outcome measures across time. The fixed regression coefficient β_4 describes the effects of confounding variables. *The fixed regression coefficient β_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 β_5 in the proposed mixed effects model (i.e., H_0: $\beta_5=0$ versus H_1: $\beta_5\neq0$). 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 δ (the estimated treatment effect divided by the standard error of the outcome), (2) the within-patient variance σ^2, (3) the between-patient variance τ, (4) the number of repeated measurements per patient M, and (5) the significance level □. We use the standardized effect size δ=0.35, which is considered "worth detecting" according to Cohen's rules,[65] σ^2=1, τ=1, M=5 and □=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.