

“Effects of a newly modified National Taiwan University Elder Life Program”

PI: Cheryl Chia-Hui Chen (National Taiwan University)

Role: Co-principal investigator

National Health Research Institutes of Taiwan: 01/01/2009- 12/31/2012

Studies have revealed that 34-50% of older patients experienced functional decline and function is by far the most important factor affecting quality of life and health care utilization in old age. To prevent functional decline, defined as a decrement in cognitive, nutritional, and activity of daily living (ADL) functions, the Hospital Elder Life Program (HELP) was developed at Yale University. The aim of this study is to evaluate a newly modified NTU-HELP, for the prevention of iatrogenic complications and functional decline during hospitalization and 6 weeks post surgery.

Three specific aims will be accomplished; (1) develop up-to-date evidence-based protocol books of the NTU-HELP core intervention; (2) conduct a single-blind, one-center, randomized controlled trial to test the effects of NTU-HELP in preventing iatrogenic complications (postoperative delirium, posture hypotension, dehydration and compromised sustained maximal inspiration, hand grip strength and time to flatus) and minimizing functional decline {score reductions on mini-mental state examination (MMSE), min-nutritional assessment (MNA) and barthel index (BI)} in older patients during hospitalization and two, four, six weeks post elective midline incision abdominal surgery; and (3) establish predictive models of functional decline(defined by $\geq 10\%$ score reductions on MMSE, MNA, and BI from admission baseline) and functional trajectory (defined as changes in functional scores over multiple points in time).

Phase I: Using a focus group approach, we will develop the protocol books and implantation kits for three major core interventions in the first half year from 1/2009-6/2009.

Phase II & III: A prospective, single-blind, one-center randomized controlled trial (RCT) using a computer generalized randomization list with a block size of four, will be conducted to test the effects of NTU-HELP in preventing iatrogenic complications and functional decline in older patients from admission baseline (T0) to discharge (T1), two weeks (T2), four weeks (T3), and 6 weeks (T4) post surgery. In phase II, scheduled from 7/2009-12/2009, a pilot study of 30 subjects using identical study protocol will precede the full scope RCT to ensure the feasibility and quality of upcoming trial.

Sample will be recruited consecutively from four surgical units, 9A, 9C, 7B, 6A, at NTU hospital with a target population of older patients aged 65 years and older who undergoing elective midline incision abdominal surgery with a length of stay over 6 days. Based on power analysis, a sample size of 350 is sufficient to reach 80% power of analysis. Stratified random assignment by the type of surgery (gastric versus colorectal) to the experimental or the usual care group will be performed to have the most precision of the intervention effect. Strict adherence to the resulting randomization will be ensured.

The intervention consisted of a daily care protocol on three core interventions, orientation and cognitive stimulation, nutrition and hydration assistance, and early mobilization on top of hospital routine care. All interventions are tracked daily for full adherence and implementation and all the staff members receive regular performance review for quality assurance. Usual care consisted of standard hospital services and the same attending and resident physicians provide care to patients in both experimental and usual care groups.

Data will be analyzed using the SAS statistical package version 9.1 and the R language version 2.6.2. The intention-to-treat principle will be used. Given the hierarchical nature of data, the mixed effects analysis will be performed to evaluate the effect of NTU-HELP. Additionally, Generalized Estimating Equation and Regression Extension of Latent Class Analysis will be performed to develop predictive models of functional decline and functional trajectory.

This study will be the first to use a RCT design to test the effect of the HELP approach in preventing older surgical patients from iatrogenic complications and functional decline post surgery. Since more older patients presenting for major surgery, the findings of this study will have implications in both clinical practices and policy making.