This version of the research protocol is current as of 2017-01-16. The original protocol is written in Chinese and has been translated for publication reasons.

Research Protocol

Effects of a Modified Hospital Elder Life Program (mHELP)

in Abdominal Surgery Patients

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BACKGROUND & SIGNIFICANCE

As the aging population expands, older patients are increasingly presenting for surgical procedures (1). Indeed, 50% of individuals older than 65 years are estimated to undergo surgical procedures during their remaining years, with surgical admissions already outnumbering non-surgical admissions for older patients (2). Despite these trends, surgery and hospitalization remain problematic in older patients. For many, iatrogenic complications, geriatric syndromes, and functional decline occur despite successful treatment of the medical condition for which they were hospitalized (3). Indeed, the need to improve inpatient care is recognized for older people undergoing surgery (4). In a survey of more than 800 United Kingdom patients (>80 years old) who died within 30 days of various surgical procedures, adequate inpatient care was received by only slightly over one-third (38%) (5).

Older patients’ iatrogenic complications, geriatric syndromes, and functional decline can be prevented and reduced by the Hospital Elder Life Program (HELP), whose core interventions include a protocol for daily visits/orientation, therapeutic (cognitive) activities, early ambulation, vision/hearing adaptation, oral intake and feeding assistance, and sleep enhancement (6). Additional program interventions include geriatric nursing assessment and intervention, interdisciplinary rounds, discharge planning, provider education, and geriatrician and interdisciplinary consultation (7, 8). The clinical effectiveness and cost-effectiveness of the HELP have been well established in several high quality studies.
However, given its comprehensiveness, the HELP might not be feasible for every health care system, particularly where reimbursement is minimal and qualified personnel are limited. On the other hand, less might be more; modifying the HELP to include key elements most relevant to surgical patients might prove more cost-effective in reducing older patients’ geriatric syndromes and functional decline after major surgery such as abdominal surgical procedures.

Indeed, our previous study suggested that many iatrogenic complications, geriatric syndromes, and functional declines are mediated by a pathophysiological mechanism based on shared risk factors (9). We, therefore, modified the HELP to include only three shared risk factors (functional, nutritional, and cognitive status) that were targeted by three nursing protocols: early mobilization, oral and nutritional assistance, and orienting communication.

Our unique innovation was to select three core protocols and allow them to be delivered during daily care by trained nursing staff for feasibility and scalability (10, 11, 12). Thus, the overall aim of this prospective, single-blind, one-center, cluster-randomized controlled trial (cluster RCT) was to develop and test this modified HELP (mHELP) for preventing iatrogenic complications, geriatric syndromes, and functional decline during hospitalization for patients undergoing elective major abdominal surgical procedures such as colorectal, gastric, and pancreatobiliary surgery. The length of hospital stay was also examined.
**Aim of the Study**

To compare treatment outcomes in older abdominal-surgery patients (≥ 65 years old) who received the mHELP (delivered daily by a mHELP nurse and comprising three protocols: *orienting communication, oral and nutritional assistance, and early mobilization*) versus usual postoperative care.

**Primary Endpoint**

- Iatrogenic complications and geriatric syndromes during hospitalization for abdominal surgery
  - Postoperative delirium incidence during hospitalization
  - Postoperative bowel dysmotility during hospitalization
- Change in functional scores during hospitalization for abdominal surgery
  - Changes in Barthel Index (BI) scores between preoperative baseline (at hospital admission) and postoperative follow-ups at discharge and 4 and 6 weeks
  - Changes in Mini-Nutritional Assessment (MNA) scores between preoperative baseline (at hospital admission) and postoperative follow-ups at discharge and 4 and 6 weeks
  - Changes in Mini Mental State Examination (MMSE) scores between preoperative admission baseline (at hospital admission) and postoperative follow-ups at discharge and 4 and 6 weeks
Frailty rates and transition between frailty states between preoperative baseline (at hospital admission) and postoperative follow-ups at discharge and 4 and 6 weeks

**Secondary Endpoints**

- Changes in body weight
- Changes in grip strength
- Changes in oral health (i.e., plaque index; screens of swallowing function)
- Changes in executive function (i.e., color trail test)
- Changes in Geriatric Depressive Scale (GDS) scores
- Length of hospital stay (LOS)

**METHOD**

For this cluster RCT, consecutive older patients (> 65 years old) admitted to two 36-bed GI wards of a 2200-bed urban medical center in Taipei were screened for enrollment. Patients were enrolled if they met two criteria: scheduled for elective abdominal surgery and expected LOS > 6 days. Patients ineligible to participate in the study due to inclusion and exclusion criteria, plus those who did not wish to participate, were recorded.

When participants returned to the GI wards after surgery, they were cluster randomized to groups based on a computer-generated list. Cluster randomization by room was necessary because the majority of patient units in Taiwan are double- or triple-occupancy rooms, threatening cross-contamination of groups if patients were individually randomized. This
randomization approach was facilitated by both GI wards having the same layout: 6 single-occupancy rooms (3 participants randomly assigned to each group), 9 double-occupancy rooms (4 randomly assigned as controls and 5 to the mHELP group), and 4 triple-occupancy rooms (2 randomly assigned to each group)

Physicians and hospital staff (surgeons, residents, and nurses) at the study site were aware of a pending nursing-intervention study, but were blinded to study design, hypothesis, group allocation, and specific protocols of the mHELP. Moreover, outcome assessors were blinded to group assignment and room assignments were re-randomized every 20 patients to minimize potential unblinding of the randomization scheme.

Usual Perioperative Care at the Study Site

Before surgery, all participants received the study site’s routine standardized, mechanical bowel preparation (for gastric and pancreatic surgery: nothing by mouth [NPO] for at least 8 hours and use of oral laxative solution 1 day before surgery; for colon surgical procedures: low-residue diet for 3 days, oral laxative solution in the following 2 days with only carbonated drinks allowed, NPO for at least 8 hours before surgery). After surgery, oral intake was withheld until the return of bowel sounds and first flatus or defecation, when a clear liquid diet was offered, progressing to a regular diet as tolerated. All participants were encouraged to ambulate and did so as tolerated. See Appendix I for details.
### Appendix I

<table>
<thead>
<tr>
<th>Perioperative Care at the Studied Site</th>
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<tbody>
<tr>
<td><strong>Preoperative Care Protocol</strong></td>
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<tr>
<td>1. Overnight starvation</td>
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<tr>
<td>2. Mechanical bowel preparation (1 day for gastric and pancreatic surgery; 3 days for colon surgery)</td>
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<tr>
<td>3. Intravenous hydration to compensate for bowel preparation</td>
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<tr>
<td><strong>Operative Care Protocol</strong></td>
</tr>
<tr>
<td>1. Mostly done with general or spinal anaesthesia</td>
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<td>2. No regular use of opioid-sparing techniques such as epidural analgesia or trunk blocks</td>
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<tr>
<td>3. Laparoscopy was used during the study period on average for 47% of abdominal surgeries</td>
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<tr>
<td>4. Routine use of nasogastric tubes, abdominal drain, and urinary catheter</td>
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<tr>
<td><strong>Postoperative Care Protocol</strong></td>
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<tr>
<td>5. Removal of nasogastric tube and abdominal drain till markers of bowel motility are observed</td>
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<tr>
<td>6. Oral intake given step-by-step (clear liquid, soft, and regular diets) once bowel motility is restored</td>
</tr>
<tr>
<td>7. Use of prokinetic agents when markers of bowel motility are delayed</td>
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<tr>
<td>8. Mobilization is encouraged but not enforced</td>
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</table>

### The mHELP Intervention and Usual Care

The intervention (mHELP) was implemented by a trained mHELP nurse who was blinded to the study hypothesis and did not assess any outcomes. The intervention consisted of the daily mHELP comprising three core nursing protocols: *early mobilization*, *orienting communication*, and *oral and nutritional assistance* (see Appendix II).

In addition to usual care, participants received all three mHELP protocols postoperatively as soon as they arrived on the inpatient ward and until hospital discharge. All
protocols were tracked daily and adherence was rated with a Likert-type scale from 0 (no compliance) to 3 (full implementation and adherence).

Usual care consisted of standard hospital care provided by surgeons, residents, nurses, and support staff (e.g., dieticians, physical therapists) on the general surgery wards. The mHELP nurses did not provide services to participants assigned to the control group. However, the same attending physicians provided care to participants in both the mHELP and control groups.

**Appendix II**

<table>
<thead>
<tr>
<th>The mHELP Protocols*</th>
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<tr>
<td><strong>Orienting Communication Protocol</strong></td>
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<td>1. Active orientation (embedded in events that interest patients, e.g., the day they underwent surgery)</td>
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<tr>
<td>• During conversations, the HELP nurse inquired about specific time-, place-, and person-related information in the context of the present day, thus reinforcing orientation</td>
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<tr>
<td>2. Daily discussion about current/past events and initiating conversation to categorize objects, for example, what are seasonal foods in autumn?</td>
</tr>
<tr>
<td><strong>Early-Mobilization Protocol</strong></td>
</tr>
<tr>
<td>1. Assess patient’s ability</td>
</tr>
<tr>
<td>2. Physically assist patient to carry out activities 3 times a day [from range-of-motion (ROM) exercise in bed, riding a stationary bicycle by hand/foot, sitting out of bed, standing, to ambulation]</td>
</tr>
</tbody>
</table>
Oral and Nutritional Assistance Protocol

1. Daily oral care involving tooth brushing, and ROM exercises for lips, tongue, and jaw
   • Facial and lingual sides of teeth are cleansed with a soft pediatric toothbrush/toothpaste
   • The tongue is cleaned and gums and mucosa are massaged using the same toothbrush
   • Ask patients to smile and pucker their lips (using exaggerated movements) and end by puffing out cheeks
   • Ask patients to stick out their tongue as far as possible and hold it; retract tongue inside and hold it against the palate; continue to stretch the tongue by working it side to side and up and down
   • Ask patients to open jaw wide, move it side to side

2. Diet education for postsurgical intake
   • Dumping syndrome diet
   • Diet after pancreatic surgery
   • Tips for digestive distress

3. Encourage oral intake and companionship during meals; feeding assistance if needed.

* The mHELP protocols were initially developed in 2008; Adapted with permission from (c) 2000 Hospital Elder Life Program, LLC

Measures

Data on delirium and bowel motility were collected Monday to Saturday by two specifically trained outcome assessors. Presence of delirium was assessed by cognitive screening tests (e.g., short-term recall, sustained attention and comprehension, and orientation to time, place, and person) and rating on the Confusion Assessment Method (CAM), based on a brief daily interview. Changes in mental status were also solicited from family members or nurses. Outcome assessors also assessed daily passage of first flatus or stool (hours) and whether patients had an unanticipated return to NPO status due to intake intolerance (yes/no).
The time of these bowel motility endpoints was determined from when the abdominal incision was closed (baseline).

Functional decline was defined as a decline in performance on functional tests relative to the preoperative level. Physical functional status was measured using the 10-item BI and grip strength. Grip strength was measured as kg of pressure using a digital handheld dynamometer (GRIP-D, T.K.K 5401, Takei Scientific Instruments Co., Ltd, Japan). Patients were asked to stand with the shoulder slightly abducted (approximately 10 degrees), the elbow fully extended, and forearm in a neutral position. Measurements were taken from the mean of two trials, as suggested. Nutritional status was measured using body weight and the 18-item MNA. The MNA assesses state of nourishment, with possible scores of 0-30 and higher scores indicating better nutritional status. Cognitive status was measured using the 11-item Chinese MMSE, which assesses orientation, registration, attention, calculation, recall, and language, with possible scores of 0-30; lower scores indicate cognitive impairment. In addition, executive function was assessed using the Color Trail Test (CTT) because newer evidence suggests that executive function, more than global cognition, predicts functional decline and mortality in the elderly. The CTT is comparable to the commonly used Trail Making Test with fewer cultural and educational biases.

Frailty was determined by meeting four of five of Fried’s criteria: shrinking (weight loss), weakness, exhaustion, low activity, and slow walking speed. Specifically, shrinking
was defined as measured weight loss of more than 5% from the previous time point. For example, the shrinking criterion was met if body weight at admission was 5% less than 3 months before admission, or body weight at hospital discharge was 5% less than at admission as measured using a portable digital scale. For weakness, the criterion was met when grip strength, assessed as the average of two readings using a digital handheld dynamometer, was less than the sex- and body mass index–specific cutoff points or less than that provided by Fried. The criterion for exhaustion was met by answering “no” to the question “Do you feel full of energy?” on the short-version GDS. Low activity level, based on item 7 of the Enforced Social Dependence Scale (ESDS), was defined as a participant being coded as “yes” for one of the following activity levels: restricted activity (some activities characterizing work role can no longer be performed, works half as much time as before or less, or no activity) or major activities defining role are no longer being performed. Slow walking speed, based on item 3 of the ESDS, was coded as “yes” if participants had one of the following conditions: walks with help of equipment or other person, does not walk, or unable to take any steps.

Frailty state was coded as suggested: nonfrail (0 or 1 criterion present), prefrail (2 or 3 criteria present), and frail (4 or 5 criteria present). Transitions between frailty states were also examined. Lastly, LOS data were abstracted from the medical record upon discharge.
Analysis

Data were analyzed using the SAS statistical package version 9.1 (SAS Institute, Inc., Cary, NC) and the R language version 2.6.2 (http://www.r-project.org/). Data were checked for completeness before entry and double-entered to assure accuracy. Characteristics of the sample and participants’ health status were analyzed by descriptive statistics. Data are reported as number (percentage), mean (standard deviation; SD), or as median (interquartile range; IQR) when not normally distributed.

Characteristics at admission (baseline) were compared between patients in the mHELP and usual care groups, using the two-sample t-test for continuous variables and chi-square test for categorical variables. In addition, the CONSORT guidelines for reporting RCT results were followed. All analyses were based on an intention-to-treat approach; that is, all participants were included in the group to which they were randomized, regardless of the intervention they actually received, with no imputation to replace missing outcome data.

An important feature of cluster RCTs is the extent of within-cluster correlation for endpoints. The ICC, defined as the ratio of between-cluster variance to total variance, refers to the proportion of variance attributed to the cluster level. The ICC and its 95% confidence interval were calculated for each outcome using the ICCest function in the R software ICC, which adopted the variance components from a one-way ANOVA for the calculation.
Moreover, the between-group cumulative incidence of delirium during hospitalization was compared using Kaplan–Meier analysis and the log-rank test. All statistical tests were two-tailed and $P < .05$ was considered to indicate statistical significance.

**Approvals and Human Subject Protection**

The study was carried out in accordance with the Helsinki Declaration. The study was approved by the Research Ethics Review Committee at the National Taiwan University Hospital and registered at ClinicalTrials.gov (identifier NCT01045330). At the beginning of all contacts with patients, the purpose of the study was explained, participants’ right to refuse to answer all or some of the questions was described, and written consent was obtained. Consent material was at the 8th grade reading level with a font size of 14-12 to facilitate reading for older patients. All information provided to subjects contained the following elements: title of study, name of investigator and affiliation, purpose of study, description of procedures, duration of participation, as well as expected risks, inconvenience, and benefits. If necessary, data were collected in two sessions to alleviate participants’ potential response burden. Mechanisms were in place to ensure the safety of patients when implementing mHELP interventions.


