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Three Nurse-administered Protocols Reduce Nutritional Decline and Frailty in Older Gastrointestinal Surgery Patients: A Cluster Randomized Trial

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Abstract

Objective: To evaluate the effects of the modified Hospital Elder Life Program (mHELP) comprising three nurse-administered protocols in older patients undergoing gastrointestinal (GI) surgery.

Design: Cluster randomized trial.

Setting: Two 36-bed GI wards at a university-affiliated medical center in Taiwan.

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Ethical approval

This cluster RCT was approved by the Research Ethics Review Committee at the National Taiwan University Hospital and registered at [ClinicalTrials.gov](https://clinicaltrials.gov) (identifier NCT01045330).

Conflicts of interest

We declare no conflicts of interest.

Participants: Older patients (> 65 years, $N=377$) were recruited if they were scheduled for elective GI surgery with an expected length of hospital stay >6 days. After transferring to the GI ward after surgery, participants were randomly assigned to the mHELP or control group (1:1) by room rather than individually since most patient units are double- or triple-occupancy rooms.

Intervention: The mHELP protocols (early mobilization, oral and nutritional assistance, and orienting communication) were administered daily with usual care by a trained nurse until hospital discharge. The control group received usual care only.

Measures: Outcomes were in-hospital nutritional decline, measured by body weight and Mini-Nutritional Assessment (MNA) scores, and Fried's frailty phenotype. Return of GI motility was examined as a potential mechanism contributing to observed outcomes.

Results: Participants (mean age=74.5 years; 56.8% male) primarily underwent colorectal (56.5%), gastric (21.2%), and pancreatobiliary (13.8%) surgery. Participants who received the mHELP (for a median of 7 days [interquartile range=6–10 days]) had significantly lower in-hospital weight loss and decline in MNA scores (weight -2.1 vs. -4.0 lb., $P=.002$; score -3.2 vs. -4.0 , $P=.03$) than the control group. The mHELP group also had significantly lower rates of incident frailty during hospitalization (12.0 vs. 21.7%, $P=.022$), and persistent frailty (50.0 vs. 92.9%, $P=.03$). Participants in the mHELP group had trends toward an accelerated return of GI motility.

Conclusion and implications: The mHELP effectively reduced nutritional decline, prevented new frailty, and promoted recovery of frailty present before admission. These nurse-administered protocols might be useful in other settings, including conditions managed at home or in nursing facilities.

TRIAL REGISTRATION: clinicaltrials.gov Identifier: NCT01045330

Keywords

Frailty; Hospital Elder Life Program; Ileus; Nutritional status; Surgery

1. Introduction

Patients undergoing gastrointestinal (GI) surgery often experience in-hospital nutritional decline (defined as reductions in body weight and nutritional score over the hospital stay) and increased risk of frailty during hospitalization.^{1,2} Indeed, in-hospital nutritional decline is frequently observed in GI surgery patients because of a transient episode of GI dysmotility³ and worsening nutritional status independently associated with detrimental outcomes, including prolonged hospital stays,⁴ higher risk for geriatric syndromes,⁵ and mortality.⁶ As an overarching geriatric syndrome, frailty is characterized by declines in physiologic reserve and increased vulnerability for adverse outcomes, including more than twice the risk (OR 2.54; 95% CI=1.12–5.77) of developing postoperative complications⁷ and a higher 1-year mortality, particularly within the first few days after surgery.⁸

Frailty prevalence rates for geriatric inpatients, determined by Fried's phenotypic criteria,⁹ have been reported as 10.4%,⁷ 13.9%,¹⁰ 27%,¹¹ and 40%.¹² These rates were determined in a prospective cohort study of 594 US patients (> 65 years) before receiving elective surgery,⁷

a retrospective study using Hospital Episode Statistics to estimate prevalent frailty for patients (< 65 years) across England,¹⁰ a cohort study of 309 consecutive older US patients (> 70 years) admitted to a cardiology service for coronary heart disease in US,¹¹ and a prospective study of 511 consecutive older Belgian patients (> 70 years) when admitted to the acute geriatric ward of a tertiary hospital.¹²

Hospitalization for a major surgical procedure represents a threat to older patients for developing incident or worsening frailty.^{2,13} Most studies on frailty during hospitalization were descriptive and measured frailty only once, focusing on prevalent frailty (e.g., frailty present at hospital discharge). However, frailty for geriatric inpatients measured at admission and discharge might reflect functional loss that occurred before admission due to illness and additional functional loss during hospitalization. Moreover, frailty is thought to be reversible, with patients being able to move from frail to non-frail status,¹⁴ and incident frailty (new frailty developing during hospital stays) is increasingly recognized as a surgical complication in older patients.⁵ Incident and/or persistent frailty (preexisting frailty persisting from admission to discharge) might be reduced in the postoperative period by paying closer attention to patients' functional status, nutritional intake, and cognition.^{15,16} Nonetheless, hospital-based interventions are scarce.⁵

We had demonstrated in a pre-and-post-intervention pilot study (N=179) that three nurse-administered protocols (*early mobilization, oral and nutritional assistance, and orienting communication*; called the modified Hospital Elder Life Program [mHELP]) effectively reduced not only patients' functional decline but also prevalence rates of frailty and delirium at hospital discharge.¹⁷ Later, a cluster randomized trial (N=377) verified that these three nurse-administered protocols are effective in reducing delirium incidence and length of hospital stay (LOS).¹⁸ Currently, we aimed to use the same cohort to examine whether these three nurse-administered mHELP protocols, reduce nutritional decline (measured by changes in weight and Mini-Nutritional Assessment (MNA) scores over hospital stay) and frailty (both incident and persistent frailty) during hospitalization for older patients undergoing elective GI surgery. Since slow return of GI motility may lead to nutritional decline and frailty, we also examined whether return of GI motility^{19,20} might serve as a mechanism for the findings.

2. Methods

2.1. Trial design and participants

The trial was registered at the Clinical Trials Registry (Trial No: [NCT01045330](#)) and approved by the Human Research Ethics Committee at the study site. As reported,¹⁸ older patients (> 65 years) admitted consecutively to two 36-bed GI wards of a university-affiliated, tertiary medical center were eligible for the study if they were scheduled for elective GI surgery with expected LOS > 6 days. Of these patients, 20 were excluded because of profound dementia, 158 refused participation (patient, family, or physician refusal), and 42 were not enrolled due to critical/terminal illness, respiratory isolation, or severe hearing or visual impairment that precluded communication. Patients with feeding tubes were not excluded. Power analysis for the cluster continuous outcomes indicated that 270 patients were required for 80% power, and 360 patients were required for 90% power.

Finally, we recruited 377 of 597 eligible patients (63.1%). All participants were assessed at admission, daily during hospitalization, and at hospital discharge. At admission, we evaluated participant characteristics (age, gender, education, diagnosis, Charlson comorbidity index,²¹ diabetes mellitus, duration of surgery, laparoscopy, and ostomy) and baseline cognitive status (Mini-Mental State Examination²²). Within 24 hours of admission and discharge, participants were assessed for nutritional status (MNA²³), body weight (in pounds), and frailty (yes/no) using Fried's criteria.⁹ Each participant signed written informed consent before participating in the study.

2.2. Randomization, concealment, and blinding

When participants returned to the GI wards after surgery, they were cluster randomized 1:1 to the mHELP (intervention) or usual-care (control) groups based on a computer-generated list. This design minimized contamination among participants in different groups by ensuring that all participants in one room belonged to the same group. In total, two GI wards had 38 rooms including 6 single-occupancy rooms (3 randomly assigned to each group), 9 double-occupancy rooms (4 randomly assigned to the control group and 5 to the mHELP group), and 4 triple-occupancy rooms (2 randomly assigned to each group). See Figure 1.

Additionally, room assignments were re-randomized every 20 participants to minimize potential unmasking of the randomization scheme. In no instance did one room have patients in both groups despite participants' various LOS. Every participant was assessed by two research nurses who were masked to intervention status. Working rules were in place prohibiting research nurses and the mHELP nurse from working with a patient at the same time. That is, if a nurse found another team member working with a patient, she would come back later; research nurses started at one ward, while the mHELP nurse started from the other). Additionally, hospital staff members were not informed about the specific mHELP protocols or participants' group allocation.

2.3. Intervention and usual care

The intervention group received usual care and the mHELP as soon as they transferred to the inpatient ward after surgery, and all interventions ended at hospital discharge. Interventions were provided only on weekdays (not on weekends or holidays). As shown in Appendix I, the intervention consisted of the hospital-based mHELP comprising three nursing protocols: *early mobilization*, *oral and nutritional assistance*, and *orienting communication*.¹⁶ Briefly, we aimed to get participants up and moving through range-of-motion (ROM) exercises and ambulating three times per day. The duration of mobilization varied based on patients' tolerance. We also provided daily oral care (tooth brushing and oral-facial ROM exercises for the tongue, lip, and jaw) along with postoperative diet education and feeding assistance (if needed) 2 meals per day (breakfast and lunch) to facilitate oral intake. No nutritional supplement, however, was provided. Once daily, we provided an active form of reality orientation and simple cognitive-stimulating activities as the mHELP nurse started a conversation embedded in events that interested patients (i.e., the day of surgery) and inquired about time-place, and person-related information in the context of the present day, thus reinforcing orientation. Some participants needed to be assisted for mobilization, oral intake, and cognitive orientation two or three times daily, but some only needed supervision

to ensure they were mobile, well-fed, and oriented. Nevertheless, nurses daily logs were tracked to ensure compliance with protocols. The mHELP was implemented by a trained mHELP nurse who was blinded to the study hypothesis and did not assess any outcomes.

Usual care consisted of standard hospital care provided by physicians and nurses on the general surgery wards. Preoperatively, all participants received the study site's routine standardized, mechanical bowel preparation and had nothing-by-mouth (NPO) for at least 8 hours. Postoperatively, oral intake was withheld until the return of 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. Additional care from a dietician or physical therapist was only provided at the request of the attending physicians.

2.4. Outcome assessment (nutritional decline, frailty)

Two research nurses, blinded to group assignment, evaluated outcomes of nutritional decline and frailty at both admission and discharge. Specifically, nutritional decline was defined as changes in body weight and nutritional status between admission and hospital discharge. Body weight (in pounds) was measured by a calibrated digital scale. Nutritional status was assessed using the 18-item MNA, with possible scores ranging from 0 to 30 and higher scores indicating better nutritional status.²³ Timely intervention is associated with improvement of MNA scores, and the MNA can be used as a follow up assessment tool.²⁴

Frailty was determined by meeting four of five of Fried's criteria (shrinking, weakness, exhaustion, low activity, and slowness).^{7,9} In contrast with the original criteria, we replaced the two physical measurements of slowness and low activity with questions. *Shrinking* was defined as unintended weight loss of more than 5% from the previous time point (i.e., weight measured at discharge was 5% less than at admission). For *weakness*, the criterion was met when grip strength, assessed by a digital handheld dynamometer, was less than the sex- and body mass index-specific cutoff or less than that provided by Fried.⁹ For *exhaustion*, the criterion was met by answering "no" to the question "Do you feel full of energy?" on the Geriatric Depression Scale.²⁵ *Low activity* was not measured by the Minnesota Leisure Time Activity Questionnaire, as proposed.⁹ Instead, we determined participants' activity levels by asking them questions from the Enforced Social Dependency Scale (ESDS).²⁶ The criterion of low activity was met if a participant had "restricted activity (i.e., some activities characterizing usual household role can no longer be performed)" or "no activity (i.e., major activities are no longer being performed)." Slowness was not measured by gait speed. Instead, we used the ESDS question: "Do you walk and get about in the same way you did before?" The slowness criterion was met if participants had one of the following conditions: walks with help of equipment or other persons, does not walk, or unable to take any steps.²⁶ Incident frailty (frailty that develops during hospital stay) and persistent frailty (frailty persists from admission to discharge) were coded separately.

Additionally, return of GI motility was assessed daily including time to 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 bowel motility endpoints was determined from when the abdominal incision was closed (baseline).

2.5. Statistical analysis

Data were double-entered to ensure accuracy. Intention-to-treat analyses were performed using SPSS, version 20 (IBM Corp., 2011) for all analyses. Sample characteristics were compared by treatment group at baseline. Data were reported as number (percentage), mean (SD), or median (interquartile range [IQR]) when not normally distributed. No adjustments were made for cluster effects because all intraclass correlation coefficients were not significantly different from 0 (Appendix II), suggesting that the true values are small. Hypotheses, therefore, were tested at the individual patient level. Differences by group were analyzed using the independent t-test or Mann-Whitney U test for continuous variables and χ^2 test or Fisher Exact test for categorical variables. For incident and persistent frailty, we calculated relative risk (RR) and 95% confidence interval (CI) from 2×2 tables. All statistical tests were two-tailed, and $P < 0.05$ was considered to indicate statistical significance.

3. Results

All participants' (N=377) baseline characteristics are presented by group in Table 1, i.e. those who received the mHELP (n=197) and usual care (n=180). The two study groups did not differ significantly in baseline characteristics. Participants in the mHELP group received a median 7 days (IQR=6–10) of the three mHELP protocols, with 1.7 sessions provided daily. The mHELP nurse spent a median 30 minutes (IQR=25–40) per session, for a total 58 minutes (IQR=45–67) spent with participants per day. No intervention-related adverse events were reported in the mHELP group.

3.1. In-hospital nutritional decline

As shown in Table 2, participants in the mHELP group lost significantly less weight (2.1 lb) than those in the usual care group (4.0 lb), resulting in a 1.9-lb group difference ($P=.002$). Likewise, the decline in MNA scores by hospital discharge was significantly less for the mHELP group than the control group (3.2 vs. 4.0 points for controls, $P=.03$).

3.2. Incident and persistent frailty

For incident frailty, 20 of 167 (12%) mHELP participants developed frailty during the hospital stay vs. 30 of 138 (22%) control individuals (Table 2). These differences were significant, with a RR of 0.55 for frailty, representing a risk reduction of 45% in the mHELP group (95% CI=0.33–0.93; $p=.02$; number needed to treat to prevent one case of frailty=11). Notably, among participants with preoperative frailty at admission, persistent frailty was identified in 6/12 (50.0%) mHELP participants vs. 13/14 (92.9%) control individuals with a RR of 0.54 (95% CI=0.30–0.97; $p=.03$).

3.3. Return of GI motility as a Potential Mechanism

As a potential mechanism contributing to in-hospital nutritional decline, we found only a non-significant trend toward accelerating return of patients' GI motility after surgery. The mHELP group had a shorter median time than controls to first flatus (69.5 vs. 76.0 hours; $P=.06$). Participants receiving the mHELP also had a shorter median time than controls to first defecation (91.0 vs. 99.0 hours; $P=.05$). Only 9.2% of participants in the mHELP group

had an unanticipated return to NPO status compared to 15.7% of participants in the control group ($P=.06$)

4. Discussion

Aimed at keeping patients mobile, well-fed, and oriented, these three nurse-administered mHELP protocols benefited older patients undergoing GI surgery by reducing their in-hospital weight loss by 1.9 pounds, preventing new frailty by 45%, and reducing their persistent frailty by 46%. Indeed, nutritional decline (i.e., weight loss) and development of frailty during hospitalization may reflect a transiently heightened vulnerability after surgery, arising from synergistic effects of admission diagnoses, surgical procedures, and hospital environmental factors, e.g., immobility, poor nutritional intake, multiple transfers in medical settings, and confusion created by staff-shift changes. These problematic areas commonly seen in acute and subacute care settings are targeted by the mHELP with a full-time–equivalent trained mHELP nurse to ensure its consistent daily application.

Delivering all three mHELP protocols to address the fundamental needs of older patients²⁷ requires a daily, extra 58 minutes of nursing time per patient (provided as an average of 1.7 sessions/day, with a median time of 30 minutes/session). One might wonder why many protocol-prescribed activities were delivered in only a median time of 30 minutes/session. In fact, not all participants required the same level of care in the three mHELP protocols and for the entire length of their hospital stay (i.e., not everyone needed to be assisted two or three times daily and not everyone required help in all three categories). Most participants required two sessions daily for the first 3 days after surgery and one shorter session with supervision afterward. In addition, we involved family members (who usually accompany older patients in Taiwan's hospitals) and coached them how to get patients moving in and out of bed, brushing teeth/doing oral-facial exercises, and eating well. After a few sessions, family members could help patients to walk or with their oral care and/or intake while the nurse worked with another patient. Nevertheless, ensuring intervention fidelity requires not only reserving sufficient nursing time for the trained mHELP nurse, but also securing the commitment and continued collaboration among hospital administrators, medical directors, physician and nursing leadership to achieve high adherence rates to these three nursing protocols.

Frailty and nutritional decline indeed are not necessarily a reason to withhold surgical treatment, but rather a means to structure acute and subacute care in a more patient-centered fashion to prevent new or worsening frailty. Currently, no interventions have been consistently shown to promote recovery of preexisting frailty in acute and subacute care settings, including conditions managed at home or in nursing facilities.^{2,28} Thus, the potential of the mHELP to prevent frailty and to reduce persistent frailty is highly significant. This finding extends our prior report that the mHELP effectively reduces prevalent frailty and suggests that both new frailty and persistent frailty are reduced by keeping older GI surgery patients mobile, well-fed, and oriented during their postoperative recovery period. The results should be confirmed and extended in future studies, ideally multicenter studies with larger samples in different acute and subacute care settings. Lastly, the mechanism for the observed benefit of the mHELP is unclear, requiring further research.

Accelerated return of bowel motility may not be the major mechanism as the mHELP only had marginal effects in reducing time to first flatus, time to first defecation, and return to NPO status. The reduction in nutritional decline or frailty was likely driven by improvements in overall functioning impacted by the mHELP.

Although this study had noteworthy strengths, including its randomization design and careful prospective evaluation of 377 older GI surgery patients, it also had important limitations. First, this study analyzed secondary outcomes of the original trial. Second, we used Fried's criteria to define frailty, but adapted several frailty criteria. We replaced the two physical measurements of slowness and low activity with questions on walking limitations and reduced activity levels. This modification likely captured functional decline during hospitalization, instead of a true frailty phenotype. Moreover, participants from both groups likely answered "yes" to the "reduced activity" question of not performing usual household roles, resulting in a measurement ceiling and favoring not finding an intervention effect. On the other hand, participants in the mHELP group more likely answered "yes" to the "slowness" question of walking and getting about in the same way they did before; thus, the between-group difference in frailty incidence was likely overestimated, favoring an intervention effect. The results of our study, therefore, need to be interpreted cautiously, and it may be difficult to generalize across populations whose frailty was assessed using other frailty measures. Third, despite efforts to blind team nurses, it is possible that they ran into each other; by seeing the mHELP nurse at bedside, research nurses would have known the patient's group assignment. Thus, it is possible that nurses became unblinded in rare cases despite our precautions. Fourth, we only measured "total time spent" instead of "level of care provided by each protocol," "number of times each protocol was delivered," or "number of sessions in which family members helped and with which components"; thus, we cannot assess whether results differed by intervention dose. Fifth, the sample was not large enough to allow more advanced subgroup analyses (i.e., by intervention dose or surgical type). Finally, we did not study the potential impact of polypharmacy and other geriatric syndromes, including depression on the magnitude of benefit, and we recruited patients with exclusion criteria from one medical center, which may also have limited the generalizability of our findings.

5. Conclusions/ Relevance

Physicians, nurses, and medical directors will face great challenges in caring for the increasing numbers of frail older patients since frailty is recognized as a key determinant of surgical outcomes.^{29,30} Research should be prioritized to develop clinically feasible and scalable programs to promote high quality care that allows frail older patients to achieve their treatment goals. The mHELP, comprising three nursing protocols of *early mobilization*, *oral and nutritional assistance*, and *orienting communication*, appears to be feasible and effective in preventing new frailty and reducing persistent frailty, thus augmenting its clinical implications to advance surgical care, and may be useful in other settings, including conditions managed at home or in nursing facilities.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

Acknowledgments

Sponsor's Role:

The sponsor did not have any role in the design, methods, subject recruitment, data collection, data analysis, and preparation of the paper.

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Figure 1.
Participant Enrollment Flowchart

Table 1.Participants' baseline characteristics by group ($N = 377$)

Variable	mHELP n=197	Control n=180	P
Age (years) *	74.3 (5.8)	74.8 (6.0)	.38 [†]
Male gender	111 (56.4)	103 (57.2)	.95
Education			.54
Illiterate	25 (12.7)	29 (16.1)	
Elementary/Middle school	90 (45.7)	84 (46.7)	
High school and above	82 (41.6)	67 (37.2)	
Diagnosis			.78
Gastric cancer	39 (19.8)	41 (22.8)	
Colorectal cancer	111 (56.4)	102 (56.7)	
Pancreatic/Periampullary cancer	28 (14.2)	24 (13.3)	
Other [‡]	19 (9.6)	13 (7.2)	
Charlson Comorbidity Index [§]	1 (2)	1 (2)	.83
Diabetes mellitus	47 (23.9)	48 (26.7)	.61
Duration of surgery (min) [§]	195 (105)	213 (98)	.10 [†]
Laparoscopy (196/179)	84 (42.6)	93 (51.6)	.10
Ostomy (195/179)	41 (20.8)	36 (20.0)	.93
MMSE at admission * (196/179)	27.0 (3.8)	26.8 (3.1)	.61 [†]
Body weight (lb) at admission * (196/180)	130.3 (22.6)	132.8 (23.9)	.30 [†]
MNA at admission * (196/180)	24.7 (3.7)	24.5 (3.9)	.70 [†]
Frailty at admission (197/180)	16 (8.1)	15 (8.3)	.94

Values in parentheses are percentages unless indicated otherwise; significance was determined by χ^2 test unless indicated otherwise; MMSE=mini-mental state examination; scores ranged from 0–30, with higher scores indicating better cognitive status; MNA=mini-nutritional assessment; scores ranged from 0–30, with higher scores indicating better nutritional status

* mean (standard deviation)

[†] Student t-test

[‡] Splenic tumor, mesothelioma, gastrointestinal stromal tumor, and pseudomyxoma peritoneiduodenum tumor.

[§] median (interquartile range)

Table 2.Comparison of nutritional decline and frailty rate ($N=377$)

Variable	mHELP $n=197$	Control $n=180$	Relative Risk (95%CI)	P
Nutritional declines, mean (SD)				
Changes on body weight (lb) (183/157)	-2.1 ± 5.5	-4.0 ± 5.7		.002 [‡]
Changes on MNA score (183/156)	-3.2 ± 3.4	-4.0 ± 3.4		.03 [‡]
Frailty rate, n (%)				
Incident frailty during stays ($n=167/138$)	20 (12.0)	30 (21.7)	0.55 (0.33–0.93)	.02
Persistent frailty ($n=12/14$)	6 (50.0)	13 (92.9)	0.54 (0.30–0.97)	.03 ^F

[‡]Chi-square test[‡]Student t-test^FFisher exact test

Change=discharge (T1)–admission (T0).

MNA, mini-nutritional assessment; scores ranged from 0–30 with higher score indicating better nutritional status.

Incident frailty refers to “new case” (i.e., free from frailty at admission but attained a frail status at hospital discharge; non-frail to frail).

Persistent frailty refers to “remained frail from admission to discharge (i.e., frail to frail)”