



Alliance A231601CD: Improving Surgical Care and Outcomes in Older Cancer Patients Through Implementation of an Efficient Pre-Surgical Toolkit (OPTI-Surg)

George J. Chang, MD, MS

The University of Texas MD Anderson Cancer Center

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RETURN TO
KIOSK MENU

NCI Community Oncology
Research Program

A program of the National Cancer Institute
of the National Institutes of Health

Rationale

Objective

Study Schema

Intervention

Eligibility Criteria

Follow Up

The number of older adults who undergo major surgery is expected to double from 7 million to 14 million by 2030. [1] Frailty, an age-related decline in physiologic reserve, is present in least half of older adults who undergo elective surgery. [2-4] There is strong evidence that components of frailty—functional and cognitive impairment, malnutrition, depression, and social vulnerability—put patients at risk for complications, mortality, prolonged length of stay, discharge to an institution and not home, functional decline, and poor quality of life. [3-10] Mounting evidence indicates that multimodal interventions aimed at optimizing vulnerabilities associated with frailty before surgery result in decreased complications, enhanced functional recovery, increased discharge to home, reduced length of stay, and decreased hospital cost. [11-14] Recently published best practices guidelines for the optimal care of the geriatric surgical patient released by the American Geriatrics Society and the American College of Surgeons state that these vulnerabilities should be identified and optimized preoperatively. [15] In current surgical practice, however, routine screening for or attempt to address these vulnerabilities before surgery is not performed. Screening tools are perceived to be cumbersome and primary surgical providers are not equipped to directly address the uncovered vulnerabilities. The goal of the proposed study is to evaluate the implementation of an efficient tool in surgical practices that can detect and optimize the components of frailty before surgery.

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TAP TO
RETURN TO
KIOSK MENU



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Primary

- To compare 8-week postoperative function among elderly patients between sites randomized to implement the OPTI-Surg toolkit with or without a coach versus sites randomized to usual care.

Secondary

- To compare postoperative morbidity between sites randomized to implement the OPTI-Surg toolkit with or without a coach versus sites randomized to usual care.
- To compare the penetration of the OPTI-Surg toolkit between sites randomized to implement the OPTI-Surg toolkit with a coach versus sites randomized to implement the OPTI-Surg toolkit without a coach.

Exploratory

- To compare postoperative mortality, hospital length of stay, discharge to a facility, and hospital readmission between sites randomized to implement the OPTI-Surg toolkit with or without a coach versus sites randomized to usual care.
- To assess subsequent initiation and follow through of appropriate referral for the indicated optimization intervention and assess practice-level structural factors associated with uptake of the OPTI-Surg package.
- To document and assess barriers and facilitators to implementation and dissemination through mixed-methods research.

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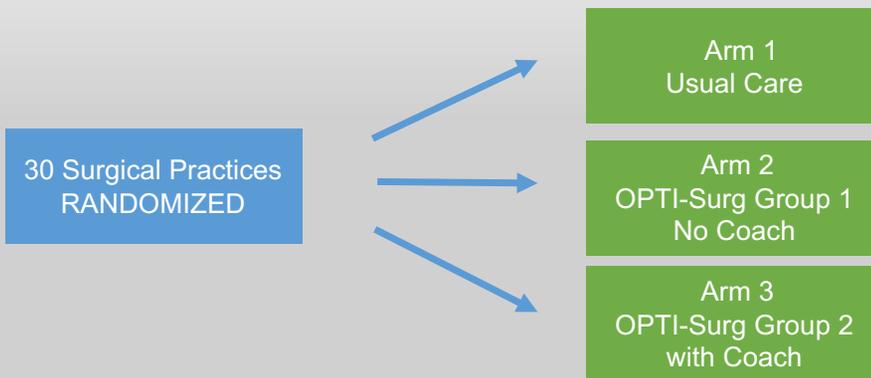


Study Schema

- Rationale
- Objective
- Study Schema**
- Intervention
- Eligibility Criteria
- Follow Up

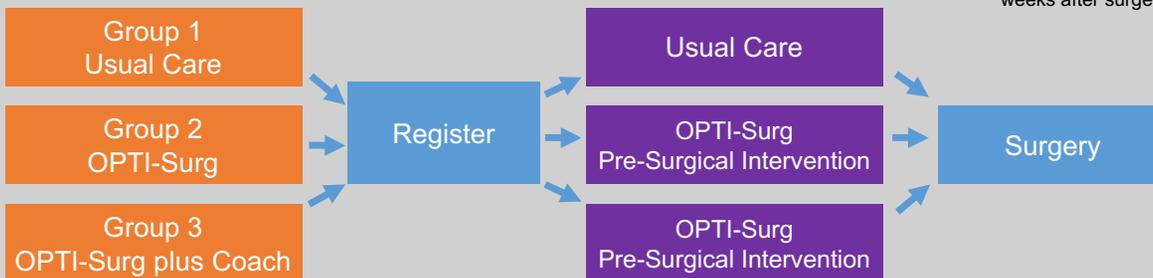
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Institutional Randomization



Sample size is about 15 consented patients per each of 30 surgical practices (450 consented patients) Consented patients will complete the CHAMPS and EQ-5D questionnaires at baseline and 8 weeks post-surgery.

NOTE: Practice-level data will be collected for all eligible patients (including those not registered to the trial) over the entire study duration. Surgical complications will be assessed for all eligible patients at 8 and 12 weeks after surgery.





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TAP TO
RETURN TO
KIOSK MENU



- Rationale
- Objective
- Study Schema
- Intervention**
- Eligibility Criteria
- Follow Up

Intervention

Healthcare providers/institutions are randomized to 1 of 3 arms. Patients/participants receive the intervention based on which arm their healthcare provider is in.

Arm I

Healthcare providers/institutions perform usual care.

Arm II

Healthcare providers/institutions receive OPTI-Surg training and informational materials.

Arm II (web-based breast cancer surgery decision aid)

Healthcare providers/institutions receive OPTI-Surg training and informational materials and meet with a coach.

After conclusion of study, participants are followed up at 8 and 12 weeks post surgery, and healthcare providers/institutions are followed up 6-9 months after the last patient is registered.

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TAP TO
RETURN TO
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- Rationale
- Objective
- Study Schema
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- Eligibility Criteria**
- Follow Up

Eligibility Criteria

Patient Eligibility

- Patients must have known or suspected cancer diagnosis and have one of the following cancer-directed operations planned: gastrectomy; colectomy; proctectomy; esophagectomy; pancreatectomy; hepatectomy; totalcystectomy; total nephrectomy; lung lobectomy/pneumonectomy
- Age \geq 70 years
- Patients with known metastatic disease with a plan for curative intent resection are eligible.
- Patients with double primaries undergoing planned curative operation for both are eligible.
- Patients undergoing emergent surgery are not eligible.
- Patients with second primary, or metachronous malignancy are not eligible.
- Patients with known metastatic disease who are undergoing palliative resection are not eligible.
- Patients with psychiatric illness or other mental impairment that would preclude their ability to give informed consent or to participate in the prehabilitation program are not eligible.
- Patients must be able to speak and complete questionnaires in English.

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TAP TO
RETURN TO
KIOSK MENU

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Please use the headings above to navigate through the different sections of the poster

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