BMC Cancer

STUDY PROTOCOL

Open Access

# Comparative effectiveness of perioperative physical activity in older adults with lung cancer and their family caregivers: design of a multicenter pragmatic randomized trial

Virginia Sun[1*], Katherine A. Guthrie[2], Kathryn B. Arnold[2], Mara Antonoff[3], Loretta Erhunmwunsee[4], Andrea Borondy-Kitts[5], Judy Johnson[6], Lee Jones[7], Maria Ramirez[8], Betty C. Tong[9], Jacob R. Moremen[10], Chi-Fu Jeffrey Yang[11], Thomas Ng[12], Samuel S. Kim[13], Lisa M. Brown[14], Justin D. Blasberg[15], Natalie S. Lui[16], Peter J. Kneuertz[17], Eric M. Toloza[18,19], Jae Y. Kim[4] and Dan J. Raz[4]

## Abstract

**Background** With a median age at diagnosis of 70, lung cancer remains a significant public health challenge for older Americans. Surgery is a key component in treating most patients with non-metastatic lung cancer. These patients experience postoperative pain, fatigue, loss of respiratory capacity, and decreased physical function. Data on quality of life (QOL) in older adults undergoing lung cancer surgery is limited, and few interventions are designed to target the needs of older adults and their family caregivers (FCGs). The primary aim of this comparative effectiveness trial is to determine whether telephone-based physical activity coaching before and after surgery will be more beneficial than physical activity self-monitoring alone for older adults and their FCGs.

**Methods** In this multicenter comparative effectiveness trial, 382 older adults (≥ 65 years) with lung cancer and their FCGs will be recruited before surgery and randomized to either telephone-based physical activity coaching or physical activity self-monitoring alone. Participants allocated to the telephone-based coaching comparator will receive five telephone sessions with coaches (1 pre and 4 post surgery), an intervention resource manual, and a wristband pedometer. Participants in the self-monitoring only arm will receive American Society of Clinical Oncology (ASCO) physical activity information and wristband pedometers. All participants will be assessed at before surgery (baseline), at discharge, and at days 30, 60, and 180 post-discharge. The primary endpoint is the 6-minute walk test (6MWT) at 30 days post-discharge. Geriatric assessment, lower extremity function, self-reported physical function, self-efficacy, and QOL will also be assessed.

**Discussion** The trial will determine whether this telephone-based physical activity coaching approach can enhance postoperative functional capacity and QOL outcomes for older adults with lung cancer and their FCGs. Trial results will provide critical findings to inform models of postoperative care for older adults with cancer and their FCGs.

*Correspondence:
Virginia Sun
vsun@coh.org

Full list of author information is available at the end of the article

**Trial Registration** ClinicalTrials.gov Identifier: NCT06196008.

**Keywords** Lung cancer, Surgery, Family caregivers, Functional recovery, Older adults

## Background

It is estimated that by 2040, 73% of cancer survivors will be 65 years and older [1]. This demographic shift highlights the urgent need for attention to the geriatric oncology population. With a median age at diagnosis of 70, lung cancer represents an enormous public health problem among older Americans. An estimated 19,000 people age 65 and older undergo lung cancer surgery annually in the United States [2]. Older adults undergoing lung cancer surgery are often frail with limited physiologic reserves, multi-morbidities, and functional impairments. These clinical challenges are compounded by systems-related trends, including variability in the use of minimally invasive techniques to reduce complications and postoperative pain, early postoperative discharge, and pressures to reduce readmissions. Postoperatively, older adults with lung cancer often have significant acute and chronic caregiving needs. As postoperative hospital stays have become shorter, a greater proportion of the caregiving burden after discharge has fallen on family caregivers (FCGs) [3]. Key challenges include supporting postoperative recovery, managing the patient's symptoms, functional needs, and coping with the practical aspects of caregiving [4].

Participation in physical activity is a promising approach to supporting the perioperative quality of life (QOL) of older adults undergoing lung cancer surgery and their FCGs. In lung cancer surgery, pre-and postoperative physical activity is associated with improved aerobic and functional capacity, reduced postoperative hospital stays, decreased postoperative complications, and improved quality of life (QOL) in both patients and FCGs [5–8]. Despite the evidence on the benefits of physical activity in cancer, few trials are designed specifically to address the needs of older adults with lung cancer and their FCGs in the surgical oncology setting. Alternative, scalable approaches that promote postoperative functional recovery and QOL in older adults with lung cancer and their FCGs are needed to advance the field. The aim of this paper is to describe the study protocol for a multicenter comparative effectiveness trial of perioperative physical activity to improve lung cancer surgery outcomes in older adults and their FCGs.

## Methods/design

### Study design and aims

This is a comparative effectiveness trial (1:1 parallel randomization) of a perioperative physical activity intervention in 382 English- and Spanish-speaking older adults undergoing lung cancer surgery and their FCGs. The overarching purpose is to test whether telephone-based physical activity coaching before and after surgery will be more beneficial than physical activity self-monitoring alone in promoting functional capacity before and after surgery for older adults undergoing lung cancer surgery and their FCGs. The trial is coordinated at City of Hope, in collaboration with the SWOG Cancer Research Network.

The study has three specific aims. **Specific Aim 1**: Compare the impact of telephone-based physical activity coaching vs. physical activity self-monitoring only on patient-centered outcomes, including functional capacity, dyadic self-efficacy, and dyadic QOL; **Specific Aim 2**: Compare the impact of telephone-based physical activity coaching vs. physical activity self-monitoring only on patient surgical outcomes, clinical outcomes and healthcare resource use, including time at home and away from the hospital, readmission rates, postoperative complications, image-based sarcopenia, and digital frailty biomarkers (pedometer daily steps); and **Specific Aim 3**: Explore perioperative experiences in participants and surgeons.

The primary objective of the trial is to compare changes in objective patient functional capacity (6-minute walk test −6MWT) from before surgery to 30 days post-discharge between the intervention and control arms. Secondary objectives are to compare changes from before surgery in 6MWT at 60 and 180 days post-discharge; patient short physical performance battery (SPPB), patient and FCG self-efficacy, patient and FCG physical function, and patient and FCG QOL at 30, 60, and 180 days post-discharge; patient time at home and away from the hospital through 60 days post-discharge; hospital readmissions rate; postoperative complications through 60 days post-discharge; image-based sarcopenia; and, pedometer documented daily steps.

### Participant eligibility criteria and recruitment

The trial aims to enroll 382 older adults with lung cancer and their FCGs. Patient eligibility criteria include the following: (1) documented informed consent of participation and/or legally authorized representative; (2) agreement to allow the use of preoperative chest CT scan for exploratory analysis; (3) agreement to wear pedometer during study duration; (4) age ≥ 65 years; (5) ability to read and speak English or Spanish and willingness to complete participant-reported outcomes and assessments; (6) patient diagnosis of lung cancer or presumed lung cancer; and (7) scheduled to undergo surgery for lung cancer or suspected lung cancer with curative intent

(neoadjuvant therapy allowed). FCG eligibility criteria include: (1) documented informed consent of the participant and/or legally authorized representative; (2) a family member or friend identified by the patient and defined as a person who knows the patient well and is involved in the patient's medical care before and after surgery; (3) age ≥ 18 years; and 3) ability to read and speak English or Spanish and willingness to complete participant-reported outcomes and assessments. Exclusion criteria include (1) patient's lung surgery scheduled in less than 7 calendar days from the time of registration; and (2) prospective participants who, in the opinion of the investigator, may not be able to comply with all study procedures (including exercise program and compliance issues related to feasibility/logistics). Patients are not excluded if they are unable to identify a FCG. Based on our previous experiences, 80–90% of the eligible patients will be able to identify a FCG for trial participation. The study schema is presented in Fig. 1.

Participants are recruited from 12 participating sites in diverse geographic locations nationally (see Fig. 2). Site investigators and research teams will collaborate to identify, screen and consent potential participants. Participating site research staff will contact potential participants, explain the study purpose, answer questions, and obtain informed consent from patients and FCGs. The recruitment process and procedures will be developed by each site based on their own thoracic surgical care infrastructures and institutional policies. Several overall strategies are included to achieve success in recruitment and retention, including (1) monthly site coordinator calls; (2) site training materials and webinar; (3) IRB-approved study brochures for potential participants; and (4) regular engagement with site investigators. The trial follows the single IRB reliance rule, with WCG serving as the IRB of record. Baseline assessments are completed following informed consent and prior to registration.

### Randomization

Following registration, each patient and their FCGs, if available, are randomly assigned to telephone-based physical activity coaching or physical activity self-monitoring only, with stratification by preoperative frailty score (<14 vs. ≥14 – Modified Geriatric Assessment 8), age (≥80 vs. <80 years), planned surgical approach (minimally invasive vs. open surgery), and FCG participation (yes vs. no). Stratified randomization helps to ensure that the distributions of measured and unmeasured covariates are balanced across comparator arms. Randomization assignments are revealed to site research staff through Research Electronic Data Capture (REDCap). Participants are notified of their assignment by the site research staff.

Each patient and FCG is given a Vivofit 4 (Garmin, Switzerland) wristband pedometer. This device is a commercially available tracking wristband pedometer. It continuously monitors daily step progress 24/7 without battery change for one year. It is also waterproof and can be worn in the shower. The coordinating center (City of Hope) calls the participants to remotely set up the watch.

## Conceptual framework

This study is guided by the Chronic Care Self-Management Model (CCM) [9–11]. The CCM transforms a reactive health system into one that improves outcomes through proactive planning and self-efficacy building. Within this framework, self-management is defined as "the systematic provision of education and supportive

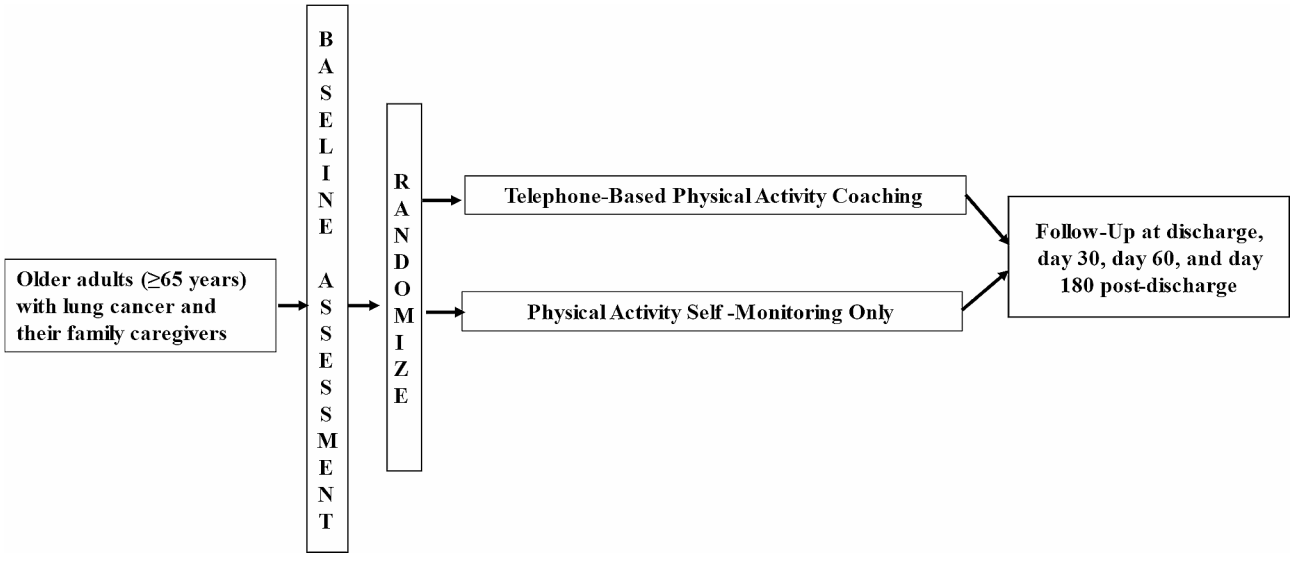


**Fig. 1** Study schema

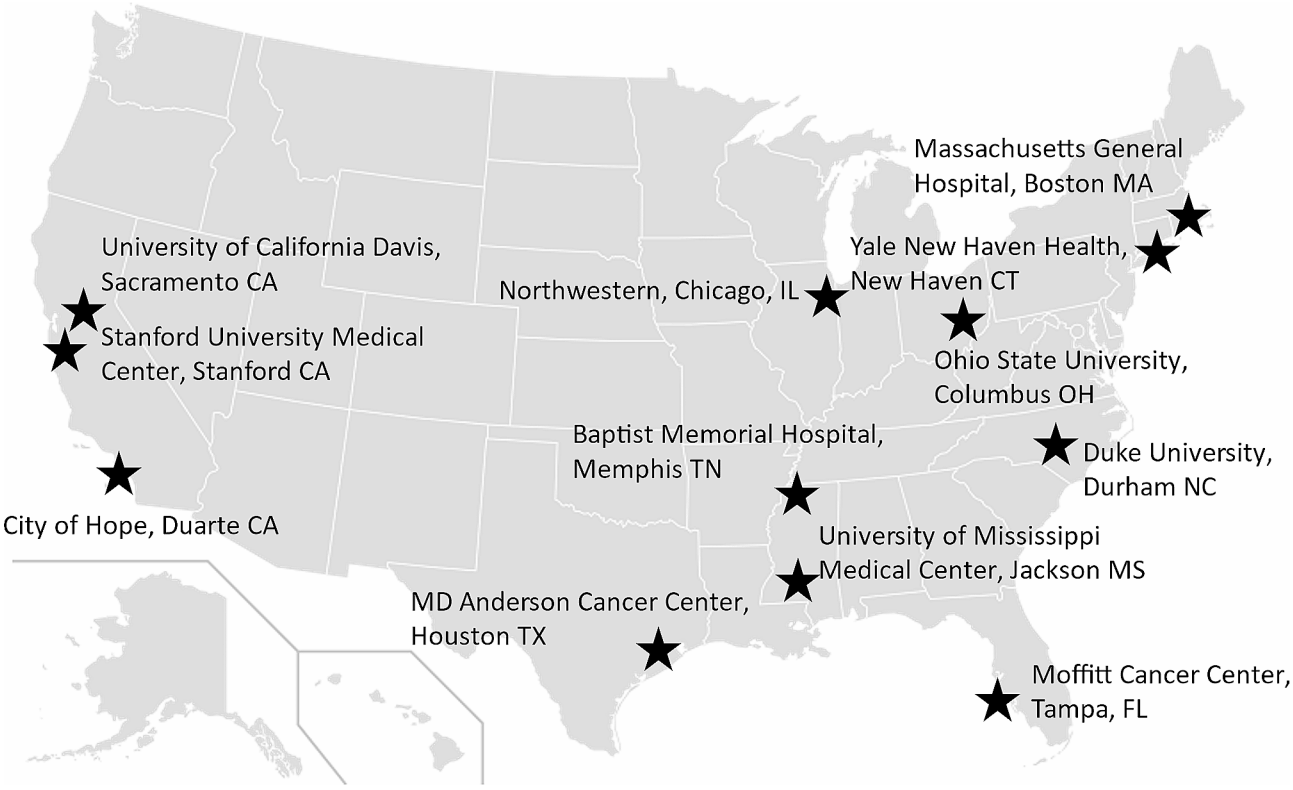


**Fig. 2** Participating sites

interventions to increase survivors' skills and confidence in managing their health problems, including goal-setting and problem-solving" [12]. Self-management coaching complements traditional education in supporting patients and FCGs to live their best possible quality of life (QOL) [12]. Whereas traditional patient and FCG education offers information and technical skills, self-management education enhances self-efficacy and supports problem-solving skills and cognitive restructuring. A central construct of self-management is self-efficacy, defined as the confidence to carry out behaviors necessary to achieve the desired goal [13]. Self-efficacy is enhanced when participants build confidence in their ability to manage their health.

Telephone-based physical activity coaching focuses on proactive planning and building self-efficacy to empower and engage individuals in their own care and is accessible to older individuals [14]. Sessions are highly participative, and the fundamental principle is setting SMART (Specific, Measurable, Attainable, Relevant, Timely) physical activity goals that assure progress over time. Proactive planning includes identifying barriers, developing an action plan to overcome the challenges, problem-solving, attention to perioperative anxiety, and coping to promote participation in physical activity. As a patient and FCG practices the strategies, self-efficacy is increased, and physical activity is achieved.

## Telephone-based physical activity coaching design and content

The intervention is a conceptually based and patient and FCG-focused model of personalized physical activity in lung cancer surgery. It includes the following key components: (1) a personalized walking program based on preoperative screening and assessments; (2) provision of a resource manual; (3) telephone coaching personalized to individual patient and FCG needs, tolerance, and preference; (4) self-monitoring through a wearable device (Vivofit 4); and (5) FCG coaching to serve as "walking buddies."

The intervention is delivered through five telephone sessions over approximately two months. Sessions are centrally administered nationally by trained bilingual (English, Spanish) coaches with physical therapy (PT), occupational therapy (OT) and nursing degrees; the interventionists are located in Southern California (primary study site). The estimated time to complete each session is 20–50 min. Each session includes both the patient and the FCG.

Session #1 is delivered within 5–30 days before surgery by PT/OT coaches (see Table 1). Using baseline geriatric assessment and objective functional assessments, the coaches develop a personalized walking program for each patient and FCG, with attention to functional status, tolerance, preference, and home environment. The

**Table 1** Telephone-based physical activity coaching content

| Session | Content |
|---|---|
| Session #1 (7–30 Days before surgery) | • Program overview<br>• Personalized walking program with target daily steps<br>• Assessment of home/community environment<br>• SMART goals for walking before surgery<br>• Identify challenges/barriers to walking<br>• Develop an action plan to meet SMART goals and overcome challenges<br>• Self-monitoring using Vivofit 4<br>• Simple lower extremity exercises<br>• Safety precautions<br>• FCGs as "walking buddies" and walking for their own well-being |
| Session #2 (Day 7 post-discharge) | • Assess SMART goal achievements before surgery<br>• Review/refine postoperative walking program with target daily steps<br>• SMART goals for walking after surgery<br>• Identify challenges/barriers to walking<br>• Develop an action plan to meet SMART goals and overcome challenges<br>• Self-monitoring using Vivofit 4<br>• Review simple lower extremity exercises<br>• Review safety precautions<br>• FCGs as "walking buddies" and walking for their own well-being |
| Sessions #3, #4, #5 (Day 14, 21, 51 post-discharge) | • Assess SMART goal achievements after surgery<br>• Review/refine postoperative walking program with target daily steps<br>• SMART goals for walking after surgery<br>• Identify challenges/barriers to walking<br>• Develop an action plan to meet SMART goals and overcome challenges<br>• Self-monitoring using Vivofit 4<br>• Review simple lower extremity exercises<br>• Review safety precautions<br>• FCGs as "walking buddies" and walking for their own well-being |

*SMART* = Specific measurable attainable relevant, timely

*FCG* = Family caregiver

walking program covers a personalized target number of daily steps that the participants should aim for before surgery. Guidance on safety precautions and simple lower extremity exercises (sit to stand, step up and down-front, step up and down-sideways, standing wall push-away) are provided. Together with the coaches, the patient and FCG identifies SMART goals for walking, potential challenges to meeting the goals, and problem-solving action plan to overcome the identified challenges. Goal setting is combined with self-monitoring (Vivofit 4) to promote self-efficacy and adherence to physical activity behavior change. FCGs are coached to serve as "walking buddies", given information on facilitating social support, and educated on the potential benefits of physical activity on their own well-being. A fully developed resource manual with support reference materials and session content are provided to participants.

Session #2 is delivered on day 7 post-discharge by trained nurse coaches. Preoperative SMART goals achievement is assessed. Participants set SMART postoperative goals, work with the coaches to discuss challenges and barriers to walking and develop postoperative action plans for walking. Lower extremity strengthening exercises and safety precautions are reviewed. Using assessment data before hospital discharge, personalized walking programs are reviewed and revised as needed based on postoperative tolerance. Sessions #3, #4, and #5 are delivered on days 14, 21, and 51 post-discharge by trained nurse coaches. These sessions will follow the same procedures as described in Session #2. Participants may access existing institutional rehabilitation or other specialty consultations at their discretion or that of the thoracic surgery teams.

#### Physical activity self-monitoring only

This comparator involves self-monitoring principles only and the provision of a one-page print material on physical activity from the American Society of Clinical Oncology (ASCO). Patients and FCGs each receive a Vivofit 4 wristband pedometer for self-monitoring. Participants also may access existing institutional rehabilitation or other specialty consultations at their discretion or that of the thoracic surgery teams.

#### Treatment fidelity

The fidelity monitoring plan includes the following: (1) a coaching manual to layout intervention goals, strategies to achieve them, and standard operating procedures; (2) training and supervision of coaches; and (3) audio-recording of all sessions. The first 10 intervention sessions will be reviewed for fidelity and thereafter a random sampling of 5% of sessions will be reviewed every 3 months. Using session recordings, intervention fidelity will be monitored through a checklist. Each intervention key element will be assessed using a present or absent response format, to determine if coaching behaviors were completed.

#### *Collaborator engagement*

In accordance with Patient-Centered Outcomes Research Institute (PCORI) metrics, several engagement activities are planned for the trial. A Collaborator Advisory Council (CAC) was formed to provide consistent and ongoing feedback on study design and conduct. CAC members include four patient and FCG partners and thoracic surgeons, with additional guests with expertise in health policy, payor, and health administration. In addition to the CAC, bi-annual gatherings during the American Association of Thoracic Surgery (AATS) meeting and the fall SWOG Cancer Research Network group meeting are conducted to enhance surgeon collaborator engagement

and solicit feedback. To enhance engagement with trial participants, quarterly patient and FCG virtual panels will be formed with patients and FCG's who have completed the intervention to solicit participant feedback on the trial and comparators. Between 3 and 6 patient and FCG participants will be included in each panel, and panels will alternate based on language preference. Results from the collaborator engagement activities will be used for Aim 3 analysis.

#### Outcome measures

Data collection occurs at baseline, before discharge, and at 30, 60 and 180 days post-discharge, and takes approximately 30–45 min to complete per timepoint. Baseline sociodemographic characteristics are collected for both patients and FCGs. Surgical and clinical outcomes (e.g. surgical procedure, length of stay, surgical complications at discharge, hospital readmissions, receipt of adjuvant systemic and radiation therapy) are collected through a form modeled after the Society of Thoracic Surgeons (STS) data collection form at day 60 post-discharge. Types of supportive care services (including additional PT/OT encounters) that participants received during the study period are collected at day 60 post-discharge. Patients and FCGs each receive a remuneration of $25 after completing each of the five assessments (total of $125).

The 6MWT is a performance-based measure of functional exercise capacity commonly used in older adults. It measures the distance that an individual can walk over a total of six minutes on a hard, flat surface [15, 16]. To help with recruitment and minimize loss to follow-up, the 6MWT can be completed at satellite facilities that may be closer to the patient and FCG. Additionally, in cases where the patient cannot get to the facility for the 6MWT, it can be done using the "Timed Walk" smart phone app. The SPPB is designed to quantify lower extremity function, physical performance and decline over time. It includes a 4-meter walk to measure gait speed, one chair stand, and balance stands with the feet held in different positions for 10 s each [17, 18].

The Modified Geriatric Assessment 8 (mG8) is a 6-item screening tool consisting of weight loss, mobility, body mass index, medication intake, self-reported health, activities of daily living, and age [19]. The mG8 score ranges from 0 (severe frailty) to 19 (no frailty); a score $\leq$ 14 indicates potential frailty. Patient and FCG reported self-efficacy and physical function are assessed using the Patient-reported outcomes measurement information system (PROMIS) self-efficacy for managing daily activities-short form 4 and the PROMIS physical function-short form 6. The self-efficacy tool focuses on confidence in managing daily activities [20, 21]. Items are scored on a 5-point Likert scale. Patient QOL is measured by the Functional assessment of cancer therapy-lung (FACT-L). The FACT-L is a cancer-specific version of the Functional Assessment of Chronic Illness Therapy (FACIT) System and contains the FACT-General (FACT-G) scales with 27-items divided into physical, social and family, emotional, and functional well-being domains. A 10-item lung cancer-specific symptom index (LCS) is included [22, 23]. FCG QOL is assessed using the City of Hope-quality of life–family (COH-QOL-Family), a 37-item instrument that measures QOL in the physical, psychological, social, and spiritual well-being domains [24, 25].

Patient time at home from before surgery and through 60 days post-discharge is adapted from Lee and colleagues, and defined as the number of days alive and spent out of the hospital and/or skilled nursing facility [26]. Home time will be calculated by subtracting the total number of days spent in hospitals and skilled nursing facilities (SNFs), including rehabilitation facilities, from the total number spent outside of the hospital/SNF. Exploratory assessments of sarcopenia are conducted through volumetric analyses of the supraspinatus muscle using standard of care preoperative CT scans of the chest normalized to height (in meters squared) [27]. Finally, digital biomarkers of aging are assessed through daily steps collected via the Vivofit 4 from before surgery through day 180 post-discharge. Hourly steps data are used to estimate daily activity time. A systematic review of 22 studies concluded that the reliability of wearable pedometers is generally high for measuring daily steps [28].

#### Data management

Centralized data management will be completed by the primary study team at City of Hope. Sites will have access to the study database housed in the City of Hope's secure REDCap website. Monitoring of clinic site-based data, and site data-related support via phone and email will be supported by the primary site. Pedometer daily steps data are transferred in real-time to the study database. De-identified preoperative CT scans will be submitted by sites securely through City of Hope's Poseidon system. Data will be transferred monthly to the SWOG Cancer Research Network's biostatistical team, with data auditing reports generated regularly.

#### Power analysis and statistical analysis plan

A Cochrane review in lung cancer [29] identified a mean difference in 6MWT between active and control arms of 57 m, 95% CI 34–80 m. This translates to an effect size of 0.37 SD. A total of 308 evaluable participants (154 per arm) will be required to detect this effect size in 6MWT between comparators at 30 days post-discharge, assuming an approximately normally distributed outcome, 90% power, and a 1-sided alpha of 0.025. To account for

potential ineligibility of 5% and loss to follow-up of 15%, we will enroll a total of 382 participants. A recent clinical trial demonstrated a standard deviation for the difference in PROMIS-Physical Function score between groups at follow-up of 12.5 [30]. Assuming this estimate, the sample size of 308 participants will provide 80% power to detect a 4-point clinically important change in this scale (0.32 SD effect size) with a 1-sided alpha of 0.025. Secondary results from a lung cancer trial demonstrated a SD of 8.3 for the difference in FACT-L subscale score between groups [31]. Assuming this estimate, the sample size of 308 participants will provide 88% power to detect a 3-point clinically important change (0.36 SD effect size) with a 1-sided alpha of 0.025.

All statistical hypothesis testing will be preceded by exploratory data analysis. For longitudinal secondary and exploratory outcomes, patterns of missing data will be described according to length of follow-up and reason for withdrawal (as needed). Analyses will include all eligible participants who contribute any relevant data, regardless of adherence to the intervention, with adjustment or stratification to account for informative missingness.

The primary endpoint analysis will be a study arm comparison via linear regression model of the 6MWT at 30 days, with adjustment for baseline 6MWT and stratification factors. Study arm comparisons of other continuous outcomes at 30, 60, and 180 days (SPPB, self-efficacy, physical function, QOL) will be assessed via repeated measures linear regression models with adjustment for baseline value of the outcome, stratification factors, and time point. Robust standard errors will be estimated via generalized estimating equations to adjust for correlation between repeated outcome measures. Incidences of postoperative complications and readmission will be compared by study arm via logistic regression and days at home by linear regression models with adjustment for stratification factors. Study arm comparisons of changes from baseline in sarcopenia and daily steps will be assessed via linear regression models with adjustment for stratification factors.

Qualitative data from quarterly patient and caregiver stakeholder panels will be analyzed using the conventional content analysis approach [32]. Data from the audio-recorded panel sessions will be transcribed and analyzed. All data will be read repeatedly to achieve immersion and obtain a sense of the whole. Then, data will be read to derive codes, and sorted into themes based on links and relationships. The SAC will conduct a final validation review of the codes and themes to ensure consistency and clarity across all qualitative data. Data discordantly coded will be discussed for refinement and consensus purposes.

### Quality assurance and site engagement

Several strategies are included to minimize protocol deviations and maintain data quality. The protocol includes detailed study flow diagrams to clearly delineate communication and site activities. Site coordinators and investigators must complete a 45-minute recorded webinar that reviews study implementation and procedures before enrolling study participants. Monthly site coordinator calls are held to serve as a regular forum for site specific questions on study procedures, troubleshooting of potential challenges, and site engagement. Regular monthly emails with graphic displays of accrual progress (total and by site) will be sent to site investigators and coordinators. Finally, the core research team meets weekly to discuss recruitment and quality assurance challenges.

## Discussion

More than 65% of people with lung cancer are older than 65 [33]. Data on QOL in older adults undergoing lung cancer surgery is limited. Moreover, baseline physical function and QOL measurements are on average lower among older adults, such that lung cancer surgery leads to more severe symptoms and physical impairment in older adults [34, 35]. Older adults also have a much greater range of physiologic reserve, underscoring the importance of personalized interventions to improve functional and QOL outcomes after lung cancer surgery. Finally, older adults are more likely to live alone and rely on FCGs for postoperative recovery needs than younger adults [36–38]. Evidence-informed and personalized interventions to maximize postoperative physical function and QOL are critical to the quality of survivorship for older adults following lung cancer surgery and their FCGs.

The concept of perioperative physical activity is not new, and several published trials, including "prehabilitation" (rehabilitation programs beginning in the preoperative period), reported benefits on surgical outcomes [5, 39, 40]. Although published studies have demonstrated a clear benefit to physical activity in the perioperative period for patients undergoing lung cancer surgery, such programs are not commonly utilized due to challenges in design and implementation. This physical activity coaching intervention design aims to address these design and implementation challenges. To date, most perioperative physical activity interventions have relied mainly on in-person approaches. In-person interventions may be unfeasible due to travel burden and resource availability. The telephone-based design of the physical activity coaching comparator aims to maximize access to coaching support. The inclusion of FCGs and coaching them to serve as "walking buddies" leverages social support as a driver of physical activity behavior change. The use of self-management coaching and classic principles of

behavior change aims to maximize positive perioperative outcomes and promote long-term physical activity behaviors in older adults with cancer. Long- term participation in physical activity benefits participants beyond the treatment phase of the cancer care continuum. Self-monitoring using wearable devices may enhance motivation for participation in physical activity.

The comparative effectiveness trial is expected to enroll participants over four years, with data analysis planned in 2029. The telephone-based physical activity coaching approach is expected to enhance postoperative functional capacity and QOL for older adults with lung cancer and their FCGs. If successful, the intervention can serve as a national model for postoperative functional recovery in lung cancer survivorship.

**Acknowledgements**
We acknowledge the SWOG Cancer Research Network Recruitment and Retention Committee for feedback on site training and study engagement/recruitment strategies. The trial's participating institutions include the following: Baptist Memorial Hospital, City of Hope, Duke University, Massachusetts General Hospital/Harvard, MD Anderson Cancer Center, Moffitt Cancer Center, Northwestern University, Ohio State University, Stanford University, University of California at Davis, University of Mississippi, Yale University/New Haven Health.

**Author contributions**
V.S. wrote the main manuscript text and D.R. prepared Figs. 1 and 2. All authors reviewed the manuscript.

**Funding**
Research reported in this article was funded through a Patient-Centered Outcomes Research Institute (PCORI) Award (HA-2021C3-24773). The statements in this article are solely the responsibility of the authors and do not necessarily represent the views of PCORI, its Board of Governors or Methodology Committee.

**Data availability**
No datasets were generated or analysed during the current study.

## Declarations

Dr. Chi-Fu Jeffrey Yang: advisory board, AstraZeneca and Genentech; honorarium, AstraZeneca. Dr. Peter Kneuertz: speaker and proctor, Intuitive Surgical. Dr. Mara Antonoff: consultant, AstraZeneca, BMS, Ethicon, and Merck.

**Ethics approval and consent to participate**
The study protocol was reviewed and approved by the WCG (Protocol # 20234018), which serves as the central IRB for the study. All participants complete informed consent prior to study participation.

**Consent for publication**
Not applicable.

**Competing interests**
The authors declare no competing interests.

**Author details**
[1]Department of Population Sciences, City of Hope, 1500 East Duarte Road, Duarte, CA 91010, USA
[2]SWOG Statistics and Data Management Center, Fred Hutchinson Cancer Center, Seattle, WA, USA
[3]Department of Thoracic and Cardiovascular Surgery, Division of Surgery, MD Anderson Cancer Center, Houston, TX, USA
[4]Division of Thoracic Surgery, Department of Surgery, City of Hope, Duarte, CA, USA
[5]Family Caregiver Research Advocate, Jupiter, FL, USA
[6]Family Caregiver Research Advocate, St. Louis, MO, USA
[7]Patient Research Advocate, Arlington, VA, USA
[8]Patient Research Advocate, Lancaster, CA, USA
[9]Division of Cardiovascular and Thoracic Surgery, Department of Surgery, Duke University, Durham, NC, USA
[10]Division of Thoracic Surgery, University of Mississippi Medical Center, Jackson, MS, USA
[11]Division of Thoracic Surgery, Massachusetts General Hospital, Boston, MA, USA
[12]Division of Thoracic Surgery, University of Tennessee Health Sciences Center, Memphis, TN, USA
[13]Division of Thoracic Surgery, Northwestern University, Chicago, IL, USA
[14]Division of General Thoracic Surgery, UC Davis Health, Sacramento, CA, USA
[15]Division of Thoracic Surgery, Yale University, New Haven, CT, USA
[16]Department of Cardiothoracic Surgery, Stanford University School of Medicine, Stanford, CA, USA
[17]Division of Thoracic Surgery, The Ohio State University Wexner Medical Center, Columbus, OH, USA
[18]Department of Thoracic Oncology, Moffitt Cancer Center, Tampa, FL, USA
[19]Departments of Surgery, Department of Oncologic Sciences, University of South Florida Health Morsani College of Medicine, Tampa, FL, USA

Received: 19 June 2024 / Accepted: 18 July 2024
Published online: 08 August 2024

**References**

1. DeSantis CE, Miller KD, Dale W, Mohile SG, Cohen HJ, Leach CR et al. Cancer statistics for adults aged 85 years and older, 2019. 2019;69(6):452 – 67.
2. Phillips JD, Bostock IC, Hasson RM, Goodney PP, Goodman DC, Millington TM, et al. National practice trends for the surgical management of lung cancer in the CMS population: an atlas of care. J Thorac Dis. 2019;11(Suppl 4):S500–8.
3. Tan JY, Molassiotis A, Lloyd-Williams M, Yorke J. Burden, emotional distress and quality of life among informal caregivers of lung cancer patients: an exploratory study. Eur J Cancer Care. 2018;27(1):e12691-n/a.
4. Mosher CE, Jaynes HA, Hanna N, Ostroff JS. Distressed family caregivers of lung cancer patients: an examination of psychosocial and practical challenges. Supportive care cancer: Official J Multinational Association Supportive Care Cancer. 2013;21(2):431–7.
5. Carli F, Charlebois P, Stein B, Feldman L, Zavorsky G, Kim DJ, et al. Randomized clinical trial of prehabilitation in colorectal surgery. Br J Surg. 2010;97(8):1187–97.
6. Carli F, Silver JK, Feldman LS, McKee A, Gilman S, Gillis C, et al. Surgical Prehabilitation in patients with Cancer: state-of-the-science and recommendations for Future Research from a panel of subject Matter experts. Phys Med Rehabil Clin North Am. 2017;28(1):49–64.
7. Ni HJ, Pudasaini B, Yuan XT, Li HF, Shi L, Yuan P. Exercise Training for patients pre- and postsurgically treated for Non-small Cell Lung Cancer: a systematic review and Meta-analysis. Integr cancer Ther. 2017;16(1):63–73.
8. Loh KP, Lin PJ, Uth J, Quist M, Klepin H, Mustian K. Exercise for managing cancer- and treatment-related side effects in older adults. J Geriatric Oncol. 2018;9(4):405–10.
9. Coleman K, Austin BT, Brach C, Wagner EH. Evidence on the Chronic Care Model in the new millennium. Health Aff. 2009;28(1):75–85.
10. Wagner EH, Bennett SM, Austin BT, Greene SM, Schaefer JK, Vonkorff M. Finding common ground: patient-centeredness and evidence-based chronic illness care. J Altern Complement Med. 2005;11(Suppl 1):S7–15.
11. Wagner EH, Austin BT, Davis C, Hindmarsh M, Schaefer J, Bonomi A. Improving chronic illness care: translating evidence into action. Health Aff. 2001;20(6):64–78.
12. McCorkle R, Ercolano E, Lazenby M, Schulman-Green D, Schilling LS, Lorig K, et al. Self-management: enabling and empowering patients living with cancer as a chronic illness. CA Cancer J Clin. 2011;61(1):50–62.
13. Lorig KR, Holman H. Self-management education: history, definition, outcomes, and mechanisms. Annals Behav Medicine: Publication Soc Behav Med. 2003;26(1):1–7.
14. Merluzzi TV, Pustejovsky JE, Philip EJ, Sohl SJ, Berendsen M, Salsman JM. Interventions to enhance self-efficacy in cancer patients: A meta-analysis of randomized controlled trials. Psycho-oncology. 2019;0(ja).

15. Bohannon RW, Crouch R. Minimal clinically important difference for change in 6-minute walk test distance of adults with pathology: a systematic review. J Eval Clin Pract. 2017;23(2):377–81.
16. Enright PL. The six-minute walk test. Respir Care. 2003;48(8):783–5.
17. Pavasini R, Guralnik J, Brown JC, di Bari M, Cesari M, Landi F, et al. Short physical performance battery and all-cause mortality: systematic review and meta-analysis. BMC Med. 2016;14(1):215.
18. Volpato S, Cavalieri M, Sioulis F, Guerra G, Maraldi C, Zuliani G, et al. Predictive value of the short physical performance battery following hospitalization in older patients. Journals Gerontol Ser Biol Sci Med Sci. 2011;66(1):89–96.
19. Martinez-Tapia C, Canoui-Poitrine F, Bastuji-Garin S, Soubeyran P, Mathoulin-Pelissier S, Tournigand C, et al. Optimizing the G8 Screening Tool for older patients with Cancer: diagnostic performance and validation of a six-item version. Oncologist. 2016;21(2):188–95.
20. Jones RS, Stukenborg GJ. Patient-reported outcomes Measurement Information System (PROMIS) Use in Surgical Care: a scoping study. J Am Coll Surg. 2017;224(3):245–54. e1.
21. Gruber-Baldini AL, Velozo C, Romero S, Shulman LM. Validation of the PROMIS((R)) measures of self-efficacy for managing chronic conditions. Qual life Research: Int J Qual life Aspects Treat care Rehabilitation. 2017;26(7):1915–24.
22. Cella D, Eton DT, Fairclough DL, Bonomi P, Heyes AE, Silberman C, et al. What is a clinically meaningful change on the Functional Assessment of Cancer Therapy-Lung (FACT-L) questionnaire? Results from Eastern Cooperative Oncology Group (ECOG) Study 5592. J Clin Epidemiol. 2002;55(3):285–95.
23. Cella DF, Bonomi AE, Lloyd SR, Tulsky DS, Kaplan E, Bonomi P. Reliability and validity of the Functional Assessment of Cancer Therapy-Lung (FACT-L) quality of life instrument. Lung Cancer. 1995;12(3):199–220.
24. Ferrell BR, Grant M, Borneman T, Juarez G, ter Veer A. Family caregiving in cancer pain management. J Palliat Med. 1999;2(2):185–95.
25. Ferrell BR, Grant M, Chan J, Ahn C, Ferrell BA. The impact of cancer pain education on family caregivers of elderly patients. Oncol Nurs Forum. 1995;22(8):1211–8.
26. Lee H, Shi SM, Kim DH. Home Time as a patient-centered outcome in administrative Claims Data. J Am Geriatr Soc. 2019;67(2):347–51.
27. Nemec U, Heidinger B, Sokas C, Chu L, Eisenberg RL. Diagnosing Sarcopenia on thoracic computed tomography: quantitative Assessment of skeletal muscle Mass in patients undergoing transcatheter aortic valve replacement. Acad Radiol. 2017;24(9):1154–61.
28. Kooiman TJ, Dontje ML, Sprenger SR, Krijnen WP, van der Schans CP, de Groot M. Reliability and validity of ten consumer activity trackers. BMC Sports Sci Med Rehabil. 2015;7:24.
29. Cavalheri V, Tahirah F, Nonoyama M, Jenkins S, Hill K. Exercise training for people following lung resection for non-small cell lung cancer - a Cochrane systematic review. Cancer Treat Rev. 2014;40(4):585–94.
30. Huffman JC, Golden J, Massey CN, Feig EH, Chung WJ, Millstein RA, et al. A positive psychology-motivational interviewing program to promote physical activity in type 2 diabetes: the BEHOLD-16 pilot randomized trial. Gen Hosp Psychiatry. 2021;68:65–73.
31. Sommer MS, Trier K, Vibe-Petersen J, Missel M, Christensen M, Larsen KR, et al. Perioperative Rehabilitation in Operable Lung Cancer patients (PROLUCA): a feasibility study. Integr cancer Ther. 2016;15(4):455–66.
32. Hsieh HF, Shannon SE. Three approaches to qualitative content analysis. Qual Health Res. 2005;15(9):1277–88.
33. Jaklitsch M, Billmeier S. Preoperative evaluation and risk assessment for elderly thoracic surgery patients. Thorac Surg Clin. 2009;19(3):301–12.
34. Berry LL, Dalwadi SM, Jacobson JO. Supporting the supporters: what family caregivers need to care for a loved one with Cancer. J Oncol Pract. 2017;13(1):35–41.
35. Carmack Taylor CL, Badr H, Lee JH, Fossella F, Pisters K, Gritz ER, et al. Lung cancer patients and their spouses: psychological and relationship functioning within 1 month of treatment initiation. Annals Behav Medicine: Publication Soc Behav Med. 2008;36(2):129–40.
36. Jayani R, Hurria A. Caregivers of older adults with cancer. Semin Oncol Nurs. 2012;28(4):221–5.
37. Vacas S, Cole DJ, Cannesson M. Cognitive decline Associated with anesthesia and surgery in older patients. JAMA. 2021.
38. Hanratty B, Addington-Hall J, Arthur A, Cooper L, Grande G, Payne S, et al. What is different about living alone with cancer in older age? A qualitative study of experiences and preferences for care. BMC Fam Pract. 2013;14:22.
39. Halloway S, Buchholz SW, Wilbur J, Schoeny ME. Prehabilitation interventions for older adults: an integrative review. West J Nurs Res. 2015;37(1):103–23.
40. Bruns ER, van den Heuvel B, Buskens CJ, van Duijvendijk P, Festen S, Wassenaar EB, et al. The effects of physical prehabilitation in elderly patients undergoing colorectal surgery: a systematic review. Colorectal Disease: Official J Association Coloproctology Great Br Irel. 2016;18(8):O267–77.


## Publisher's Note