Improving supportive care for patients with Thoracic Malignancies – A randomized controlled trial

Manali I. Patel [a,b,*], Lakedia Banks [b], Millie Das [b]

[a] *Division of Oncology, Stanford University School of Medicine, Stanford, CA, United States*
[b] *Medical Services, Veterans Affairs Palo Alto Health Care System, Palo Alto, CA, United States*

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ABSTRACT

Veterans have higher lung cancer incidence and mortality rates than civilians. Frequently, Veterans with lung cancer suffer from undertreated symptoms due to complex comorbidities, limited social support, and reluctance in discussing symptoms with their oncologists. Evidence supports proactive symptom screening among civilians with cancer; however, no studies to date have evaluated whether Veteran volunteer-led proactive symptom screening is feasible and effective among Veterans with lung cancer.

The "Improving Supportive Care for Patients with Thoracic Malignancies" study was co-developed by a pre-established Veteran and Family Advisory Board. Veterans with lung cancer are randomized in a 1:1 allocation to either a 9-month intervention combined with usual oncology care (intervention group) or usual oncology care alone (control group). A Veteran volunteer is assigned to all Veterans in the intervention group and conducts weekly symptom assessments using validated symptom surveys and reviews all symptom scores with an oncology nurse practitioner. The primary outcome is to evaluate whether the intervention improves documentation of symptoms at 6 months post-enrollment among Veterans in the intervention group as compared with the control group. Secondary outcomes include changes in patient-reported outcomes (i.e., symptom burden, patient activation, patient satisfaction with decision, health-related quality of life) and differences in acute care use (i.e., emergency department visits, hospitalizations) from baseline (time of enrollment in the study) to 3-, 6-, and 9-months post enrollment.

This study addresses a significant concern expressed by Veterans and their caregivers. Findings can advance our understanding of how to improve symptom-burden among Veterans with lung cancer.

ClinicalTrials.gov Registration #NCT03216109.

1. Background

Lung cancer is an urgent priority among Veterans specifically due to the higher incidence and mortality from this disease as compared with non-Veterans, or civilians [1,2]. Despite the Veterans Health Administration serving as America's largest integrated health clinic, providing Veterans with equal access to healthcare, many Veterans remain at risk of poorer outcomes from lung cancer due to multi-level barriers. These barriers include complex comorbidities, psychosocial concerns, poor social support, severe complications from social determinants of health such as food and housing insecurity [3], and limited transportation [4], that impact Veterans' ability to engage fully in their care after a diagnosis of cancer [5–9].

Veterans newly diagnosed with lung cancer express significant symptom burden with at least 45% reporting undertreated severe symptoms [10]. Prior studies show that Veterans frequently suffer from barriers such as communication and care coordination challenges regarding their symptom-burden including lack of activation and engagement in their care [11,12]. In our qualitative study to better understand challenges patients face after a diagnosis of cancer, many Veterans and their caregivers expressed concerns that their symptoms were "inevitable" and they "did not want to bother their doctor about their symptoms." [11] Veterans and their caregivers suggested that proactive symptom assessment by a trusted peer Veteran volunteer or community health worker may help to overcome some of the inherent communication challenges they faced [11].

In collaboration with our pre-established Veteran and Family Advisory Board, comprised of 8 Veterans with lung cancer and 7 family

members and/or friends, we developed a novel approach that embeds trained Veteran volunteers into lung cancer care with the specific intent to proactively assess Veterans' symptoms. We met with the Veteran and Family Advisory Board every month for 6 months to co-design this study. This work built off our prior randomized controlled trial in the Veterans Affairs Palo Alto Health Care System (VAPAHCS), where we demonstrated the positive effect of a lay health worker or community health worker-led advance care planning intervention on Veteran satisfaction with their care, goals of care documentation and reductions in acute care use and total costs at the end of life [13,14]. It remains unknown, however, whether the use of a Veteran volunteer to proactively assess Veterans' symptoms after a diagnosis of lung cancer is feasible and effective.

The aim of this randomized controlled trial (RCT) is to determine whether a Veteran volunteer-led proactive symptom assessment intervention is feasible (primary outcome). Feasibility was defined by our Veteran and Family Advisory board as 75% of Veterans in the intervention group with their symptom-burden documented in the electronic health record by their oncology clinician within 6 months of their diagnosis.

The secondary outcome was to determine whether the intervention could improve patient-reported outcomes (symptom burden, patient activation, patient satisfaction with decision, and health-related quality of life) and lower acute care use (emergency department visits and hospitalizations) from baseline (time of enrollment) to 3-, 6- and 9-months post-enrollment more than usual cancer care alone.

We hypothesize that the intervention is feasible. Secondarily, we hypothesize that Veterans in the intervention group will experience lower symptom burden, greater improvements in patient activation, patient satisfaction with decision, and health-related quality of life, and lower acute care use than Veterans in the usual care group. The objective of this manuscript is to describe the design of this double-blinded randomized controlled trial, which was funded, in part, by an investigator-initiated grant provided to the Principal Investigator (MP) by Carevive, Inc [15].

2. Methods

2.1. Participants and settings

The site for this study is the Veterans Affairs Palo Alto Health Care System (VAPAHCS) in Palo Alto, California. The VAPAHCS has a medical oncology section housed within the Medical Services department. The medical oncology section is comprised of 5 medical oncologists, 2 of whom (MP, MD) subspecialize in the care of Veterans with lung cancer. Survival rates for lung cancer at the VAPAHCS consistently mirror or exceed both state and national averages. Over 175 Veterans with newly diagnosed lung cancer are seen annually at the VAPAHCS.

Prior to study start, the Veteran and Family Advisory Board and the Principal Investigator (MP) created a study protocol with objectives. Together, the Veteran and Family Advisory Board and the 2 lung cancer oncology clinicians and the oncology nurse practitioner (LB) at the VAPAHCS (MP, MD) reviewed the objectives and determined the inclusion criteria which includes: 1) age greater than 18 years; 2) newly diagnosed with lung cancer or currently an established patient with a diagnosis of lung cancer; 3) any patient with newly progressive or recurrent cancer.

Exclusion criteria included: a) no capacity to consent to study procedures and b) planning to be seen at the VAPAHCS for a second opinion only. The primary oncologist introduces eligible patients to the study and refers them to the site clinical research coordinator who confirms eligibility and obtains written consent. The VAPAHCS Research Committee reviewed and approved study procedures and recommended review by the Stanford University Institutional Review Board which provided official approval for all recruitment and consent procedures prior to study start.

2.2. Study procedures

Fig. 1 depicts the study flow. All participants complete baseline evaluations and then are randomly assigned to either one of two study groups: a) Veteran volunteer-led proactive symptom assessment intervention (intervention group) with usual cancer care b) usual cancer care alone (control group). Randomization occurs in a 1:1 allocation and performed using a statistician-generated random allocation table uploaded into Research Electronic Data Capture (REDCap) [16], a secure web-based tracking and online data acquisition system. After completion of the baseline assessment, a study research assistant enters the participant's record into Carevive [15], a secure cancer care management and patient engagement technological platform. Participants are assessed at baseline (T1) and 3-months (T2), 6-months (T3), and 9-months (T4) after patient enrollment or until patient's death, whichever is first. All research protocols and forms are available on ClinicalTrials.gov NCT03216109.

2.3. Measures

Several outcomes will be used to assess the effect of the intervention. We will use electronic health record and patient-reported data to assess the intervention effect as compared with usual care alone on our primary (feasibility) and secondary outcomes (patient reported outcomes (i.e., symptom burden, patient activation, patient satisfaction with decision, health-related quality of life) and acute care use). A trained study research assistant will conduct electronic health record chart review and participant surveys for each participant at baseline, 3-months, 6-months, and 9-months post-enrollment.

2.3.1. Feasibility

Feasibility was defined by the Veteran and Family Advisory Board as 75% of Veterans in the intervention group with symptom documentation in the electronic health record within 6 months of enrollment in the study.

2.3.2. Symptom burden

Symptom burden is measured by the validated Edmonton Symptom Assessment Scale [17], a 10-item measure that assesses the degree to which patients experience symptom burden. Surveys will be conducted at baseline, 3-, 6-, and 9-months post-enrollment for both the control and the intervention groups.

2.3.3. Patient activation

Patient activation is measured by the validated Patient Activation Measure-10, a 10-item measure that assesses an individual's knowledge, skill, and confidence for managing their health and healthcare [18,19]. The scale is 0–100 and segments patients into one of four activation levels based on an empirically and validated derived continuum. Each activation level reveals insight into health-related characteristics, including attitudes, motivators, behaviors, and outcomes. Surveys will be conducted at baseline, 3-, 6-, and 9-months post-enrollment for both the control and the intervention groups.

2.3.4. Patient satisfaction with decision

Satisfaction with Decision is measured by the validated Satisfaction with Decision Scale (SWD) [20], a 6-item measure that assesses the degree to which patients are satisfied with their decision-making. The SWD is used to ensure that patients are satisfied with their medical and treatment decisions. Surveys will be conducted at baseline, 3-, 6-, and 9-months post-enrollment for both the control and the intervention groups.

2.3.5. Health-related quality of life

Health-related quality of life is measured by the validated Functional Assessment of Cancer Therapies – Lung 38-question scale [21] that
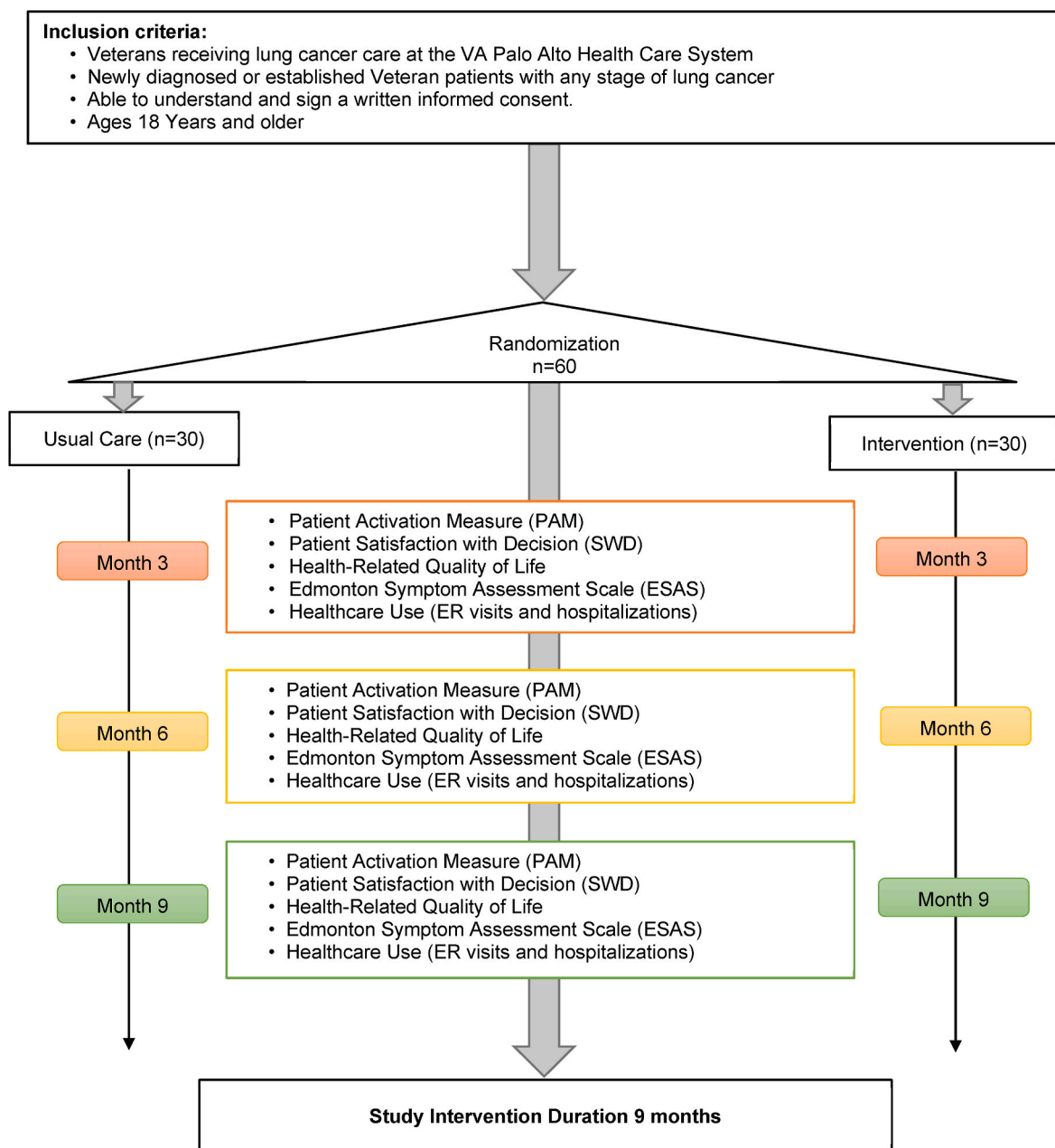
Inclusion criteria:
- Veterans receiving lung cancer care at the VA Palo Alto Health Care System
- Newly diagnosed or established Veteran patients with any stage of lung cancer
- Able to understand and sign a written informed consent.
- Ages 18 Years and older

Randomization
n=60

Usual Care (n=30)

Intervention (n=30)

Month 3

- Patient Activation Measure (PAM)
- Patient Satisfaction with Decision (SWD)
- Health-Related Quality of Life
- Edmonton Symptom Assessment Scale (ESAS)
- Healthcare Use (ER visits and hospitalizations)

Month 3

Month 6

- Patient Activation Measure (PAM)
- Patient Satisfaction with Decision (SWD)
- Health-Related Quality of Life
- Edmonton Symptom Assessment Scale (ESAS)
- Healthcare Use (ER visits and hospitalizations)

Month 6

Month 9

- Patient Activation Measure (PAM)
- Patient Satisfaction with Decision (SWD)
- Health-Related Quality of Life
- Edmonton Symptom Assessment Scale (ESAS)
- Healthcare Use (ER visits and hospitalizations)

Month 9

Study Intervention Duration 9 months

Fig. 1. Study design.

assesses overall physical, social/family, emotional, and functional well-being and has a lung subscale that measures symptoms, cognitive function, and regret of smoking. The scale is measured from 0 (not at all) to 4 (very much). Subscale scores are added to obtain the total score and includes the Trial Outcome Index (TOI) which is the sum of the Physical, Functional and Lung Cancer Subscales. The TOI is reported to be an efficient and precise summary index of physical and functioning outcomes. Surveys will be conducted at baseline, 3-, 6-, and 9-months post-enrollment for both the control and the intervention groups.

2.3.6. Acute care use

A trained research assistant will conduct an electronic health record chart review that contains all VA and non-VA care use in order to obtain all acute care use (i.e., emergency department visits and hospitalizations), including dates of acute care use, for both groups, for up to 9-months post-enrollment or death whichever occurs first.

2.3.7. Demographic and clinical factors

Participants will complete surveys at the time of enrollment that will include information on their age, gender identity, marital status, income level, education, and race/ethnicity at time of enrollment. The electronic health record will be used to abstract clinically relevant information including the date of the cancer diagnosis, cancer histology, and cancer stage and one-way travel distance (miles) from their home residence to the VAPAHCS.

2.4. Control and intervention conditions

2.4.1. Usual cancer care (control)

Usual Cancer Care consists of an oncology clinician who provides oncology treatment and care, oncology nurse practitioner who provides follow-up on identified clinical concerns, social worker who provides coordination of housing, transportation, and case management needs, and a behavioral health specialist who conducts routine distress

screening on every Veteran with a newly diagnosed cancer and provides follow-up behavioral medicine support for any identified needs. Palliative care teams and hospice are referral based. All Veterans also have access to the 24-h VA regional telephone care program to report symptoms and to obtain advice from off-site non-oncology nursing staff. The medical oncology section at the VAPAHCS hosts a twice-monthly multi-disciplinary conference with the facility thoracic surgeons, medical thoracic oncologists, thoracic radiation oncologists from the affiliated university center (Stanford University), pathologists, pulmonologist, radiologists, and any medical trainees such as clinical oncology fellows, clinical pulmonary fellows, and medical residents to review cases of Veterans with lung cancer and discuss treatment options.

2.4.2. Intervention

2.4.2.1. Overview and conceptual framework. The intervention is based on the Donabedian Quality Framework. The framework outlines how the underlying healthcare system structure determines processes of care delivery which, in turn, determine the clinical outcomes of patients [22]. The proactive symptom assessment intervention for this study builds on our prior tested and effective intervention in which we embedded Veteran volunteers and community health workers into cancer care to assist Veterans in advance care planning after a diagnosis of advanced stages of cancer [13]. The current intervention integrates Veteran volunteers into lung cancer care to overcome structural barriers that may be responsible for undertreated symptom burden. These include: 1) limited time by oncology clinicians to assess symptoms; 2) lack of proactive symptom assessment strategies by the clinic; 3) lack of routine clinician-patient interaction between clinic visits to assess any symptom that may arise between clinic visits and 4) reliance on in-person visits for any cancer-related need. These structural problems inherent in the clinic usual care processes result in lack of effective assessment of Veteran symptoms and delivery of appropriate and immediate symptom management among Veterans with lung cancer [11, 23,24].

Prior to study start, two Veteran volunteers will be hired and trained (see below) by the study Principal Investigator (MP) and the oncology nurse practitioner (LB). Each participant randomized to the intervention group will receive usual cancer care (described above) and will be assigned to a Veteran volunteer. The Veteran volunteer will contact the Veteran by telephone within one week after their enrollment in the study and will conduct weekly proactive symptom assessments by telephone using the validated Edmonton Symptom Assessment Scale (ESAS) [17]. All symptom scores will be entered into the Carevive [15] platform. Any score of 4 or above and/or any score that has increased by 2 points from a prior assessment will be discussed and reviewed with the oncology nurse practitioner in the clinic (LB) that same day who will conduct the appropriate clinical intervention and will document any clinical intervention in response to symptoms in the electronic health record as per usual cancer care. The cutoff scores for ESAS were pre-determined by our prior work [25].

The Veteran volunteer will mail each participant a letter after each weekly contact that provides detailed management strategies for the specific symptom(s) for which the Veteran scored 4 or above and/or any symptom score that increased by 2 or more points from prior assessments. The goal is to provide participants with proactive symptom management initiated by the clinic rather than the current reactive system which relies on Veterans to independently communicate their symptom-burden with their cancer care teams. The goal is to activate Veterans to engage in their lung cancer care so that they can independently and proactively discuss their symptom burden with their clinicians by the completion of the intervention at 9 months post-enrollment.

2.4.3. Selection, training, and supervision of veteran volunteers

2.4.3.1. Selection of veteran volunteers. As part of the study, we will select two Veteran volunteers to participate in this study from the VAPAHCS Volunteer Office. As part of this recruitment, we created job descriptions and recruitment materials that we distributed online through various external volunteer sites including posting the positions at Stanford University (the affiliated university). We selected two Veteran volunteers out of a pool of eight who volunteered. The two volunteers we selected had previously worked in customer service, had a Bachelor of Arts degree, and were specifically interested in volunteering for Veterans with lung cancer given their personal history of taking care of family members with lung cancer.

2.4.3.2. Veteran volunteer training. Volunteers at the VAPAHCS are required to undergo standardized training through the facility's Volunteer Office. Specifically, volunteers are required to complete all VA security and patient privacy training, are trained on the use of the electronic health record, and must pass all VA security clearances. In addition to the standardized training provided by the VAPAHCS Volunteer Office, we trained the two Veteran volunteers on the protocol for this study and the Carevive [15] platform. The training was led by the Principal Investigator (MP) and the oncology nurse practitioner (LB).

2.4.3.3. Supervision of veteran volunteers. Each volunteer is supervised by the oncology nurse practitioner (LB). The nurse practitioner reviews all participant symptom scores with the volunteers (as described above) and conducts any clinical intervention as per usual cancer care in co-ordination with the primary oncologist for the patient.

2.4.3.4. Assessment of fidelity to the intervention. We will use several processes to assess fidelity of the intervention delivery. First, the Veteran volunteers will keep detailed logs of all of their intervention activities, including date and time of each contact with the Veteran participant, minutes spent with each participant, issues discussed with the Veteran participant and any other issues encountered during their interaction with the Veteran participant. All detailed logs will be kept in the Carevive [15] platform for the Veterans assigned to the intervention group. The oncology nurse practitioner will meet with each volunteer weekly to ensure that all protocol activities are being adhered to and will review documentation of each participant's chart weekly to ensure that all intervention components were completed.

2.5. Proposed statistical analysis

2.5.1. Analysis

We will use intent to treat analysis for this study (all participants will be included in the analysis based on the group they are randomized to). The unit of analysis will be at the participant-level. We will conduct assess differences in demographic (i.e., sex, age, race/ethnicity) and clinical differences (i.e., stage of cancer) between both the randomized and control groups to ensure balanced variables in the randomization across groups. We will use generalized mixed effect linear regression models for repeated measures to compare the change in score of patient-reported outcomes (symptom scores, health-related quality of life, patient activation, and patient satisfaction with decision) between study groups from baseline to 3-, 6-, and 9-months post-enrollment. We will compare acute care use (the total number of emergency department visits and hospitalizations) using exact Poisson regression models with an offset term for length of follow-up for both groups. We will adjust models for covariates that are found to be unbalanced between the groups, such as age, race/ethnicity, or cancer stage.

We will adhere to intent to treat principles. As this population has a high likelihood of death, we anticipate some missing data. We plan to use generalized mixed linear regression models where we are assuming

that the data is not missing completely at random but are missing at random. We also assume that the missingness will be associated with observed characteristics. However, we will conduct sensitivity analyses that include demographic and clinical variables associated with missingness and will conduct multiple imputation assuming that the data are not missing at random. We will conduct all significance testing at a two-sided p-value of 0.05.

2.5.2. Sample size considerations

The study's primary outcome is to measure the feasibility of the intervention, which is defined as at least 75% of participants in the intervention group with their symptom-burden documented in the electronic health record by the primary oncology clinician. Our sample size of 60 participants (with at least 30 participants randomized to the intervention group) provides us with greater than 90% power to detect a 40% difference in proportions of participants with their symptom assessment documented in the electronic health record within 6-months follow-up. The anticipated 40% difference in proportions is based on our baseline data electronic health record review showing that only 35% of Veterans newly diagnosed with lung cancer have their symptom-burden documented in the electronic health record by the oncology clinicians in this VA facility.

3. Discussion

Lung cancer in the Veterans Affairs is an urgent priority due to higher incidence and mortality rates among Veterans as compared with civilians [1,2]. Although symptom management is a component of national guideline-recommended care for all patients after a diagnosis of lung cancer [26], due to complex comorbidities, psychosocial concerns, and complications from social determinants of health [5,6], Veterans often do not engage in or advocate for such care [8,9,12]. Furthermore, due to systems-level barriers, such as limited clinician time and lack of clinic capacity, long travel distances, and limited interaction between in-person clinic visits, symptom management among Veterans with lung cancer is often reactive rather than proactive [11,23]. Integrating proactive, clinic-led, Veteran-centered symptom assessment approaches such as the use of telephone-based care delivery and dedicated Veteran volunteers to assess symptoms under the supervision of a nurse practitioner may provide a sustainable and effective solution to improving supportive care among Veterans with lung cancer.

In prior work, the principal investigator (MP) conducted a randomized trial in which Veteran volunteers and lay or community health workers assisted patients with advance care planning. The intervention resulted in improvements in electronic health record documentation of Veteran care preferences, Veteran satisfaction, and reductions in acute care use and total healthcare costs at the end-of-life as compared to usual cancer care [13]. Although we have shown that community health worker-led proactive symptom screening among civilians in community oncology clinics is associated with lower symptom burden, less acute care use, and lower total costs of care as compared to usual care [25,27], the feasibility and applicability of using such approaches among Veterans remains unknown. This randomized trial will provide high-level evidence regarding the feasibility and the effect of such an approach on Veteran-reported outcomes and healthcare use.

The strengths of this study include the use of community-based participatory research principles in which the protocol was co-developed by a Veteran and Family Advisory Board based on their experiences and unmet needs. Another strength is that, to our knowledge, this study is one of the first randomized controlled trials to date that evaluates proactive symptom assessment among Veterans with lung cancer within the Veterans Health Affairs. This study, therefore, will fill a gap in our current knowledge regarding feasible and effective approaches to improve Veteran health after a diagnosis of lung cancer. This study also has some weaknesses. We chose to focus on lung cancer given the significant prevalence of this cancer diagnosis among Veterans.

However, because we are limiting this study to lung cancer, it is possible that the results from this study may not be generalizable to Veterans with other cancer diagnoses. Another concern is whether we can accrue enough Veteran participants in this randomized controlled trial. In our prior work, we were able to successfully enroll our target sample size of 213 Veterans into our advance care planning clinical trial within 18 months. In this study, we have partnered closely with our pre-established Veteran and Family Advisory Board to select a research question that was of utmost interest to the Veteran population with lung cancer. We will work closely with the Veteran and Family Advisory Board to determine best recruitment approaches and monitor enrollment. Finally, we are not planning to adjust for multiple hypotheses given that our primary hypothesis is feasibility as defined by the Veteran and Family Advisory Board. We plan to obtain point estimates of our secondary outcomes in anticipation of a larger planned multi-site study upon completion of this randomized controlled trial.

4. Conclusions

In summary, the Improving Supportive Care for Patients with Thoracic Malignancies is a randomized controlled trial aimed to primarily determine whether a Veteran-led proactive symptom assessment intervention is feasible and secondarily whether it is effective in reducing symptom burden, improving patient-reported outcomes, and reducing acute care use among Veterans with lung cancer. This randomized controlled trial co-designed by a Veteran and Family Advisory Board will provide important data to inform the use of this intervention among Veterans with lung cancer and could serve as a model for other VA facilities.

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