Self-System Therapy for Older Adults with Advanced Lung Cancer (SST-LC)

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Purpose of the Study

This pilot project will use Self-system therapy (SST), an empirically validated intervention based to treat depression and lung-cancer-related distress in older adults (65 years and older). We hypothesize that the SST intervention will be both feasible and acceptable. Specifically, lung cancer participants will be successfully recruited to participate in the SST intervention (H1). Participants will complete at least 85% of SST treatment sessions (H2). Participants will report satisfaction with the content and delivery of the intervention, through self-report questionnaires and focus group interviews (H3). Lastly, we hypothesize that participants depression scores will improve from baseline to post-intervention as a function of receiving the SST intervention (H4).

Background & Significance

Older adults diagnosed with advanced lung cancer are highly vulnerable to experiencing symptoms of depression (e.g., sadness; hopelessness) and anxiety (e.g., restlessness; panic; feeling tense). In addition to these symptoms, cancer patients also experience physical symptoms such as chronic pain and breathlessness that lead to sedentary behavior. From a theoretical perspective, having advanced stage lung cancer diagnosis can cause psychological distress because it threatens the individual's own sense of self – particularly, being able to live up to increasingly demanding expectations of their lung cancer care while simultaneously revising and pursuing one's own important personal goals. Faced with these demands, lung cancer patients are prone to self-discrepancies in which they believe that they are failing to meet the expectations that they have for themselves (and that they believe significant others have for them). Older adult lung cancer patients are likely to benefit from learning how to maintain the motivation to pursue important personal goals (e.g., related to emotional and physical health) and how to modify those goals which are not adaptive to their current circumstances. Learning (or relearning) how to set and pursue personal goals that promote growth or accomplishment while modulating or eliminating goals that are unreachable or self-defeating is a key skill for maintaining well-being.

Furthermore, combining this general goal-focused approach with a specific emphasis on becoming more active in the pursuit of quality-of-life-enhancing behaviors would be an ideal match for the needs of these patients and their families. A theory-based, targeted, and readily disseminated intervention for addressing the mental health needs of older adults with advanced lung cancer represents a promising approach to enhancing their psychological and physical well-being.

Design & Procedures

Patients will be recruited from clinics of the Duke Cancer Institute.

Focus Groups or Individual Interviews: We will conduct focus groups (or as needed individual interviews) of older adults with late stage lung in cooperation with Duke's Behavioral Health and Survey Research group (BSHR). These focus group (or as needed individuals) interviews will focus on perceived stresses of everyday living with lung cancer (emotional and physical symptoms), actual-self, ideal-self and ought-self beliefs associated with having an advanced lung cancer diagnosis, self-discrepancy, self-efficacy, stress-related emotions and physiological reactions. Information from the focus groups will be used to

modify the existing evidence-based SST protocols. Each focus group (or individual interview) will be audio-recorded and transcribed for analysis. We will then transcribe the audio recordings and use the grounded theory approach already instantiated in the BHSR's data analytic procedures for qualitative data to identify the main themes and concerns raised by participants.

Creation of a Project Advisory Group of Lung Cancer Patients:

Based focus group (including individual interview) feedback, the project team will identify a subset of who will meet with the project team every four months to receive an updated report on our progress and to solicit ongoing feedback and advice about logistical or other issues that arise during user testing and the pilot trial. Following completion of the focus groups, we will conduct user testing of the developed SST-LC protocol with five older adults with lung cancer. Feedback from user testing will be used to make final revisions to the SST-LC protocol prior to beginning the pilot trial.

Dr Ramos is adding a measure to assess the impact of covid on research participants.

Selection of Subjects

Patients will be recruited from clinics of the Duke Cancer Institute. Inclusion/Exclusion criteria are listed below. These will be determined by medical chart review to ensure that participant involvement is appropriate. We are utilizing the duke opt out policy for recruitment purposes.

Inclusion criteria:

- Age ≥ 65 years
- English-speaking
- Patient has diagnosis of late stage (III-IV) lung cancer and is living at her/his home.

Exclusion criteria:

- Unable to provide informed consent
- Visual or hearing impairments that preclude participation
- Serious mental illness

On the basis of the patients coming to these oncology clinics and our previous studies with similar populations, we expect that approximately 50% of the sample to be male and 50% female. Based on the ethnic make-up of patients coming to Duke clinics, we anticipate that the ethnic make-up of the entire sample will likely include Caucasian (75%), African-American (15%), Asian (5%) and Hispanic (5%). Recruitment efforts will focus on actively seeking to attract an ethnically diverse sample representative of demographics of the local recruitment area.

Risk/Benefit Assessment

Potential medical risks and discomforts: We do not anticipate any significant medical risks or discomforts to lung cancer patients who consent to participate in the study. Should the health status of

a patient in a way that precludes further study participation, that participant will be able to withdraw from the study as needed (which will be stipulated in the consent form as per Duke University policy).

Potential psychological risks and discomforts: The study is not targeting treatment of psychiatric illnesses, and we do not anticipate that the participants will be at substantial risk of suicidality, self-harm, or harm to others. The PI is a licensed clinical psychologist and works in a research lab that has an in-place, IRB-approved procedure for protection of research participants experiencing acute increases in distress which will be available throughout the duration of this project. All study staff will be trained in this existing procedure (which includes 24-hour phone access to the PI as needed). A situation in which a study participant is at imminent risk of harming him/herself or others may necessitate involuntary reporting and intervention. This risk of loss of confidentiality will be discussed and disclosed to potential participants at the time of consenting. Because psychological interventions for emotional distress invariably require the patient to attend to discomfort and associated thoughts and feeling, participation in the study will be associated with some risk of increased psychological distress, which may include discomfort with attention to unpleasant thoughts, feelings or body sensations. Some individuals may experience an initial increase in undesirable feelings with increased attention to them. SST already contains procedures for identifying, anticipating, and minimizing discomforts that often characterize psychotherapy and related preventive interventions, and the interventionists will be thoroughly trained in how to use those techniques to simultaneously protect participants and assist them in gaining benefit from the intervention. The clinician rating and self-report measures are commonly used for research and clinical purposes. There are no known risks related to their administration, although these assessments may uncover strong and potentially disturbing feelings about the subject's past or present emotional state. In previous studies (spearheaded by co-mentors Drs. Keefe and Strauman) involving over 1,000 patients, using similar self-report batteries, they have encountered little resultant distress. We will, however, train research staff collecting data to be sensitive to the nature of illness-related issues. When necessary, participants who experience psychological distress related to filling out self-report questionnaires will be referred for appropriate psychiatric or psychological care.

Other risks: The other risks of this study are those associated with confidentiality. In any research project of this type, there is some risk attendant to confidentiality of self-report data. To ensure confidentiality of data, all records will be identified by the participant's identification number, not by name. All raw data will be kept in a locked file cabinet. Protocols and completed measures will be coded by number only, for the purpose of data tabulation and analysis. Data will be stored in protected research computer servers/systems at Duke which employ strict procedures to ensure subject confidentiality. All data will be entered into the computer by study staff only, utilizing code numbers only for subject identification. All information given by the participants will be kept confidential. There will be only one exception to this strict confidentiality policy, which pertains to information obtained during the research assessment which would indicate that the participant is seriously suicidal and may pose a significant and acute risk of self-harm, or if there is a risk of elder abuse. Subjects will be informed of this exception, and will also be informed that such information will be shared with the P.I. of the study and their Attending Physician so that timely and appropriate arrangements for psychiatric assessment and care can be made. This information is included in the Informed Consent form.

Potential Benefits of the Proposed Research to Human Subjects and Others.

There are several potential benefits to study participants. First, participants who receive SST may experience improvements in quality of life, mental health, physical functioning, and self-efficacy. Second, this study will provide data on the feasibility, acceptability, and promise of the new intervention. If study findings suggest that the intervention is feasible, acceptable, and shows promise, we will propose a subsequent, larger multi-site RCT the aims of which will be to test the short- and long-term efficacy of the new intervention on patient outcomes, and on health care utilization. This program of research has the potential to meaningfully enhance the mental health, physical functioning and overall well-being of older adults with late stage lung cancer, change clinical practice, and substantively enhance the quality of life of patients.

Importance of the Knowledge to be Gained.

The risks associated with this study are small compared to the information that will be obtained. The information gathered may lead to major advances in our understanding of how to protect the emotional health physical health of patients with lung cancer. If successful, it may enlarge our repertoire of methods for effectively enhancing the well-being of cancer patients.

Data Analysis & Statistical Considerations

We will use an alpha=5% level of significance to test hypotheses associated with the specific aims. Statistical models will be implemented in statistical software packages (e.g., SAS V9.4 package). Where possible, will use multiple linear regression models (PROC GLM) for continuous outcomes/scales after transforming them to normality, and generalized linear regression models (PROC LOGISTIC, PROC GENMOD) for Likert/ordinal scales and binary outcomes.

For outcomes that are repeatedly assessed throughout the course of the study (e.g., CORE-10), we will use linear mixed-effects regression models implemented in PROC MIXED. All necessary quality-control measures will be implemented to prevent attrition and drop outs to follow-up. All models will be fitted under assumption of MAR utilizing full information likelihood functions, if missing outcomes/covariates are unavoidable.

Evaluating feasibility and acceptability. These measures will be assessed using standard summary statistics and exploratory data analyses.

Initial evaluation of efficacy. Due to small sample size, a simpler model will used instead based on the pre-post difference Likert scales as the dependent variable and use a paired t-test. Specifically, we will compute post-treatment/pretreatment difference scores to assess changes in several outcome measures (that are measured at three time points; distress/CORE-10, depression/BDI, functioning/FACT-L, and physical activity/PASE using simple paired t-tests.

Additional secondary data analysis: We will assess Treatment Quality and Fidelity using evaluations of each VC session by trained raters.

Sample size/power considerations. Sample size of N=30 has been chosen based on effect sizes estimated from previous studies, and after accounting for a 15% attrition rate. We will recruit N=30 older adults, resulting in N=25 effective number of participants. Using the PASS 2015 power program, to attain 80% power at alpha=5% level, we can detect an effect size (Cohen's d) around 0.37 for analyses analyzing pre to post change scores, using paired t-tests, paralleling published findings.iii Similarly, for testing the time effect on the repeatedly assessed distress outcome, we can detect a Cohen's F around 0.50 using a mixed-effects within-subject model with T=12 repeated assessments.

Data & Safety Monitoring

Adverse events will be assessed and fully documented using the standard adverse event forms (including determination of both Adverse Events and Serious Adverse Events as defined by HHS and NIA policies) approved by the Duke University Medical Center IRB and reported to the IRB by the Principal Investigator. For each event, the PI will provide the onset, duration, severity, expectedness, relatedness, outcome and any actions taken. Any related, unanticipated, serious adverse events (i.e., unexpected fatal or life-threatening events related to the study) and severe non-serious adverse events (i.e., requiring therapeutic intervention) will be reported to the IRB and the NIA Project Officer within 24 hours. Any related, unanticipated, moderate or mild adverse events (i.e., alleviated with simple therapeutic treatment or not requiring treatment) will be reported to the IRB and the NIA Project Officer within 3 days.

We do not plan to form a Data and Safety Monitoring Board because this is a Phase I (treatment development) project which will be adapting an existing behavioral intervention. We note that our research team has extensive experience with behavioral interventions in both medically healthy and compromised populations.

We also note that Drs. Ramos (PI), Strauman, and Keefe (co-mentors) all are licensed clinical psychologists with active clinical practices and emergency backup. As a team, we will monitor the safety of study participants by doing the following on an ongoing basis:

- Review the research protocol, informed consent documents, and plans for data and safety monitoring.
- Review methodology used to help maintain the confidentiality of study data.
- Review adverse event documentation and make recommendations regarding protection of the safety of study participants.
- Evaluate the progress of the study, including periodic assessments of data quality and timeliness, participant recruitment, accrual and retention, participant risk versus benefit, performance of the study sites, and other factors that may affect study outcome.