Resilience Measurement, Prediction, and its Role in Older Adults with Late-Stage Lung Cancer

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Purpose of the Study

This 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 psychological measures and physical performance measures as indicators of resilience will be acceptable and feasible to participants.

(Hypothesis 1) Participants will complete at least 80% of SST treatment sessions (Hypothesis 2). There will be an association between measures of psychological and physical resilience. (Hypothesis 3). Lastly, we hypothesize that participant's psychological and physical resilience scores will improve from baseline to post-intervention as a function of receiving the SST intervention.

Background & Significance

Resilience is defined as the capacity of people to effectively cope with, adjust, or recover from stress or adversity (physiologically, psychologically or socially). In the context of cancer across the disease continuum, resilience refers to an individual's protective attributes and/or personal characteristics. These attributes, which are thought to be modifiable, promote successful adaptation to cancer, including, meaning and purpose in life, sense of coherence, positive emotions, self-esteem, self-efficacy, cognitive flexibility, coping, and social support. Collectively these factors all positively correlate with quality of life, and may enhance physical functioning. Research evidence support findings that suggest prolonged stress and poor psychosocial functioning negatively impact physical health. For example, prolonged stress influences biological mechanisms that lead to hypertension and blood pressure reactivity, pro-inflammatory cytokines (e.g. C reactive protein), and the development of metabolic syndrome.

Healthcare providers and healthcare systems benefit from the knowledge and understanding of associations between psychological and physical functioning variables that promote resilience in older adult patients. These associations inform treatment, prevention, and intervention protocols through a biopsychosocial perspective. However, how resilience is studied, measured, and addressed among older adults living with serious, life-limiting illness such as advanced lung cancer is an understudied-- yet much needed area of research. In addition it is challenging to conceptualize how certain aspects of the resilience model apply to more chronic stressors.

Psychological Resilience, as noted above, is one component to enhance an older adult's quality of life. Physical resilience is yet another source to enhance quality of life. Using the NIA's definition of physical resilience as "a dynamic property which enables individuals to resist or recover from the effects of a physiological or stressor" (e.g., serious disease such as advanced lung cancer), I want to address in this proposal how I can examine the connection between psychological resilience and physical resilience in the context of a behavioral intervention to characterize different resilient phenotypes.

With the piloting of SST-LC underway with our study team, for this RCCN proposal I will 1) test measures of psychological and physical resilience on an sample of 15 older adults with late-stage lung cancer, and

2) test whether psychological resilience measures is associated with physical resilience measures in efforts to test prediction models in a future larger RCT study.

Design & Procedures

Fifteen older adults (ages 65 and older) will be recruited from clinics of the Duke Cancer Institute.

Older adults with lung cancer will receive the SST intervention with sessions that range between 8 (recommended minimum number of sessions) to a maximum of 12 sessions lasting on average of 30-45 minutes. The intervention will be delivered by video conference. The design is a single-arm study, with no control or placebo group condition.

The four content/topic areas that are covered across the 8-12 SST intervention sessions are as follows:

1) Orientation Phase of SST. Participants are provided with a rationale for treatment that focuses on the importance of self-regulation for well-being in the context of advanced cancer.

2) Exploration Phase of SST. This phase consists of having patients examine successful and unsuccessful interpersonal interactions, functional difficulties, and their self-evaluations and goal pursuit strategies while coping with advanced cancer. Patients then identify and analyze their explicit or implicit preferences for certain kinds of personal goals.

3) Adaptation Phase of SST. The patient and interventionist work together to address each treatment goal, using change strategies and compensatory strategies that include helping the patient to modify goals or to learn to pursue them via different means that are a better fit to their current life circumstances, physical, limitations, or personality traits.

4) A maintenance plan is developed with each patient. The maintenance plan includes a list of strategies to be used daily (e.g. self-monitoring forms), short-term goals (e.g. becoming more active in self-rewarding activities) and long-term goals.

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

Subject Recruitment

Potentially eligible candidates will be identified from each oncology provider's clinic schedules via medical chart review. This pre-identification process involves pre-screening of patients using their medical records on major characteristics (e.g., disease stage, current treatment status,) to reduce the unnecessary burden of contacting patients who will not screen in or of contacting patients who may be ill. Study staff will contact providers to obtain approval (as needed) to contact the potential participant. If the provider approves, a letter from the patient's provider will be sent to a candidate summarizing the research study. We will include a phone number for the patient to call to indicate that she is not interested in pursuing the study further.

A total of 15 patients will be recruited from Duke Cancer Center to complete study procedures.

Participants will have the opportunity to consent electronically via redcap database or by paper over the telephone. After completing a baseline assessment, participants will be sent sealed study materials along with the instructions regarding the study interventionist's name and contact information. All sessions will be conducted by trained interventionists with a Masters or doctoral degree in psychology or clinical social work and certified competent in the interventions by the PI. Dr. Ramos will hold regular supervision sessions among the interventionists to ensure adequate quality of the delivered interventions. All supervision sessions are confidential; no identifiable information about participants is retained in supervision records.

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 the 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.

There are no known risks related to their administration, although these assessments may uncover strong and potentially difficult feelings about the subject's past or present emotional state. In previous studies (spearheaded by co-mentor Dr. Strauman) involving over 1,000 patients, using similar self-report batteries, they have encountered little resultant distress. We will, however, train research staff to collect 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 of studying measures that capture physical and psychological resilience.

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

Because this is a small pilot study with a small sample size power calculations are inappropriate. Below is a summary of the planned data analysis:

Descriptive statistics will be used to analyze SST-LC attendance, responses to questionnaire items, and sociodemographic data. Outcome measure data will be analyzed on an as per protocol basis. Standardized mean differences (with Hedges adjustment for small sample size) and 95% confidence intervals to examine the relative size of the intervention effect across the different measures. Scores are interpreted as positive intervention effects when the post-intervention values of negative affect are lower than baseline; and when post-intervention values of efficacy, affect, cognitive appraisal, coping, resilience, physical functioning and activity are higher than baseline. Psychological resilience and physical resilience self-report scores from baseline to 1-month follow-up will also be analyzed.

All quantitative analyses will be performed using IBM SPSS statistics software.

Participants enrolled in the study will complete participation across 2-4 months.