Principal Investigator: Dr. Evelinn Borrayo, Ph.D.
COMIRB No: 16-2621
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Study Title: A Stepped Care Intervention to Reduce Disparities in Mental Health Services among Underserved Lung and Head-and-Neck Cancer Patients and their Caregivers

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You are being asked to participate in a research study because you or your loved one has received a diagnosis of lung cancer (LC) and/or head-and-neck cancer (HNC). This form provides you with information about the study. A member of the research team will describe this study to you and answer all of your questions. Please read the information below and ask questions about anything you do not understand before deciding whether or not to take part in this study.

Why is this study being done?

This study will evaluate how useful a mental health counseling program (a *stepped-care program*) is compared to *usual care* for mental health at your hospital. The *stepped-care program* aims to help LC and HNC patients and their caregivers to better manage stress and emotions, such as feeling anxious or depressed, while the patient undergoes cancer treatment.

Other people in this study

We will have up to 222 patients and 222 caregivers (a total of 444 participants) from the Denver Health and Hospital Authority, University of Colorado Cancer Center, National Jewish Hospital, and Saint Mary's Hospital and Medical Center (St. Mary's) participating in the study.

What happens if I join this study?

If you join this study, you will complete an initial survey with information about yourself. We will use this information to determine if you meet the criteria to be assigned to a clinical trial. If you do not meet criteria, you will remain in the study but you will not be assigned. Those in the clinical trial will be randomly assigned to either the *stepped-care program* or to the *usual care* at your hospital (to be *enhanced* with information about local and national mental health resources).

If you are in the *stepped-care program*, we will ask about your feelings via the initial survey. You will receive counseling in "steps" that match if you feel mild, moderate, or severe anxiety or depression. You will answer another survey about your feelings again at 6 weeks, 3 months, and 6 months. You will be moved to the next counseling step if your feelings remain or are worse. If at any time you or your Counselor thinks that your anxiety or depression is getting worse, we will give you another survey to determine if you need to (a) move up a step for more services or (b) refer you out to specialized services. Participants receiving *usual care* who feel more anxiety or depression at 6 weeks, 3 months, or 6 months will be referred to specialized mental health services at your hospital or to local community mental health services depending on availability.

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For the initial survey, you will be asked to answer questions about yourself, about your feelings, how well you believe you can cope, how stressed you feel you are, and about your quality of life (if you are a patient) or about the burden of caring for a patient in cancer treatment. If you are in the clinical trial, you will be asked to answer all of questions again at 6 weeks, 3 months, and 6 months. You can answer the questions online, over the phone, or in person at the hospital. All the questions take about 30 minutes to answer and will differ if you are a patient or a caregiver.

Initial survey and scale for all LC and HNC patients and for all caregivers (30 questions):

(1) Initial survey (30 questions) – You will report information about yourself such as your age, gender, income, etc. and about your treatment if you are a patient or about caregiving.

(2) Hospital Anxiety and Depression Scale (HADS, 14 questions) – A global measure of whether your feelings of anxiety and depression combined are normal, mild, moderate, or severe.

Six questionnaires for patients (115 question for HNC patients; 124 questions for LC patients):

(1) PROMIS-Ca Form v1.0 – Depression (30 questions) – It measures if you are feeling depressed and if your feelings are mild, moderate or severe due to your cancer diagnosis.

(2) PROMIS-Ca Form v1.0– Anxiety (22 questions) – It measures if you are feeling anxious and if your feelings of anxiety are mild, moderate or severe due to your cancer diagnosis.

(3) Coping Self-Efficacy (CSE, 26 questions) – It measures how well you feel you can deal with the stress related to your cancer diagnosis and the intense treatment you might be receiving.

(4) FACT-Lung Cancer version 4 (36 questions) – It measures how LC patients feel their health quality of life (daily living) is affected by lung cancer and its treatment.

(5) FACT-Head-and-Neck Cancer (27 questions) – It measures how HNC patients feel that their health quality of life (daily living) is affected by HNC and its treatment.

(6) Perceived Stress Scale (PSS, 10 questions) – It measures how stressful you feel that the events in your daily life have been over the last month.

Five questionnaires for caregivers (105 questions):

(1) PROMIS Form v1.0 – Depression (28 questions) – It measures if you are feeling depressed and if your feelings are mild, moderate or severe (likely due to your caregiving role).

(2) PROMIS Form v1.0– Anxiety (29 questions) – It measures if you are feeling anxious and if your feelings of anxiety are mild, moderate or severe (likely due to your caregiving role).

(3) Coping Self-Efficacy (CSE, 26 questions) – It measures how well you feel you can deal with the stress related to caring for a patient undergoing an intense cancer treatment.

(4) Perceived Stress Scale (PSS, 10 questions) – It measures how stressful you feel that the events in your daily life have been over the last month.

(5) Zarit Burden Interview (ZBI, 12 questions) – It measures how burdened you feel due to being the primary caregiver of the cancer patient.

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What are the possible discomforts or risks?

Discomforts you may experience from the study could be feeling emotional due to the interview questions. However, this is unlikely since the questions asked are not about sensitive topics. In case you feel distressed, support services are available. You can call the toll-free phone number of the Cancer Information and Counseling Line (CICL) at 1-800-525-3777. In addition, participants who feel distress or discomfort when they complete our survey can be connected to Dr. Kristin Kilbourn, who is part of our research team and is a licensed Clinical Psychologist.

What are the possible benefits of the study?

LC and HNC patients and their caregivers often suffer from a lot of stress and emotional distress while patients' undergo an intense and harsh cancer treatment. However, the usual care they receive for their distress is limited and mostly offered when patients are in crisis. Thus, an important benefit of the study is that it will compare these usual care practices to a creative and new kind of "counseling program in steps" Counseling will be offered in steps matched to the individual's feelings of distress (mild, moderate, or severe). It will seek to improve their feelings, and will allow them to potentially cope better and reduce stress among other benefits.

Who is paying for this study?

This research is being paid for by the Patient-Centered Outcomes Research Institute (PCORI).

Will I be paid for being in the study?

You will be paid $25 each time you answer our surveys. If you complete the initial survey you will receive $25. If you are assigned to the clinical trial and answer 3 additional surveys at 6 weeks, 3 months, and 6 months and will be paid another $75 for your participation in this study.

Will I have to pay for anything?

It will not cost you anything to be in the study.

Is my participation voluntary?

Taking part in this study is voluntary. You have the right to choose not to take part in this study. If you choose to take part, you have the right to stop at any time. If you refuse or decide to withdraw later, you will not lose any benefits or rights to which you are entitled.

What if I am on probation?
If you are on probation, you may still be eligible for this study. Your participation in this study will not interfere with your requirements for probation; therefore, you are still required to fulfill all requirements of your probation.

Injury and Compensation

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You should inform your care provider(s) if you decide to participate in this research study. If you have questions about anything related to the research study, you may call Dr. Borrayo at (970) 988-2201 and/or your private physician. Dr. Borrayo should be informed about any injury you experience while you take part in this study. If you are hurt by this research, we will give you medical care if you want it, but you will have to pay for the care that is needed.

Who do I call if I have questions?

The researcher leading this study is Dr. Evelinn A. Borrayo. You may ask any questions you have now but if you have questions, concerns, or complaints later, you may call her at (970) 988-2201. You will be given a copy of this form, please keep it for future reference.

If you have questions about your rights as a participant in this study, call Dr. Borrayo or you can also call the Colorado Multiple Institutional Review Board (COMIRB) at 303-724-1055.

Who will see my research information?

The University of Colorado Denver (CU-Denver) and its affiliated hospital(s) have rules to protect information about you. Federal and state laws including the Health Insurance Portability and Accountability Act (HIPAA) also protect your privacy. This part of the consent form tells you what information about you may be collected in this study and who might see or use it. The institutions involved in this study include:

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- University of Colorado Denver
- Denver Health and Hospital Authority
- National Jewish Hospital
- University of Colorado Cancer Center
- Saint Mary's Hospital and Medical Center (St. Mary's)

We cannot do this study without your permission to see, use and give out your information. You do not have to give us this permission. If you do not, then you may not join this study.

We will see, use and disclose your information only as described in this form and in our Notice of Privacy Practices; however, people outside CU-Denver and its affiliate hospitals may not be covered by this obligation.

We will do everything we can to maintain the confidentiality of your personal information but confidentiality cannot be guaranteed. The use and disclosure of your information has no time limit. You can cancel your permission to use and disclose your information at any time by writing to the study's Principal Investigator (PI), Dr. Evelinn Borrayo at the address listed below or via e-mail at Evelinn.Borrayo@UCDenver.edu. If you do cancel your permission to use and disclose your information, your part in this study will end and no further information about you will be collected. Your cancellation would not affect information already collected in this study.

Evelinn A. Borrayo, PhD
1380 Lawrence Street Suite 1100
Denver, CO 80204-2059

We will do everything we can to keep your records confidential; however, this cannot be guaranteed. Records that identify you, including a signed consent form such as this, may be viewed by the following people:

- Federal agencies that oversee human subject research.
- People at the Colorado Multiple Institutional Review Board (COMIRB).
- The study's doctors and his/her team of researchers.
- PCORI, who is the organization paying for this research study.
- Officials at the University of Colorado Denver, who are in charge of making sure that we follow all of the rules for research.

We will audio-record your Counseling sessions for supervision of the Counselor to ensure proper clinical practices but your name will not be disclosed to the supervisor. We might also talk about this research study at meetings. We might also print the results of this research study in relevant journals. But we will always keep the names of the research participants, like you, private. You have the right to request access to your personal health information from the Investigator.

This authorization does not expire. However, you may withdraw this authorization for use and disclosure of your personal health information by providing written request to the Investigator. If you withdraw this authorization, the institution, the Investigator, the research staff, and the

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research sponsor will no longer be able to use or disclose your personal health information from this study, except so far as that they have already relied on this information to conduct the study.

Information about you that will be seen, collected, used and disclosed in this study:

- Name and Demographic Information (age, sex, ethnicity, address, phone number, etc.)
- Portions of your previous and current Medical Records that are relevant to this study, including but not limited to Diagnosis(es), History and Physical, laboratory or tissue studies, radiology studies, procedure results
- Research Visit and Counseling Session(s) records (e.g., audio-recordings of sessions)
- Psychological and mental health surveys
- Alcoholism, Alcohol or Drug abuse
- Records of referrals made to specialized mental health services

Agreement to be in this study

I have read this form about the study or it was read to me. I understand the possible risks and benefits of this study. I know that being in this study is voluntary. I choose to be in this study, and I will get a copy of this consent form.

Signature: _____ Date: _____

Print Name: _____

Consent form explained by: _____ Date: _____

Print Name: _____

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