

Title: A Smoking Cessation Intervention for Oncology Clinics in Puerto Rico - A Pilot Trial

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ABSTRACT

Continued tobacco smoking following a diagnosis of cancer is associated with decreased survival time, increased risk of recurrence, second primary malignancies, increased treatment complications and treatment failure. Despite the adverse health effects of continued smoking, 50% of patients with cancer who smoked prior to diagnosis continue to do so after diagnosis. Unfortunately, tobacco use treatment is not considered a core service at most of the National Cancer Institute (NCI) cancer centers, leaving the majority of cancer patients who want to quit with no formal assistance. In addition, there have been few smoking cessation trials for cancer patients and many of the trials that have been conducted have lacked biochemical verification of abstinence. There are very few smoking cessation clinical trials that have targeted Hispanic smokers, and we are unaware of any that have targeted Hispanic smokers currently undergoing cancer treatment. A recent NCI Conference on Treating Tobacco Dependence at Cancer Centers (NCI-CTTDCC) highlighted the need for improvement in these treatments, and has called for studies that evaluate methods for integrating cessation treatment into care delivery and sustaining cessation. There is evidence that cancer patients are more nicotine dependent and have more comorbid emotional and mood symptoms than the general population of smokers, suggesting that they may need more intensive forms of treatment than what is available through standard of care approaches. Quitlines have been found to significantly increase abstinence rates compared to brief interventions. While the effectiveness of quitlines in providing cessation support to smokers in the general population is well established, the willingness of cancer patients who are currently undergoing cancer treatment to use quitlines is unknown. In line with the recommendations of the NCI-CTTDCC to evaluate strategies for integrating cessation treatment into cancer care, the current pilot study will assess the feasibility of adding a quitline counseling component to clinical practice guideline-based brief counseling provided by medical staff; and estimate the effect size of the combined brief intervention counseling and quitline (BC+) compared to the brief counseling alone (BC) on abstinence at 3 and 6 month follow-ups. To accomplish these aims, cancer patients undergoing cancer treatment who are current smokers will be randomly assigned to receive brief counseling plus smoking cessation pharmacotherapy delivered in the oncology clinic setting (BC) or the BC intervention plus 7 counseling sessions delivered by the Puerto Rico Quitline (BC+). Smoking outcomes will be assessed at 3 and 6 months post-cessation. Data from this trial will be used to support larger scale clinical trials evaluating quitline delivered smoking cessation treatments for Hispanic cancer patients.

SPECIFIC AIMS

Continued tobacco use has been documented in cancer patients.¹⁻⁵ In addition to decreasing survival time ⁶, continued smoking predisposes cancer patients to recurrence and second primary malignancies. ⁷⁻⁹ Continued tobacco smoking following diagnosis increases treatment complications and failure rates¹⁰⁻³⁰ and is related to diminished quality of life. ¹⁶ Despite these adverse health effects, 50% of patients with cancer ³¹ who smoked prior to diagnosis continue to do so after diagnosis. Unfortunately, tobacco use treatment is not considered a core service at most of the National Cancer Institute (NCI) cancer centers, leaving the majority of cancer patients who want to quit with no formal assistance.³² In addition, there have been few smoking cessation trials for cancer patients and many of the trials that have been conducted have lacked biochemical verification of abstinence.³³ Few smoking cessation clinical trials have targeted Hispanic smokers, and we are unaware of any that have targeted Hispanic smokers currently undergoing cancer treatment. A recent NCI Conference on Treating Tobacco Dependence at Cancer Centers (NCI-CTTDCC)³⁴ highlighted the need for improvement in these treatments, and has called for studies that evaluate methods for integrating cessation treatment into care delivery and sustaining cessation.^{31, 34-44} Previous trials have found that physician-based versus no treatment control, and tailored behavioral interventions versus general health education, do not significantly increase abstinence rates among cancer patients. ^{33,43,45,46} This may be due to the use of brief and less intensive interventions. There is evidence that cancer patients have high levels of nicotine dependence and comorbid emotional and mood symptoms, which suggests the need for more intensive forms of treatment. ^{40, 43, 47-56.}

Quitlines have been found to significantly increase abstinence rates compared to brief interventions. ⁵⁰ The ability to deliver counseling treatment by telephone may be an especially important benefit to cancer patients, who may be ill and experiencing side effects from their cancer treatments, and may live at great distances from their treatment settings. In addition to providing access to extended treatment with counseling relative to what is typically available in the clinic setting, quitlines can provide treatment that is tailored to patients and remove numerous barriers to treatment access. While the effectiveness of quitlines in providing cessation support to smokers in the general population is well established, the willingness of cancer patients who are currently undergoing cancer treatment to use quitlines is unknown. The current study will evaluate the feasibility of adding a quitline counseling component to clinical practice guideline-based brief counseling^{50,58} provided by medical staff; and will explore the effect of this combined treatment on smoking cessation at 3 and 6 months in cancer patients who are currently undergoing treatment. Data collected from this pilot study will be used to support larger scale clinical trials evaluating quitline delivered smoking cessation interventions for Hispanic cancer patients.

Specific Aim1: To assess the feasibility of adding a quitline counseling component to brief clinic-based counseling and pharmacotherapy (BC+) in cancer patients currently undergoing cancer treatment. Measures of feasibility will include:

- Rate of recruitment
- Rate of retention
- Completion of quitline treatment sessions

Specific Aim 2: To estimate the treatment effect of the BC + intervention relative to brief counseling and pharmacotherapy only (BC) on abstinence at 3 and 6 month follow-ups.