



Patient participation in cancer clinical trials: A pilot test of lay navigation



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ABSTRACT

Background: Clinical trials (CT) represent an important treatment option for cancer patients. Unfortunately, patients face challenges to enrolling in CTs, such as logistical barriers, poor CT understanding and complex clinical regimens. Patient navigation is a strategy that may help to improve the delivery of CT education and support services. We examined the feasibility and initial effect of one navigation strategy, use of lay navigators.

Methods: A lay CT navigation intervention was evaluated in a prospective cohort study among 40 lung and esophageal cancer patients. The intervention was delivered by a trained lay navigator who viewed a 17-min CT educational video with each patient, assessed and answered their questions about CT participation and addressed reported barriers to care and trial participation.

Results: During this 12-month pilot project, 85% (95% CI: 72%–93%) of patients eligible for a therapeutic CT consented to participate in the CT navigation intervention. Among navigated patients, CT understanding improved between pre- and post-test (means 3.54 and 4.40, respectively; *p*-value 0.004), and 95% (95% CI: 82%–98%) of navigated patients consented to participate in a CT. Navigated patients reported being satisfied with patient navigation services and CT participation.

Conclusions: In this formative single-arm pilot project, initial evidence was found for the potential effect of a lay navigation intervention on CT understanding and enrollment. A randomized controlled trial is needed to examine the efficacy of the intervention for improving CT education and enrollment.

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1. Introduction

In 2015 cancer is expected to cause more than 589,000 deaths in the US [1]. From a societal perspective, clinical trials (CT) are vital to the discovery of efficacious new cancer treatments to reduce the burden of cancer. From the perspective of a cancer patient, CT participation often represents access to clinically advanced treatment options that are delivered with meticulous attention to the treatment protocol. In the US, approximately 20% of cancer patients

are eligible for a cancer CT [2]. However only 3–5% of US cancer patients actually participate in a CT [2]. Participation rates are even lower among minority, rural, elderly and other underserved populations [3–6]. Multi-level factors hinder CT enrollment, including not being offered the opportunity to participate, lack of understanding about CTs, logistical issues such as cost, transportation, complex clinical regimens, as well as systems issues such as lack of physician knowledge about available CTs [7].

To date, most interventions to help patients overcome barriers to CT participation have involved relatively brief educational interventions. However, patient enrollment in CTs has not been impacted by brief interventions such as standard CT educational material [3–6] and modified consent forms [8,9]. More tailored and interactive educational interventions have yielded more promising

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results. In two randomized controlled trials (RCTs) that tested interactive computer-based CT educational formats, interactive formats were associated with greater willingness to enroll in a CT compared to standard CT educational videos or brochures [10,11]. In two studies that tested CT educational interventions tailored to African Americans [12] or to common patient misperceptions about CTs [11], patients reported greater willingness to participate in CTs following the intervention. Interventions with the greatest potential to increase CT enrollment may be those that are interactive or tailored to patient learning needs; but there are limited data testing these types of interventions.

The National Cancer Institute (NCI) and the American Society of Clinical Oncology (ASCO) recently summarized consensus recommendations for research strategies that need to be tested for improving patient participation in CTs [2]. In this report, patient navigation was recommended as a strategy that warrants testing. In the clinical setting, patient navigation generally refers to strategies that provide personal assistance to help patients overcome specific educational, communication, and logistical barriers to treatment and follow up medical care. The patient navigation approach could be adapted and tested with the goal of overcoming the issues that pose barriers to CT participation. Since patient navigation is an individually tailored and interactive intervention, it has strong potential as a strategy to improve personalized CT decision-making and enrollment.

However, there are many operational definitions of navigation. Applying the concept of navigation in a healthcare setting to improve CT participation, two single arm trials have tested CT nurse navigator interventions, one comprised of African American breast cancer patients and the other of all types of cancer patients [13,14]. Both studies reported greater CT participation among navigated patients compared to historical controls, providing evidence that patient navigation may be an effective strategy for supporting patients in regard to CT participation [13,14]. Thus, a lay navigation approach remains to be evaluated. The present study adds to the small but growing evidence base by evaluating a lay navigation intervention designed to provide patients with education about CTs and assistance to overcome barriers to CT participation.

2. Methods

A prospective cohort study was conducted to evaluate the feasibility and potential effect of a lay CT navigation intervention on CT understanding and enrollment. The intervention design was guided by the Chronic Care Model [15,16]. Specifically, for patients who enrolled in the CT navigation intervention, we incorporated CT decision support, linkage to community and health-system resources, education about the CT treatment regimen for patients who chose to participate in a CT to empower them in their role to adhere to the therapeutic regimens, and clinical reminders.

2.1. Setting and participants

The study population was comprised of lung and esophageal cancer patients potentially eligible for a therapeutic CT at one of three NCI-affiliated cancer centers in South Carolina and Georgia. To be eligible for this study, patients had to be age 18 or older, planning to receive primary therapy at the cancer center, and be potentially eligible for a therapeutic trial. No limitations were placed on histological type/stage of cancer or cancer recurrence status, as CTs take place across early to late stage cancers. The intervention took place between September 2010 and September 2011. The study was approved by the institutional review boards at each cancer center site, and all participants provided informed consent prior to study participation.

2.2. Clinical trial portfolio available at participating study sites

Prior to the start of the study, efforts were made to ensure that trials were available across a wide range of lung and esophageal cancer types and stages. Care was taken to ensure that trial availability reflected the patient population of the representative sites. Across the overall trial portfolio, 47% of trials were single arm trials (14% Phase 1 and 33% Phase 2) and 53% were Phase 3 randomized controlled trials, with similar proportions of single arm and randomized trials by study site. Of the 3 cancer center sites, one site had 19 lung and 3 esophageal trials open, one site had 5 lung and 3 esophageal trials open, and one site had 12 lung and 2 esophageal trials open. All study sites had 1–3 trials open for patients with Stage 1B–Stage 4 non-small cell lung cancer, but only one site had a trial open for stage 1A patients. All study sites had trials open for limited and extensive small cell disease and esophageal cancer.

2.3. Intervention design

2.3.1. Choice of lay navigators to deliver the intervention

Lay navigators were chosen to deliver the navigation intervention for several reasons. First, lay navigators who do not have clinical responsibilities can focus solely on addressing non-clinical barriers (sociocultural, economic, organization and individual) that often disrupt CT recruitment and retention. Second, lay navigators can be used as an affordable and sustainable resource to extend the reach of clinical staff in providing patient education and logistic and emotional support. Thus, the non-clinical lay navigators were non-clinical, lay staff who were recruited and trained prior to study implementation. Each study site added one salaried lay navigator who worked 20 h per week for this study. Lay navigator salaries ranged from \$30,000–\$35,000 per year (prorated to a 20 h week), with educational level ranging from a licensed practical nursing degree to a non-clinical master's degree. At each site, the navigator was supervised by a CT nurse manager and supported by a designated physician champion, whose role was to help ensure the clinical team understood the navigator's support role and responsibilities.

2.3.2. Navigator training

The lay navigators participated in a three-part training program that included a 1.5-day didactic session, shadowing experiences, a 1 day practical session in which role playing was used to reinforce mastery of navigation skills, and bi-weekly conference calls. Details of the training have been previously reported in detail [17], but briefly the training protocol is described below:

For the didactic session, content included: (1) navigator's role and responsibilities to facilitate CT education and provide practical assistance to overcome barriers to care, with a focus on scope of work boundaries (i.e. focus on CT education and support; not on CT enrollment; no clinical advice or counseling), (2) clinical aspects of lung and esophageal cancer, (3) overview of clinical trials, (4) informed consent/confidentiality, with an emphasis on core components of informed consent, neutral presentation of CT option, informed consent as a process, and patient's prerogative to decline a CT or drop out at any time; (5) health literacy, (6) navigation documentation/recordkeeping, and (7) time management/priority setting. To further ensure that all lay navigators had a robust understanding about ethical practices in CT recruitment and their expected roles, each navigator completed the University of Miami's Basic Citi Course Training for Human Subjects Research [18] and the Education Network to Advance Cancer Clinical Trials (ENACT) Foundation's Training Course on Enhancing Recruitment and Retention Practices among the Medically Underserved [19].

For the shadowing experience, navigators shadowed key clinical

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