

Original Article

Strategies to Support Recruitment of Patients With Life-Limiting Illness for Research: The Palliative Care Research Cooperative Group

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Abstract

Context. The Palliative Care Research Cooperative Group (PCRC) is the first clinical trials cooperative for palliative care in the U.S.

Objectives. To describe barriers and strategies for recruitment during the inaugural PCRC clinical trial.

Methods. The parent study was a multisite randomized controlled trial enrolling adults with life expectancy anticipated to be one to six months, randomized to discontinue statins (intervention) vs. to continue on statins (control). To study recruitment best practices, we conducted semistructured interviews with 18 site principal investigators (PIs) and clinical research coordinators (CRCs) and reviewed recruitment rates. Interviews covered three topics: 1) successful strategies for recruitment, 2) barriers to recruitment, and 3) optimal roles of the PI and CRC.

Results. All eligible site PIs and CRCs completed interviews and provided data on statin protocol recruitment. The parent study completed recruitment of 381 patients. Site enrollment ranged from 1 to 109 participants, with an average of 25 enrolled per site. Five major barriers included difficulty locating eligible patients, severity of illness, family and provider protectiveness, seeking patients in multiple settings, and lack of resources for recruitment activities. Five effective recruitment strategies included systematic screening of patient lists, thoughtful messaging to make research relevant, flexible protocols to accommodate patients' needs, support from clinical champions, and the additional resources of a trials cooperative group.

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Conclusion. The recruitment experience from the multisite PCRC yields new insights into methods for effective recruitment to palliative care clinical trials. These results will inform training materials for the PCRC and may assist other investigators in the field. *J Pain Symptom Manage* 2014;48:1021–1030. © 2014 American Academy of Hospice and Palliative Medicine. Published by Elsevier Inc. All rights reserved.

Key Words

Palliative care, recruitment, research networks, clinical trials

Introduction

Research is necessary to guide high-quality palliative care and the selection of treatments to maximize health outcomes for these patients and their families. Palliative care research encompasses patients with diverse diagnoses, all with serious and incurable illnesses that are potentially life limiting. In the period of illness leading up to death, treatments must be chosen with parsimony, maximizing benefit while avoiding harm. Studies relevant to hospice and palliative care comprise less than 1% of clinical trials, and seriously ill patients are systematically excluded from other research.¹ Few investigators have the practical and methodological expertise to conduct these studies, making it critical to disseminate successful research strategies.^{2,3}

Palliative care clinical trials must enroll sufficient numbers of patients for scientific validity, yet participation is not easy for this population.⁴ Recruitment is a major challenge—80% of palliative care investigators awarded funding from the National Cancer Institute, and the National Institute of Nursing Research (NINR) reported recruitment barriers, and participation rates of 50% or less are common.^{5,6}

Barriers to recruitment to palliative care trials are ethical and practical in nature. Patients and families become physically and emotionally vulnerable in the face of serious illness, adding potential burden, or even risk, to research. Practical concerns include communication barriers, such as expressive aphasia or delirium, or limited mobility or energy.⁷ Ethical concerns, which may influence approval by institutional review boards (IRBs), include patient vulnerability, high rates of cognitive impairment and emotional distress challenging true informed consent, clinician-researcher role conflicts, and research burden.^{7,8}

Clinical trial networks are one mechanism to pool expertise and enhance research productivity and quality.⁹ The first Palliative Care Research Cooperative Group (PCRC) in the U.S. was initiated in 2010 with foundational funding from the NINR that began in January 2011 (NINR UC4NR012584). The PCRC's overarching mission is to develop scientific methods that lead to meaningful evidence for decreasing the suffering of patients with advanced or potentially life-limiting illnesses and their caregivers. Specific objectives include expanding research capacity, conducting high-impact clinical trials, and training new investigators (Fig. 1). The conduct of the PCRC's inaugural multisite clinical trial provided a unique opportunity to examine effective strategies for enrolling seriously ill patients. We interviewed investigators and research coordinators from nine participating PCRC sites to describe barriers and strategies for recruitment to palliative care clinical trials.

Methods

To understand best practices for recruitment to palliative care clinical trials, we interviewed key research personnel from PCRC sites. Data collection consisted of semistructured

<p>PCRC Mission To develop scientifically based methods that lead to meaningful evidence for decreasing the suffering of patients with advanced or potentially life-limiting illnesses, and their caregivers including family members and providers of care.</p> <p>Vision To provide excellent palliative and end-of-life care at the bedside based on best evidence and a scientific underpinning for what we do, so that:</p> <ul style="list-style-type: none"> • No patient dies alone, in pain, or without dignity • Palliative care responds effectively to suffering at all points in the life / illness trajectory • Palliative care enhances living <p>Overarching Objectives</p> <ol style="list-style-type: none"> 1. Develop palliative and end-of-life research capacity nationally through establishment of infrastructure, data systems and procedures and metrics 2. Demonstrate feasibility of a cooperative group by supporting the conduct, analysis and dissemination of high-quality interdisciplinary research in palliative and end-of-life care. 3. Train and mentor new / future clinician-scientists from multiple disciplines committed to advancing palliative and end-of-life care research.

Fig. 1. Palliative Care Research Cooperative Group (PCRC).

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