Research site mentoring: A novel approach to improving study recruitment

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Abstract

Background/Aims: The VA Cooperative Studies Program's (CSP) Network of Dedicated Enrollment Sites (NODES) is a consortium of nine VA medical centers (VAMCs) with teams (nodes) dedicated to enhance performance, compliance, and management of CSP multi-site clinical trials. The West Haven CSP Coordinating Center (WH-CSPCC), study coordinating center for CSP #577, Colonoscopy Versus Fecal Immunochromical Test (FIT) in Reducing Mortality from Colorectal Cancer (CONFIRM) trial, and NODES piloted a "site mentoring" (hub-and-spoke) model. In this model, a node site would work one-on-one with a low enrolling CONFIRM site to identify and overcome barriers to recruitment. The aim was to determine the impact of a research site mentoring model on study recruitment and examine site-level characteristics that facilitate or impede it.

Results: Sites in the mentorship pilot had an average improvement of 5 ± 4 participants randomized per month (min −2.6; max 11.6; SD 4.3). Four of ten sites (40%) demonstrated continuous improvement in the average number of randomized participants per month after the pilot intervention and at three-month follow-up (post-intervention), as compared to the five-month period preceding the intervention. An additional two sites (20%) demonstrated improvement in the average number of randomized participants per month after the pilot intervention, and sustained that level of improvement at three-month follow-up (post-intervention). Additionally, six of ten sites (60%) demonstrated an increased number of participants screened for eligibility immediately following the intervention and at three-month follow-up (post-intervention). Only one site showed a decreased monthly average of randomized participants shortly after the intervention and through the three-month follow-up period.

Conclusions: The site mentoring model was successful in improving recruitment at low enrolling CONFIRM sites. An additional feasibility assessment is needed to determine if this mentoring model will be effective with other CSP trials.

1. Introduction

Clinical trials play a significant role in advancing healthcare and its delivery to patients around the world. Given their critical function in healthcare and biomedical research it is essential that study sites are able to effectively and efficiently recruit and enroll eligible participants, as defined by the study specific inclusion/exclusion criteria. A study’s inability to enroll its expected number of participants presents significant challenges to obtaining an adequate sample size and providing statistical power to detect clinically meaningful effects on study outcomes [1–3]. These challenges may create burnout and low morale among study team members, and potentially decrease the likelihood of a study sponsor funding a particular investigator’s future research proposals [4]. When considering these challenges, it is critical for
clinical researchers to consider and develop effective and innovative strategies during the active recruitment phase of the clinical trial. The Department of Veterans Affairs (VA) is the United States’ largest integrated healthcare system and provides comprehensive care to more than 8.9 million Veterans each year [5]. The Cooperative Studies Program (CSP), a division of the VA Office of Research and Development (ORD), was established as a clinical research infrastructure to provide coordination for and enable cooperation on multi-site clinical trials and epidemiological studies that fall within the purview of VA [6]. The West Haven CSP Coordinating Center (WH-CSPCC) is one of five CSP coordinating centers responsible for the planning and conduct of large multi-site clinical trials in the Department of Veterans Affairs [7]. The VA Cooperative Studies Program’s (CSP) Network of Dedicated Enrollment Sites (NODES) [8,9] is a consortium of nine VA medical centers (VAMCs) that have teams (nodes) in place dedicated to enhancing the overall performance, compliance, and management of CSP multi-site clinical trials. WH-CSPCC is the coordinating center responsible for CSP #577, Colonoscopy Versus Fecal Immunochemical Test (FIT) in Reducing Mortality from Colorectal Cancer (CONFIRM). CONFIRM is a large, simple, multi-site, randomized, parallel group trial directly comparing screening colonoscopy with annual FIT screening in average-risk individuals [10].

The primary aim of this pilot initiative was to determine the impact of a remote mentoring model on study recruitment at ten low enrolling CONFIRM sites. The secondary aim was to identify site-level characteristics associated with low enrollment. Results from the pilot will inform sponsors and sites on how to align resources and expectations to improve recruitment and the overall success of the clinical trial.

2. Methods

The CONFIRM study was approved by the VA Central Institutional Review Board (Protocol #: 11-03) and study participants provided informed consent either in-person or over the telephone. The study was actively recruiting in 38 VA medical facilities, had an expected weekly enrollment target of 10 study participants, and the WH-CSPCC identified ten CONFIRM sites with low study recruitment that would benefit from site-based mentoring. Eight site nodes were paired with one CONFIRM site, and the ninth was paired with two CONFIRM sites. NODES management and the WH-CSPCC developed a site assessment tool (Appendix A) to gather feedback from the CONFIRM site teams. This site assessment tool was then used by the respective NODES Manager to conduct baseline phone interviews with each site team member and their Site Investigator (SI). The results of these interviews identified common themes (Fig. 1) related to site recruitment and site team performance barriers. Based on these common themes, each NODES Manager ascertained essential resources and established action items for their assigned site, including specified metrics (e.g., individual team member goals, weekly strategy or resource application reports, etc.) ancillary to those necessitated by the WH-CSPCC. Throughout the duration of the pilot, NODES Managers provided their assigned site teams with remote mentorship, a resource allocation assessment, and performance monitoring. Remote mentorship included frequent communication with sites through e-mails, conference calls, and Microsoft Lync® during the intervention phase. There were an average of 14 contacts per site made during the intervention. The

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<th>Abbreviations</th>
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<tr>
<td>CBOCs Community Based Outpatient Clinics</td>
<td>Network of Dedicated Enrollment Sites</td>
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<tr>
<td>CONFIRM Colonoscopy Versus Fecal Immunochemical Test in Reducing Mortality from Colorectal Cancer</td>
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<tr>
<td>CSP Cooperative Studies Program</td>
<td>Office of Research and Development</td>
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<td>FIT Fecal Immunochemical Test</td>
<td>PACT Patient Aligned Care Team</td>
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<td>VA Department of Veterans Affairs</td>
<td>VA Department of Veterans Affairs</td>
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<td>VAMCs VA Medical Centers</td>
<td>VAMCs VA Medical Centers</td>
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<td>WH-CSPCC West Haven CSP Coordinating Center</td>
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The NODES identified the following common themes impacting recruitment at the ten pilot CONFIRM sites at the pre-intervention phase: Adequate Staffing (N = 7), Using Pre-Screening Algorithm (N = 5), Investigator Engagement (N = 7), Adequate Training (N = 6), PACT Clinic Engagement (N = 1), CBOC Travel Ability (N = 3), Study Activity Organization (N = 3), Adequate Patient Population (N = 3), Motivation (N = 4), Supportive Team Environment (N = 3), and Delegated Responsibilities (N = 3) (Fig. 2). The NODES pilot intervention offered personalized remedies depending on the barriers

![Fig. 1. Monthly average of randomized participants trajectories.](image-url)
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