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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, **Co**lo**n**oscopy Versus **F**ecal **I**mmunochemical Test (FIT) in **R**educing **M**ortality 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

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Abbreviations

CBOCs	Community Based Outpatient Clinics
CONFIRM	Colonoscopy Versus Fecal Immunochemical Test in Reducing Mortality from Colorectal Cancer
CSP	Cooperative Studies Program
FIT	Fecal Immunochemical Test
NODES	Network of Dedicated Enrollment Sites
ORD	Office of Research and Development
PACT	Patient Aligned Care Team
VA	Department of Veterans Affairs
VAMCs	VA Medical Centers
WH-CSPCC	West Haven CSP Coordinating Center

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 node sites 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 resource allocation assessment included review of the site infrastructure and the study teams' ability to recruit at CBOCs (Community Based Outpatient Clinics), utilize a Clinical Applications Coordinator (CAC) and Pre-Screening Algorithm, acquire electronic devices/mobile recruitment equipment, and establish access to primary care providers in Patient Aligned Care Teams (PACT). Performance monitoring included ongoing review of the standardized enrollment report and site assessment tool created for the pilot. NODES and WH-CSPCC study leadership met bi-weekly to discuss the status of each pilot site and its challenges and successes. This workgroup determined the best strategies for implementing action items identified during the initial site assessment period. The pilot was conducted over a five-month period (February 2016–June 2016) and data were reviewed, compared, and analyzed prior to the intervention (September 2015–January 2016), during the intervention and for an additional three-month follow-up period (July 2016–September 2016) to assess long-term sustainability of site improvement plans at the local level.

At the end of the pilot period, post-intervention site team interviews were conducted by the respective NODES Manager using the same site assessment tool utilized at the beginning of the pilot period. The outcomes were assessed by the WH-CSPCC and national CONFIRM study leadership teams through data and narrative reports provided by each NODES Manager, where feasibility status was determined, and/or provision of additional mentorship was provided, as needed.

3. Results

3.1. Study team, patient population, and clinic engagement summary

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

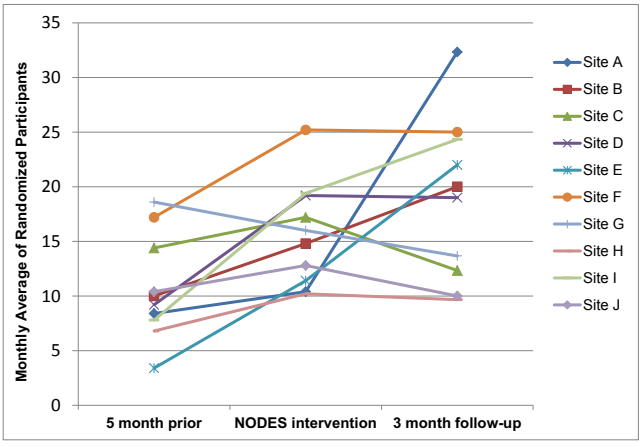

Fig. 1. Monthly average of randomized participants trajectories.