Contemporary Clinical Trials 53 (2017) 29–35

Contents lists available at ScienceDirect

Contemporary Clinical Trials

journal homepage: www.elsevier.com/locate/conclintrial

Patient Navigation in Medically Underserved Areas study design: A trial with implications for efficacy, effect modification, and full continuum assessment

Yamile Molina [a,*], Anne E. Glassgow [a], Sage J. Kim [a], Nerida M. Berrios [a], Heather Pauls [a], Karriem S. Watson [a], Julie S. Darnell [b], Elizabeth A. Calhoun [a,c]

[a] University of Illinois at Chicago, 1603 West Taylor Street, Chicago, IL 60622, USA
[b] Loyola University Chicago, 1032 W. Sheridan Road, Chicago, IL 60660, USA
[c] University of Arizona, 550 East Van Buren Street, Phoenix, AZ 85004, USA

ARTICLE INFO

Article history:
Received 11 July 2016
Received in revised form 30 November 2016
Accepted 3 December 2016
Available online 8 December 2016

ABSTRACT

Background: The Patient Navigation in Medically Underserved Areas study objectives are to assess if navigation improves: 1) care uptake and time to diagnosis; and 2) outcomes depending on patients' residential medically underserved area (MUA) status. Secondary objectives include the efficacy of navigation across 1) different points of the care continuum among patients diagnosed with breast cancer; and 2) multiple regular screening episodes among patients who did not obtain breast cancer diagnoses.

Design/Methods: Our randomized controlled trial was implemented in three community hospitals in South Chicago. Eligible participants were: 1) female, 2) 18+ years old, 3) not pregnant, 4) referred from a primary care provider for a screening or diagnostic mammogram based on an abnormal clinical breast exam. Participants were randomized to 1) control care or 2) receive longitudinal navigation, through treatment if diagnosed with cancer or across multiple years if asymptomatic, by a lay health worker. Participants' residential areas were identified as: 1) established MUA (before 1998), 2) new MUA (after 1998), 3) eligible/but not designated as MUA, and 4) affluent/ineligible for MUA. Primary outcomes include days to initially recommended care after randomization and days to diagnosis for women with abnormal results. Secondary outcomes concern days to treatment initiation following a diagnosis and receipt of subsequent screening following normal/benign results.

Discussion: This intervention aims to assess the efficacy of patient navigation on breast cancer care uptake across the continuum. If effective, the program may improve rates of early cancer detection and breast cancer morbidity.

1. Introduction

Underserved women disproportionately die from breast cancer [1,2] In 1990, Dr. Harold Freeman introduced patient navigation as a potential solution to reduce disparities through addressing patient-level barriers and optimizing coordination of care [3,4]. In 2005, the Patient Navigation Research Program (PNRP) was implemented throughout the country to assess the potential of navigation to improve cancer care uptake and outcomes [5]. One PNRP site was Chicago [6,7], which exhibited increasing disparities due to differential access to technological advances in breast cancer care [8–10]. PNRP and other efficacy studies have subsequently demonstrated navigation is effective for improving breast cancer care uptake and time to diagnostic resolution [11–22].

Gaps however exist. First, with the exception of the Denver PNRP [17], extant individual-level RCTs to evaluate the efficacy of navigation have been relatively small (<250 participants total) [19,18,21,20] or have relied on self-report outcomes [22]. There is a need for more large individual-level RCTs, especially those relying on medical records, to confirm the effects of navigation. Second, most studies have not assessed if and how intervention efficacy may depend on macro-level factors. This gap is surprising, given navigation programs are more likely to be located within less-resourced settings, including Medically Underserved Area designated communities [23]. Such communities frequently have high percentages of racial/ethnic minorities and exhibit multiple levels of disadvantage, including high rates of poverty and limited healthcare access. These communities may thus be particularly in need of and benefit from navigation services [23], although such differential effects have been understudied. There is a need to examine how the efficacy of navigation varies depending on such contextual factors.

To address these needs, we conducted the Patient Navigation in Medically Underserved Areas (PNMUA) study. PNMUA design

* Corresponding author at: 1603 West Taylor Street, Chicago, IL 60622, USA.
E-mail address: ymolin2@uic.edu (Y. Molina).

http://dx.doi.org/10.1016/j.cct.2016.12.001
1551-7144/

leveraged the following strengths in response to gaps in the literature: large sample size; electronic medical record-confirmed outcomes; and a priori plan to assess effect modification of MUA designation on intervention efficacy. The main objectives were to assess: 1) if navigation improved recommended breast cancer care uptake (screening or diagnostic mammography) and time to diagnosis following an abnormal mammogram; and, 2) if navigation effects depended on patients' residential MUA status. Our study had an additional vantage point due to its longitudinal nature. Most navigation studies concerning the full cancer care continuum have been qualitative in nature [12]. Little is known about navigation's efficacy throughout the continuum among women diagnosed with breast cancer (i.e., screening, diagnostic care, and treatment) as well as among women who do not receive cancer diagnoses (i.e., multiple episodes of screening). Thus, we also planned secondary analyses to assess the efficacy of navigation across: 1) different points of the care continuum among patients diagnosed with breast cancer; and 2) multiple regular screening episodes among patients who did not obtain breast cancer diagnoses.

2. Study design and methods

2.1. Overview

PNMUA is a large individual-level RCT, which ultimately included 9506 women (3754 navigated, 575 active control, 5177 passive control). As described above, the primary objectives were to assess the efficacy of navigation and how it might vary by macro-level factors (i.e., MUA designation). The primary predictor was study arms – intervention (navigation) and control (usual care) groups. Primary outcomes were uptake of initial recommended breast cancer care and time to diagnostic resolution. Secondary objectives were to examine the efficacy throughout the continuum among women ultimately diagnosed and ultimately not diagnosed with breast cancer. Fig. 1 depicts a simplified overview of study processes described below, including randomization and study arm-specific interactions between navigators and participants.

2.2. Conceptual framework and hypotheses

PNMUA draws from the conceptual model adopted by the eight National Institutes for Health-funded Centers for Population Health and Health Disparities (CPHHD) [24]. The model is a multilevel, transdisciplinary approach that takes into account three primary determinants for understanding how population and individual risk factors interact. First, the distal determinants are considered fundamental causes of inequities and are reflected at the population level (e.g., population social conditions, policies that affect social conditions, policymaking bodies). Second, the intermediate determinants are immediate social contexts, physical contexts, and social relationships in which the distal effects are experienced (e.g., neighborhood, social networks, pollution). Third, the proximal determinants refer to individual characteristics (e.g., demographic, intrapersonal, interpersonal).

In the context of PNMUA, patient navigators were expected to improve health outcomes through addressing the proximal determinants of health. Further, the trial selected the sites for the intervention in such a way that we could examine moderating effects of macro-level factors, specifically one at the intermediate determinant level, on our proximal-level intervention. Fig. 2 depicts these conceptualizations.

We had two primary hypotheses. First, study arms were expected to differ in breast cancer care uptake and diagnostic resolution, theoretically due to the intervention's effect on proximal determinants. Navigated women were hypothesized to be more likely to undergo screening and diagnostic care in a timely fashion, because navigators are able to diminish/remove barriers to care (e.g., cancer worry; lack of childcare; lack of transportation) relative to women randomized to standard care. This hypothesis was informed by a growing body of studies

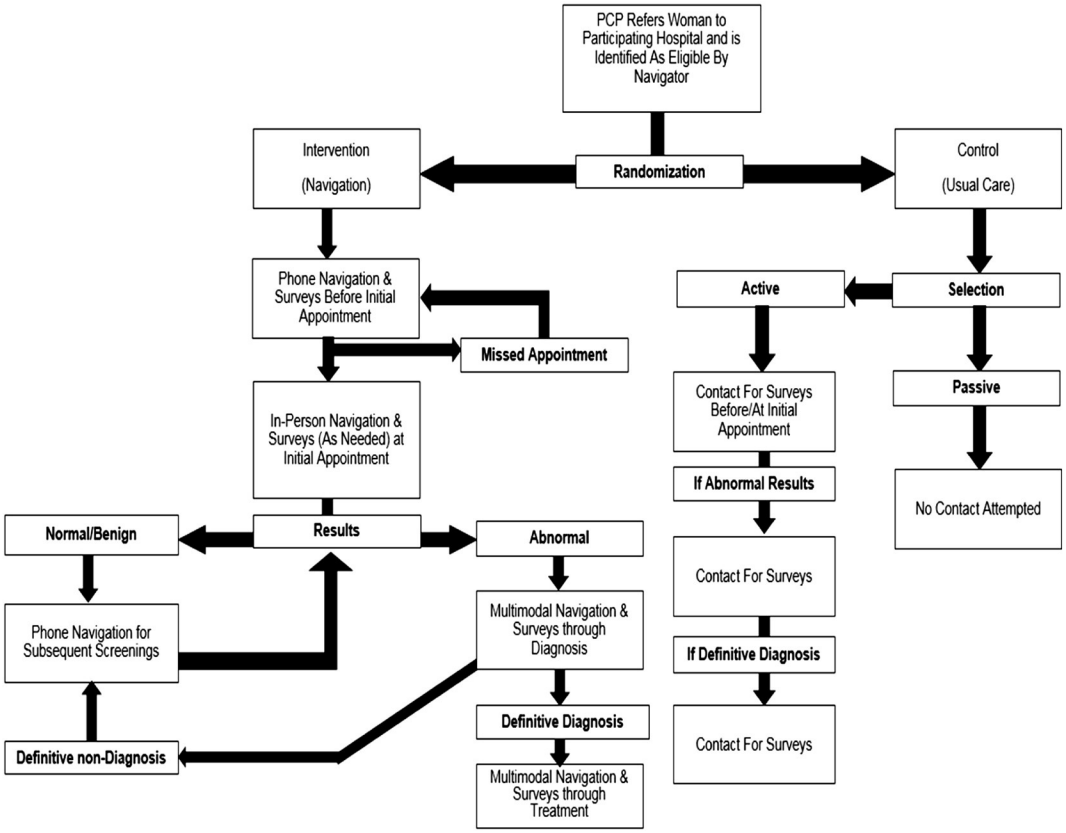

Fig. 1. Overview of PNMUA study processes.