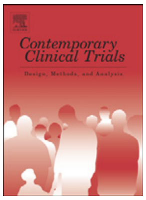
Contemporary Clinical Trials 39 (2014) 169–182

Contents lists available at ScienceDirect

Contemporary Clinical Trials

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



Review

Strategies addressing barriers to clinical trial enrollment of underrepresented populations: A systematic review

Caren Heller[a], Joyce E. Balls-Berry[b,c,*], Jill Dumbauld Nery[d], Patricia J. Erwin[e], Dawn Littleton[e], Mimi Kim[f,g], Winston P. Kuo[h,i]

[a] *Weill Cornell Medical College, Department of Medicine, Division of Medical Ethics, United States*
[b] *Mayo Clinic, Department of Health Sciences Research, Division of Epidemiology, United States*
[c] *Mayo Clinic, Center for Clinical and Translational Science Office for Community Engagement in Research, United States*
[d] *University of California San Diego, Clinical and Translational Research Institute, United States*
[e] *Mayo Clinic Libraries, United States*
[f] *NC TraCS Institute, The University of North Carolina at Chapel Hill, United States*
[g] *Center for Biobehavioral Health Disparities, United States*
[h] *Interferon Expression Signature Diagnostics, Cambridge, MA 02139, United States*
[i] *Harvard Catalyst, Laboratory for Innovative Translational Technologies, Harvard Medical School, Boston, MA 02115, United States*

ARTICLE INFO

Article history:
Received 20 March 2014
Received in revised form 1 August 2014
Accepted 2 August 2014
Available online 15 August 2014

Keywords:
Recruitment
Clinical trials
Minority

ABSTRACT

Background: Underrepresentation of racial and ethnic minorities in clinical trials remains a reality while they have disproportionately higher rates of health disparities.
Objective: The purpose of this study was to identify successful community-engaged interventions that included health care providers as a key strategy in addressing barriers to clinical trial enrollment of underrepresented patients.
Design: A systematic review of the literature on interventions addressing enrollment barriers to clinical trials for racial and ethnic minorities was performed in Ovid MEDLINE, EBSCO Megafile, and EBSCO CINAHL. The systematic review identified 360 studies, and 20 were selected using the inclusion criteria. An iterative process extracted information from the eligible studies.
Results: The 20 selected studies were analyzed and then grouped by first author, nature of the clinical research initiative, priority populations, key strategies, and study outcomes. Nine of the studies addressed cancer clinical trials and 11 related to chronic medical conditions, including diabetes, hypertension management, and chronic kidney disease. The key strategies employed were categorized according to their presumed impact on barriers incurred at distinct steps in study recruitment: clinical trial awareness, opportunity to participate, and acceptance of enrollment. The strategies were further categorized by whether they would address barriers associated with minority perceptions of the research process and barriers related to how studies were designed and implemented.
Conclusion: Multiple and flexible strategies targeting providers and participants at provider sites and within communities might be needed to enroll underrepresented populations into clinical trials.

---

* Corresponding author at: Mayo Clinic, 200 First Street SW, Rochester, MN 55905, United States.
E-mail address: ballsberry.joyce@mayo.edu (J.E. Balls-Berry).

http://dx.doi.org/10.1016/j.cct.2014.08.004
1551-7144/© 2014 Elsevier Inc. All rights reserved.

Contents

1. Introduction

It has been 20 years since the National Institutes of Health (NIH) Revitalization Act of 1993 was signed into law and resulted in the NIH policy requiring "that women and members of minority groups and their subpopulations must be included in all NIH-funded clinical research" [1]. During these two decades, there have been many approaches to address these disparities [2–6], yet the underrepresentation of women and racial and ethnic minorities in clinical trials remains a reality while they have disproportionately higher rates of chronic diseases [2,7,8]. A recent review reaffirmed that barriers continue to exist to enrolling these populations. [9].

To address these barriers more effectively, recent reviews have emphasized the importance of interventions at multiple levels, both at the community, participant, and provider level [10–12]. Recognizing the complex and interwoven barriers between these settings, Robinson and Trochim [13] solicited perspectives of barriers across stakeholders, including health professionals, researchers and lay community members, and looked for congruence among the stakeholder groups. By using concept mapping, a mixed methods approach, they could address the multiple barriers of enrollment and found barriers both within the research system and within the communities, as was found in other reviews [10,12,14]. Following up on these findings, the purpose of the present study was to identify interventions that have been described in the literature that addressed multiple levels of barriers. Additionally, because of the importance described in the literature regarding barriers to access to clinical trials at the provider site [15–17], this review also included studies that focused on access to clinical trials through provider sites. Therefore, the objective of this review was to recognize the importance of addressing multiple barriers to enrollment and to outline which strategies address barriers within the research system, at provider sites, and within the community so that future investigators could readily assess which strategies could be relevant to their needs for promoting underrepresented enrollment into clinical trials.

2. Methods

2.1. Search strategy and selection criteria

Two experienced librarians (PJE, DL) with expertise in systematic literature reviews conducted an electronic search with input from the research team. The databases used were Ovid MEDLINE, EBSCO Megafile, and EBSCO CINAHL. The timeframe for the search was January 2001 to October 2013. A mix of text words and controlled vocabulary (subject headings) was used and included the following terms: population (e.g., ethnic groups, minorities, underrepresented), clinical trial, methods or barriers to engagement and recruitment, and outcomes or effectiveness of intervention. Studies were included that addressed minorities' perceptions of the research process. Studies that targeted providers, communities, and specific minority communities were included (n = 360).

Fig. 1 shows a flow chart that details manuscript inclusion. The search results were imported into EndNote (Thomson Reuters Bibliographic Database Manager) and duplicate citations were removed (n = 282). Studies eligibility was determined by two investigators independently (CH, JBB) based on the manuscript titles and abstracts (n = 242). Disagreements for a study's inclusion were resolved by consensus. After the literature screening, 183 articles were excluded based on the following: full text articles were unavailable, articles were actually poster presentation, or articles did not meet the criteria of being a clinical research study. A full text review was conducted on the remaining 59 articles eligible by three investigators on the study team (CH, JD, JBB). The full text articles excluded did not target health care providers to increase study participant enrollment, did not have an identified community, and did not focus on a specific clinical trial. The final independent cross-check was conducted by CH.

2.2. Extraction and synthesis

An iterative process was used to create a standardized procedure to extract information from the eligible studies. Data were grouped by first author, nature of initiative, priority populations, key strategies, and study outcomes. After the initial grouping, the data were summarized into strategies that addressed barriers at the level of the research system, at provider sites, and within the community.

3. Results

3.1. Description of the publications included for review

A total of 360 studies were reviewed and only 21 met the inclusion criteria of health care providers as a major component