Contemporary Clinical Trials 45 (2015) 34–40

Contents lists available at ScienceDirect

Contemporary Clinical Trials

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

Review

Recruitment and retention strategies in clinical studies with low-income and minority populations: Progress from 2004–2014

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ARTICLE INFO

Article history:
Received 1 May 2015
Received in revised form 25 June 2015
Accepted 6 July 2015
Available online 16 July 2015

Keywords:
Recruitment
Retention
Low-income population
Minorities
Clinical studies
Review

ABSTRACT

More than 20 years have passed since the NIH 1993 Act was initiated, and while progress has been made toward better representation of minorities and women in clinical research studies, as this review will show, there is still tremendous room for improvement. The purpose of this review was to identify the current state of literature on recruitment and retention strategies in clinical studies of low-income and minority populations. We identified 165 studies published in English between 2004 and 2014. Data extracted included information on the study type (descriptive or analytical), study design, study focus (recruitment, retention, both recruitment and retention), health outcome, specific minority group, special population or age group, if specific recruitment/retention techniques were tested, and key research findings. Particular attention was given to articles that statistically analyzed the effectiveness of recruitment and retention strategies on enrollment/retention rates. Effective recruitment and retention strategies for low-income and minority groups, differential effectiveness across groups, and implications for future research are discussed.

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1. Introduction

Traditionally, women and minorities have been underrepresented in clinical trials. However, "…the 1980's saw the great awakening of mainstream medicine to issues of women's health…and finally feminists' calls for reform in federally funded biomedical research in the US were taken up by the federal government" [1]. Subsequently, many federal initiatives came forth in an attempt to readdress both gender and racial inequities. One of the most important of these was the NIH Revitalization Act [2]. The NIH soon followed with guidelines on Inclusion of Women and Minorities as Subjects in Clinical Research

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http://dx.doi.org/10.1016/j.cct.2015.07.008
1551-7144/

[3]. The guidelines required women, minorities, and their subpopulations be included in all NIH-supported biomedical and behavioral research; in phase III clinical trials in numbers adequate to allow for valid analysis of difference in intervention effect; and that cost is not an acceptable reason for exclusion of these groups. Moreover, the Act requires that the NIH initiate and support outreach programs to recruit and retain women and minorities and their subpopulations. An October 2001 Amendment provided additional guidelines on reporting analysis of sex/gender and racial/ethnic differences in intervention effects for Phase III clinical trials.

More than 20 years have passed since the NIH 1993 Act was initiated, and while progress has been made toward better representation of minorities and women in clinical research studies, as this review will show, there is still room for improvement. In the past ten years, inclusion of ethnic and racial minorities in clinical trials has improved, but significant deficiencies remain in reporting the racial and ethnic make up of the population studied [4]. This was true in 40% of the pediatric studies cited by Walsh and Ross [5]. More recently, in 2011, Geller and colleagues published an analysis of clinical trials published in major medical journals; one-fifth of the studies did not report sample sizes by racial and ethnic groups, and 64% did not provide any analysis by racial or ethnic groups [6].

The purpose of this paper is to review the current literature on recruitment and retention strategies used for low-income, minorities, and ethnically diverse samples in clinical health outcomes research over the last ten years, 2004–2014. This study will build on other review studies [4,7–14] by first conducting a descriptive analysis of the key elements of all studies, and secondly by identifying the themes in the literature over the last 10 years. Particular attention will be given to studies that empirically tested recruitment/retention techniques or barriers to recruitment/retention.

2. Methods

2.1. Review focus

This study focused on the examination of recruitment and retention strategies for low-income, minority, and underserved populations in clinical research studies with health outcomes. We conducted a targeted assessment of the existing literature published between January 2004 and December 2014 using electronic databases and review of references citied by key review articles. Only studies published in the English language were considered for review.

2.2. Search strategies

We began with a search of the Cochrane Central Register of Controlled Trials and supplemented our review list with searches in Medline, Psych INFO, and PsycABSTRACTS. We searched the electronic databases listed above using the following search terms: (1) low-income, underserved, minorities, minority, race, racial, ethnic, African American, Black, Hispanic, Latino, Native American, or American Indian, AND (2) recruitment, retention, or enrollment, AND (3) strategies or techniques. We supplemented these searches with manual searches of references listed in key research studies and manuscripts published in targeted journals. The final search list yielded 2902 studies.

2.3. Selection criteria

After reviewing the list of results, we established a list of specific exclusion criteria. Our review was confined to those minority groups federally defined as underrepresented in research. Therefore, although the group is vastly understudied and several excellent studies were found, studies exclusively focused on Asian Americans fell outside the scope of this review. Only full-length journal articles, reports, or books were examined, excluding stand-alone abstracts, presentations, editorials, and commentaries ($n \approx 1500$ excluded). Laboratory based studies or human studies at the cellular level were excluded ($n \approx 17$ excluded). We chose to omit dental outcome studies, although we acknowledge this is an emerging field of health disparities research ($n \approx 3$ excluded). Research studies that recruited doctors, dentists, nurses, medical students, health workers, and/or aid workers were also excluded ($n \approx 21$ excluded); only studies recruiting participants, patients, families, or research subjects were examined. Several studies were excluded because they dealt with increasing participation in Medicaid or health insurance, rather than a health outcome ($n \approx 6$ excluded). Many studies were excluded because the samples that were being recruited for education and training, were reporting only efficacy, or adherence studies, rather than a specific research study. For large clinical trials with multiple published reports of the same trial, only one report was counted toward the descriptive findings with a focus on the report with detailed recruitment and/or retention techniques. The remaining studies contained the largest group of exclusions and were excluded because specific information regarding recruitment or retention techniques could not be identified, leaving a final sample of 165.

2.4. Data extraction

The process of abstracting studies was performed in three separate phases by one coauthor with all three coauthors reviewing and agreeing upon the studies to be selected. Any disagreements were resolved by group discussions. The first author entered all studies into a Microsoft Excel database and extracted information into the following variables: study type (descriptive or analytical), study design, study focus (recruitment, retention, both recruitment and retention), health outcome, specific minority group, special population or age group, if specific recruitment/retention techniques were tested, and key research findings. The first author conducted a descriptive analysis of all variables and all three coauthors examined the key findings for the use of traditional recruitment and retention strategies as well as new emerging strategies.

3. Results

3.1. Descriptive results

One-hundred and sixty-five studies were identified that met our selection criteria, were published between January 2004 and December 2014, focused on recruitment and/or retention techniques, had a study sample focused on low-income or minority populations, and examined a health outcome. We began by examining 6 variables collected from the data extraction, which are displayed in Table 1.

We found that 80% ($n = 132$) of the studies presented descriptive results. Of those 132 studies, four were descriptions of lessons learned and 14 were review articles. The remaining 20% ($n = 33$) were analytical studies that either conducted surveys or focus groups, or specifically tested the effectiveness of a recruitment or retention technique. The majority of studies (63.64%) focused exclusively on recruitment, with an additional 45 focusing and reporting on both recruitment and retention. As has been previously reported by other review studies [4,9], studies detailing and reporting retention strategies remain limited with only 9.09% ($n = 15$) of studies focusing on retention. The majority of studies reported details on study design ($n = 144$ of the 165 total), with clinical trials dominating the literature (56.25%), followed by prevention or intervention trials (15.28%), longitudinal, cohort, or multiwave studies (9.72%), observational or epidemiological studies (9.03%), qualitative, focus groups, or secondary data analysis (4.17%), cross-sectional, case control, or experimental (2.78%), and exclusively community-based participatory research that was not part of clinical trial (2.78%). While the number of studies utilizing only a community-