ELSEVIER

Journal of Clinical Epidemiology 64 (2011) 872−877

Journal of Clinical Epidemiology

Preconsent education about research processes improved African Americans' willingness to participate in clinical research

Anne L. Dunlop[a,*], Zanie C. Leroy[b], Kristi M. Logue[a], Karen Glanz[c], Boadie W. Dunlop[d]

[a]*Department of Family & Preventive Medicine, Emory University School of Medicine, Atlanta, GA 30322, USA*
[b]*Department of Women's Wellness, Atlanta Veterans' Affairs Medical Center, Decatur, GA 30033, USA*
[c]*Department of Biostatistics and Epidemiology, Schools of Medicine and Nursing, University of Pennsylvania, Philadelphia, PA 19104, USA*
[d]*Department of Psychiatry & Behavioral Sciences, Emory University School of Medicine, Atlanta, GA 30322, USA*

Accepted 21 November 2010

Abstract

Objective: To determine whether preconsent education about research processes and protections affects the willingness of African Americans to participate.

Study Design and Setting: This study examined the willingness of 192 African American outpatients (stratified by age, gender, and education) to participate in a hypothetical clinical study under varying consent conditions: phase I participants underwent a typical informed consent process and were asked to indicate whether they would be willing to participate in the hypothetical clinical study and the reasons for their decision; their responses were used to develop a preconsent educational digital video disk (DVD). Phase II participants viewed the DVD before the consent process. We compared the proportion of those who stated they were willing to participate in the clinical study using Fisher's exact tests and used qualitative methods to analyze open-ended responses.

Results: When the consent process included education about research processes and protections, significantly more patients reported willingness to participate in the hypothetical clinical study (43% vs. 27%; $P = 0.002$). Patients receiving preconsent education were significantly less likely to cite mistrust, fear of side effects, lack of perceived benefits, and privacy as reasons for not participating.

Conclusion: Preconsent education may improve the willingness of African Americans to participate in clinical research and may address important concerns about research participation.

Keywords: Clinical trial; Informed consent; Education; HIPAA; Minority groups; Patient participation

1. Introduction

African Americans are disproportionately affected by hypertension, heart disease, and cancer and experience poorer health outcomes from chronic diseases compared with whites, but they are underrepresented in clinical research trials for these and other diseases [1−3]. The adequate representation of racial and ethnic minorities in clinical trials is critical to the development of appropriate strategies to promote health and treat disease among these populations. Increasing the representation of minorities in clinical research is a national priority [4].

Numerous barriers to the participation of African Americans in clinical research have been identified, with mistrust of medicine and research being a consistent finding [5−7]. A systematic review and a study involving focus groups with urban African Americans conclude that the consent process and the language of the consent form are potential barriers to research participation and may foster mistrust [8,9]. Focus group research also reveals that accurate knowledge about research is limited among potential participants and lack of understanding and trust of informed consent procedures is problematic [10] and that the goal of the consent process is often misinterpreted by minorities as the ''signing away rights'' [11,12].

Attempts to increase the participation of African Americans in clinical research have been hampered by a lack of evidence-based successful recruitment and retention strategies.

Funding/Support: Support for the conduct of this research study was provided by the Greenwall Foundation.

* Corresponding author. Department of Family & Preventive Medicine, Emory University School of Medicine, 1256 Briarcliff Road NE, Bldg A, Ste 210-11, Atlanta, GA 30322, USA. Tel.: +404-712-8520; fax: +404-727-4562.

E-mail address: amlang@emory.edu (A.L. Dunlop).

0895-4356/$ - see front matter
doi: 10.1016/j.jclinepi.2010.11.008

What is new?

Key finding

This study compared the proportion of African American outpatients who reported willingness to participate in a hypothetical clinical research study under varying conditions: standard consent vs. preconsent education via digital video disk (DVD).

The preconsent educational DVD conveyed information about general research processes and human research protections. The study found that a significantly greater proportion of those who viewed the preconsent DVD reported willingness to participate in the clinical research study. Additionally, those who received the preconsent educational DVD were significantly less likely to cite concerns related to mistrust, fear of side effects, lack of perceived benefits, and privacy as reasons for not participating.

What this study adds to what is known?

Our study is different from previous studies because the preconsent educational DVD evaluated in our study provided general information about research processes and human research protections rather than study-specific information.

Implications of this study

Clinical investigative teams should consider incorporating preconsent educational materials into their informed consent study procedures. Given the time and expense that might be required for developing study-specific materials, it may be more feasible for some researchers or research institutions to invest in general educational materials that could be used for a host of studies rather than study-specific materials.

2. Methods

2.1. Design overview

This study examined patients' willingness to participate in a hypothetical clinical research study (involving a phase III clinical research trial of an experimental antihypertensive medication) and elicited open-ended responses regarding reasons for participating or not participating, under one of two experimental consent conditions. The study was conducted in two phases, with separate samples participating in each phase. During phase I (standard consent), participants underwent a typical informed consent process. A qualitative content analysis [13] of textual data from phase I participant responses was performed, and these findings were used to guide the development of an educational digital video disk (DVD) addressing research processes and human research protections. During phase II (preconsent education), participants viewed the educational DVD before undergoing informed consent. The main outcome was the proportion of participants in each phase who stated that they were willing to participate in the clinical research study and the reported reasons for declining enrollment (among those who were not willing). This study was approved by the Institutional Review Board of Emory University.

2.2. Setting/participants

Study participants were recruited from two private and two public primary care clinics affiliated with an academic medical center in metropolitan Atlanta. Eligible participants were African American (self-identified) outpatients aged 18 years or older, who spoke English, and who were able to provide informed consent. For each phase, a purposive strategy was used to systematically construct a sample of 192 African American outpatients stratified by age (<40 years or $\geqslant 40$ years), gender (male or female), and educational level ($\leqslant$high school diploma or $>$high school), resulting in 16 cells with 12 individuals per cell in each group. The goal of sampling was to include participants with a range of demographic characteristics with sufficient power to detect intergroup differences by age, gender, and education categories. Data collection took place at the clinic sites from August 2005 through May 2006 (phase I) and from September 2006 through February 2007 (phase II).

2.3. Experimental intervention

Phase I participants underwent a typical informed consent process for a hypothetical phase III clinical research study comparing an experimental antihypertensive medication with an established medication. The consent document was prepared according to recommended templates available from the Emory University Institutional Review Board (http://www.irb.emory.edu/researchers/formstools/formstools.cfm). The "additive" approach [14] of including all language required for authorization into the consent process was used because this is the process required by most institutional review boards [15].

After reviewing the informed consent document with the potential participant, an interviewer asked the patient whether he or she would be willing to participate in the clinical research study (yes/no) and the reasons for their decision (using an open-ended approach). Verbatim audio-recorded responses were analyzed (as described below) with the goal of understanding patient concerns about participating in the hypothetical clinical research study.

Identified patient concerns were used to develop a preconsent educational DVD (11 minutes in duration) to provide targeted patient education about research processes