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Minority recruitment into clinical trials: Experimental findings and practical implications

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Abstract

Racial and ethnic minorities in the US suffer disproportionately from obesity and related comorbidities, yet remain underrepresented in health research. To date, research on practical strategies to improve minority reach and recruitment into clinical trials is primarily descriptive rather than experimental. Within a randomized behavioral weight management trial for obese women, this recruitment experiment examined whether two characteristics of direct mail letters, an ethnically-targeted statement and personalization, increased the response rate among minority women. The ethnically-targeted statement noted ethnic-specific information about health risks of obesity. Personalized letters included recipients' names/addresses in the salutation and a handwritten signature on high-quality letterhead. Of women sent direct mail letters ($N=30,000$), those sent letters with the ethnically-targeted statement were more likely to respond than women sent letters with the generic statement, 0.8% ($n=121$) vs. 0.6% ($n=90$) respectively, $p=.03$, a 34.4% increase. Women sent personalized letters were no more likely to respond than women sent non-personalized letters, $p=.53$. In the weight management trial itself, of 267 women randomized into the trial, 33.7% ($n=90$) were minorities. Of minority women randomized into the trial, 68.9% ($n=62$) were recruited by direct mail letters: 75.8% ($n=47$) of those were sent a letter and 24.2% ($n=15$) were referred by friends/family who were sent a letter. The results indicate that a simple modification to a standard recruitment letter can have a meaningful impact on minority reach and recruitment rates. Practical implications include using ethnically-targeted, non-personalized direct mail letters and recruiting through friends/family at no additional cost.

Keywords

Ethnic minorities; diversity; recruitment; clinical trials; weight management

Racial and ethnic minorities in the US suffer disproportionately from obesity and associated co-morbidities. Yet the clinical trial literature lacks sufficient attention to these populations [1]. Indeed, 86% of weight management studies between 1966 and 2003 failed to even

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report the race/ethnicity of recruited participants [2]. Successful “reach” to minority populations—with adequate representation in randomized clinical trials—is crucial to eliminating health disparities [3].

Research on minority recruitment for randomized clinical trials is primarily descriptive. Suggested strategies for clinical trials—which typically require a high level of participant commitment and thus pose unique recruitment challenges—include direct mail, community outreach, and mass media [4, 5]. Direct mail offers two unique advantages. First, and critical to minority engagement, direct mail can simultaneously reach different minority groups dispersed across wide geographical areas and/or living in ethnically integrated areas (i.e., contexts where in-person community outreach is less feasible), and can reach individuals without access to clinical trial gatekeepers (e.g., physicians) or to community organizations with strong in-person outreach (e.g., churches).

Second, direct mail can reach many individuals with relatively little staff time and effort [6]. Letters are typically sent to tens of thousands of individuals. Thus, even a very low response rate (due to the small proportion of recipients meeting trial-specific eligibility criteria [6]) can yield sufficient absolute numbers relative to recruitment goals [7]. Response efficiency can be improved using commercially-available, worksite, or clinic mailing lists that include key eligibility criteria such as gender or age [8]. Indeed, targeting (i.e., communications for specific audiences based on group-level characteristics) is used across consumer and health research arenas [9–13].

Descriptive research shows that direct mail is an effective clinical trial recruitment strategy for the general population [e.g., 14, 15], and more effective than mass media for recruiting minorities [16, 17]. However, experimental studies are scarce [18, 19]. A recent review [20] identified only six experimental studies of direct mail recruitment strategies tested within randomized clinical trials [7, 21–25]; only two addressed minorities, described below [7, 21].

One direct mail characteristic tested experimentally within clinical trials is ethnically-targeted statements. While arguably “superficial,” social psychological research suggests that “surface-level” cues may affect minorities’ initial trust and desire to engage [26, 27]. Corporate recruitment materials with pro-diversity statements (where ethnicity was valued) increased trust among African Americans more than “colorblind” materials (where ethnicity was immaterial) [27]. Indeed, trial recruitment letters with ethnic-specific health risk information yielded a 40% higher response rate among Latinos than letters with generic information (although not statistically significant given limited sample size, $N=561$) [7]. This is consistent with evidence that effective recruitment strategies focus on recipients—their awareness of the health problem and potential impact on their own health [20]. In contrast, letters focusing on sender characteristics (e.g., same race/ethnicity as recipients) or general benefits for an ethnic group have not improved participation rates [21].

Another direct mail characteristic is personalization, e.g., addressing recipients by name [28–31]. Experimental research within randomized clinical trials is sparse; two studies found an advantage [7, 32], whereas one did not [22]. However, all three compared personalized letters to shorter communications (e.g., flyers), leaving the influence of personalization unclear.

Here, we examined whether two characteristics of direct mail letters, an ethnically-targeted statement about minority health disparities and personalization, increased response rates.

Methods

This experiment was conducted within an 18-month randomized behavioral weight management trial [33]. In the weight management trial, women ($N=267$) were recruited from Northern California communities using multiple methods, e.g., direct mail, friend/family referral, and newspaper advertisements. Women were middle-aged (48.4 ± 10.8 years old), obese ($BMI=32.1\pm 3.5$), and 33.7% ($n=90$) were non-White including Latina/Hispanic (10.5%, $n=28$), multiethnic (2 races/ethnicities; 10.1%, $n=27$), Asian (9.4%, $n=25$), Black/African American (3.0%, $n=8$), and Native Hawaiian/Pacific Islander women (0.7%, $n=2$). The trial was approved by the Stanford University Human Subjects Committee.

Participants

For the experiment, a commercial direct marketing firm identified minority women ages 21–75 years ($N=30,000$) from each racial/ethnic category in 65 diverse zip codes (M proportion of minority residents=43%) representative of the local minority distribution [34]. Women self-identified their race/ethnicity and recruitment method (e.g., direct mail) in an online screening questionnaire. Recruitment via letters was confirmed by cross-checking self-reported and mailing list contact information.

Experimental Design

To experimentally test the effect of two direct mail characteristics, women were randomly assigned to one of four letter types based on a 2×2 factorial design: statement (ethnically-targeted vs. generic) \times personalization (personalized vs. non-personalized). We tested the effect of one characteristic (e.g., statement) while adjusting for the other (e.g., personalization) using Cochran-Mantel-Haenszel chi-square tests. The experiment was not powered to detect a statement \times personalization interaction. With a total sample size of 30,000 letters, the experiment had 80% power to detect a 50% increase in response rates (0.6% vs. 0.9%), two-tailed $\alpha=.025$ (.05/2, adjusting for the two characteristics). Collapsing by characteristic, 15,000 of 30,000 letters had an ethnically-targeted statement whereas 15,000 had a generic statement; likewise, 15,000 letters were personalized whereas 15,000 were non-personalized. The primary outcome was response rate, i.e., proportion completing the online screening questionnaire.

Letter Characteristics

All letters included 10 recommended elements to increase response rates: the trial's purpose/significance, benefits to recipients, recipients' importance, how recipients were selected, sender's appreciation, sender's importance, institution's importance, style, format/appearance, and brevity [7, 28, 29].

All letters noted weight loss reduces cardiovascular disease (CVD) risk. Letters with the generic statement described health risk information for the general population:

“[CVD], such as having a heart attack, kills more women in California than any other cause of death, including breast cancer.”

Letters with the ethnically-targeted statement included the statement above and an additional statement noting health disparity risk information for multiple minority groups:

“Less well known is that many ethnic minority women—including African American, Asian American, Latina, Native American, and Pacific Islander women—are at higher risk for [CVD].”

Expanding on an approach examined previously [7], this sentence was purposefully broad, reflecting the geographic area's diversity.

Non-personalized letters were addressed “Dear Community Member” with black-and-white photocopies of the principal investigator’s signature and letterhead on standard quality paper (the ethnically-targeted, non-personalized letter is available upon request). Personalized letters included communication elements to increase response [28]: recipients’ names and addresses in the salutation and the principal investigator’s handwritten signature in blue ink on high-quality letterhead.

Results

In the experiment, the overall response rate was 0.7% ($n=211/30,000$). Women sent letters with ethnically-targeted statements were more likely to respond than women sent letters with generic statements, 0.8% ($n=121/15,000$) vs. 0.6% ($n=90/15,000$), $p=.03$, a 34.4% increase. Women sent personalized letters were no more likely to respond than women sent non-personalized letters, $p=.53$. Of 211 respondents identified as minorities by the commercial firm’s algorithm, 148 self-identified as minorities (i.e., 70.5% concordance). Of self-identified minorities ($n=148$), those sent letters with ethnically-targeted statements were more likely to respond than those sent letters with generic statements, 59.5% ($n=88$) vs. 40.5% ($n=60$), $p=.03$, a 46.7% increase.

In the weight management trial itself, 68.9% ($n=62$) of minorities randomized into the trial were recruited via letters. Interestingly, of those, 75.8% ($n=47$) were sent a letter and 24.2% ($n=15$) were referred by friends/family who were sent a letter.

Discussion

An ethnically-targeted statement in direct mail letters noting health disparities among multiple minority groups improved response rates to a weight management clinical trial. As a “surface-level” cue, the targeted statement may have suggested that ethnic identity [35] would be acknowledged in the trial setting, thereby increasing engagement [27]. Importantly, the targeted statement focused on recipients’ own health rather than sender characteristics or general benefits for an ethnic group [7, 20]. Personalized letters—costly and time-consuming to produce—did not improve response rates. Given proliferation of computerized direct mail marketing, recipients may be increasingly indifferent to seemingly disingenuous personalization.

Results suggest innovative avenues for future experimental research and replication: whether ethnically-targeted statements must be consciously perceived as personally salient, require a focus on recipients’ health, or are affected by ethnic identity [35, 36]; how to optimize recruitment through friends/family [13, 14]; and how to engage heterogeneous minority groups, such as Asian subgroups [37] and multiethnic individuals—an emerging yet understudied US demographic [38].

Study limitations included lack of data on men or on socioeconomic status and acculturation among recipients. The commercial firm’s race/ethnicity identification was not perfectly concordant with women’s self-identification (although high, 70.5%). The overall response rate was low given recipients had no affiliation with the research center. However, where recipients have established affiliations with senders (e.g., worksites, clinics), the overall response rate is likely to be higher [e.g., 6.5%; 7], and the differential effect of ethnically-targeted letters—a 34% increase with a simple, no-cost modification—is likely to have even greater potential impact. Despite study limitations, strengths included the experimental design, large sample size, breadth of minority groups recruited across a wide geographic and ethnically-integrated area, and context of an actual randomized clinical trial.

Undoubtedly, successful minority engagement depends upon substantively conveying respect, trustworthiness, and importance of diversity throughout a trial [39], not only during recruitment. Yet, these results suggest a simple modification to recruitment letters can meaningfully impact minority reach and initial engagement. Practical implications include using ethnically-targeted, non-personalized direct mail letters and recruiting through friends/family at no additional cost.

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