ann. behav. med. (2010) 40:40–48
DOI 10.1007/s12160-010-9189-1

ORIGINAL ARTICLE

Recruitment for an Internet-Based Diabetes Self-Management Program: Scientific and Ethical Implications

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Published online: 22 April 2010

Abstract
Background Little is known about the reach of Internet self-management interventions.
Purpose The aim of this study was to evaluate different definitions of participation rate and compare characteristics among subcategories of participants and nonparticipants on demographic and clinical factors using de-identified electronic medical record data.
Methods Data are presented on recruitment results and characteristics of 2,603 health maintenance organization members having type 2 diabetes invited to participate in an Internet self-management program.
Results There was a 37% participation rate among all members attempted to contact and presumed eligible. There were several significant differences between participants and nonparticipants and among subgroups of participants (e.g., proactive volunteers vs. telephone respondents) on factors including age, income, ethnicity, smoking rate, education, blood pressure, and hemoglobin A1c.
Conclusion These results have important implications for the impact of different recruitment methods on health disparities and generalization of results. We provide recommendations for reporting of eligibility rate, participation rate, and representativeness analyses.

Keywords Recruitment · Participation · Clinical trials · Representativeness · Research methods

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Introduction

A key issue in the translation of research to practice concerns the characteristics of participants in research studies. As traditionally conducted, recruitment procedures and research requirements may exclude those at high risk (often unintentionally) and result in a sample that is more motivated, has more resources, and may not represent those in the general patient population to which the research is intended to apply [1–3]. This is especially an issue with studies that use "convenience sampling" or that rely on interested volunteers to contact the research project versus studies that use one or more outreach approaches. Of particular concern is that ethnic and racial minority patients do not participate in scientific research at rates comparable with their representation in the patient population [4, 5]. However, it is poorly understood if decreased participation rates are due to inadequate outreach, an unwillingness to participate in research, or barriers to participation [6].

Interactive computer-tailored behavior-change approaches have been touted as solutions to such participation concerns because they require few or no face-to-face meetings and are available at places and times of the participant's choice [7, 8]. However, these same approaches may not be reaching certain populations due to "digital divide" issues of differential access to the Internet and other computer

technologies among different demographic groups [9–10]. Despite the importance of these issues, relatively few studies have reported on the reach of behavioral interventions in general [11] or of interactive behavior-change technologies more specifically [12]. Those reporting on reach have used a variety of definitions of participation rate, including rates among those who proactively contact the study, those who are able to be contacted and are determined to be eligible, and those attempted to contact [1, 12, 13]. In their recent review of methodological issues in Internet interventions in behavioral medicine, Danaher and Seeley [14] concluded, "More research should focus on how recruitment is best accomplished…as well as its impact on representativeness and external validity."

While there is an emerging if nonstandard literature on participation rates, far fewer studies report data on the characteristics of participants versus nonparticipants [11]. This is understandable because of the combination of human subjects issues limiting use of information on nonparticipants, lack of information about the underlying population from which research participants are recruited, and the frequent unwillingness of those who decline participation to provide information on themselves. Studies that report such data typically have been limited to basic information such as age and gender [15].

This article addresses the reach of an Internet-based intervention study on diabetes self-management that recruited from a population-based sample of health maintenance organization members having type 2 diabetes, documenting and comparing the characteristics of participants and nonparticipants. Participation issues are particularly relevant in this population, given that diabetes impacts a large and growing number of people in the USA, and racial and ethnic minorities are represented disproportionately [16]. Although the Internet has been criticized for not reaching high-risk subgroups and suffering from digital divide limitations [10, 17], there are examples of Internet-based programs that have been successful in recruiting diverse samples [18, 19].

The wealth of data available in the present study allowed us to address content issues related to participation among older adults with diabetes in this type of Internet-based intervention as well as methodological issues related to recruitment for clinical trials. Careful tracking of responses of potential participants at each stage of recruitment, along with availability of de-identified data for aggregate analyses from electronic medical records (EMRs), provided much more comprehensive information than is usually available.

The primary purpose of this study is to address the following questions: (a) What is the participation rate? (b) What are the characteristics of participants versus nonparticipants? (c) Are there differences among subgroups of participants (e.g., those who proactively volunteered vs. those who were called for participation) and nonparticipants (e.g., those who declined on the telephone vs. those unable to be contacted)? Finally, based on the results of different definitions of participation rate, we make recommendations for (a) definitions and calculation of participation rate and (b) reporting of representativeness analyses in future studies.

Methods

Design

We employed a three-arm, patient-randomized practical effectiveness trial [20, 21] to evaluate the impact of two multimedia, diabetes self-management programs, relative to "enhanced" usual care. The two Internet-based interventions were (a) a largely self-administered computer-assisted self-management condition, based on social-ecological theory and the five A's self-management model [22, 23], and (b) this program with the addition of enhanced social support that included practical but extensive ongoing support. These study conditions were compared with enhanced usual care that provided health-risk-appraisal feedback, controlled for computer interactions and inperson sessions, and recommended preventive care behaviors, but did not include the hypothesized key intervention processes of goal setting, barriers identification, problem solving, or social–environmental support. The interventions are described in more detail in Glasgow et al. [24].

Recruitment

This study was conducted within Kaiser Permanente Colorado (KPCO), an integrated managed care organization serving more than 450,000 members, including Medicare recipients. Utilizing KPCO's electronic prevention and disease population management system, HealthTrac, and the associated EMR system, HealthConnect, adults with type 2 diabetes were identified from 5 of the 14 KPCO primary care medical offices. Clinics were selected based on variability in size, location, and socioeconomic status (SES) of surrounding neighborhoods and to maximize percentage of Latino patients. All clinics and all physicians in those clinics approached for the study agreed to participate. Of the 76 Primary Care Physicians (PCPs) having patients in the study, 69% practiced in internal medicine and 31% in family practice. The number of PCPs per clinic ranged from 9 to 21. All procedures were approved by the KPCO institutional review board.

Patients eligible to participate in the study were 25 to 75 years of age and met the following inclusion criteria: (a) diagnosed with type 2 diabetes for at least 1 year and (b) body mass index (BMI) of 25 kg/m^2 or greater and at least

one other risk factor for heart disease (diagnosis of hypertension, low-density lipoprotein [LDL] cholesterol >100 mg/dL or currently prescribed a lipid-lowering agent, hemoglobin A1c >7%, or a current smoker). Patient lists from participating medical offices were derived from these characteristics. Additional eligibility criteria, determined through telephone screening, required that patients: (a) lived independently, (b) had access to a telephone, (c) had at least biweekly access to the Internet, (d) were able to read in English or Spanish, and (e) had the ability to perform mild to moderate physical activity as assessed by the Brief Physical Activity Readiness Questionnaire (PARQ) [25].

Prior to telephone recruitment, participating physicians were asked to review a list of patients from their practices having the above characteristics to identify potential participants deemed unfit to participate.

Recruitment occurred from April 2008 to July 2009. Potential participants were first mailed a letter on KPCO letterhead that explained the project and invited them to participate. The letter said that a research team member would telephone in about 10 days. The recruitment letter was written in both English and Spanish and signed by the primary investigator and the coinvestigator physician. A self-addressed, postage-paid, return postcard was included so that potential participants could proactively indicate whether they would like to receive a telephone call (opt in) or decline further contact (opt out). If no postcard was received, a project recruiter can be telephoned to provide further study information and determine eligibility.

Research assistants then called to ascertain interest, eligibility, and patient-reported demographic information regarding marital status, race, ethnicity, education level, and annual household income. Patients responding positively to the Brief Physical Activity Readiness Questionnaire were unable to complete recruitment until their PCPs validated the appropriateness of unrestricted mild to moderate activity. Eligible and interested patients were scheduled for a baseline visit at the medical office location of their respective PCPs.

Measures

Reach was assessed in two ways. First, the percent of presumed and verified eligible patients from the recruitment call who participated in the study was calculated (Fig. 1). We applied the same eligibility rate for those who ended the call before eligibility could be determined as for those whose eligibility status was verified. We also calculated a conservative participation estimate based on attempted contact by assuming that all people not contacted had declined participation, and then applying the same eligibility rate to them. The other Reach calculations determined representativeness by comparing participants to eligible patients who declined the study, using de-identified demographic and medical history information.

As shown in Fig. 1, our recruitment procedures allowed us to categorize participants and nonparticipants into different subgroups. Among those agreeing to participate on the telephone, three subgroups were identified. (a)

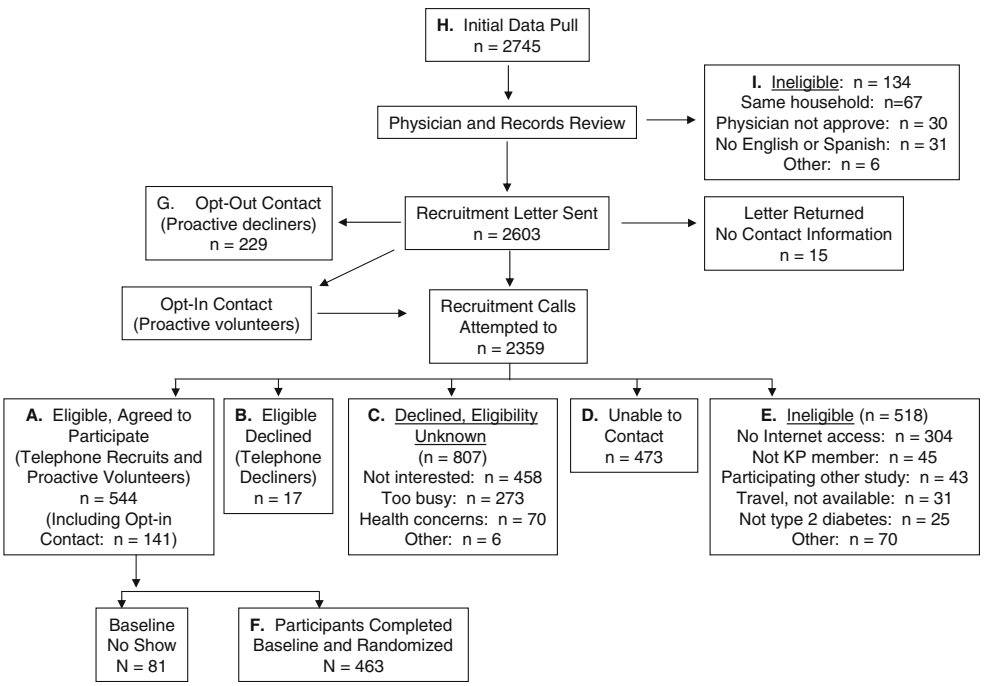

Fig. 1 Flow diagram of *My Path* recruitment result

Proactive volunteers were defined as participants who either returned the opt-in postcard or called the project office asking to volunteer after receiving the recruitment letter. They reflect a highly motivated sample such as is obtained in studies relying on advertisements or individuals who contact a project office. (b) *Telephone recruits* were those who did not proactively contact the project but agreed to participate when called and then completed baseline assessments. (c) *No shows* were those who agreed to participate but failed to show for baseline assessments despite at least eight attempts to reschedule. This subgroup is seldom described in published reports, and members of this group are sometimes considered participants and sometimes not.

We also categorized nonparticipants into three subgroups. (a) *Proactive decliners* were those who returned opt-out postcards. (b) *Unable to contact* were those who could not be reached via telephone despite making at least six attempts at different times and leaving two messages on different days. (c) *Telephone decliners* were those who declined to participate at some point during the recruitment call, usually before eligibility could be determined.

Patient Characteristics

Some demographic and clinical data were obtained via EMR or the recruitment call. Reasons for declining participation were also collected during the call. Remaining baseline data were collected at the initial visit. Demographic variables included age, gender, race, Latino ethnicity, marital status/household composition, household income, education, employment status, extent of computer use, and language preference. Biological variables included BMI, hemoglobin A1c, total cholesterol, LDL cholesterol, high-density lipoprotein (HDL) cholesterol, smoking status, and systolic blood pressure.

Hemoglobin A1c was measured on a Bio-Rad Variant II Turbo liquid by high-pressure liquid chromatography. The total cholesterol test was a serum test that first removed the cholesterol from its esters and then measured the free concentration biochemically through a modified version of the Abell Kendal method. LDL cholesterol was calculated, unless the triglyceride was >399 mg/dL, in which case it was measured directly with Roche assay on the Modular chemistry analyzer. Lipids (total, LDL, HDL, and a ratio of total to HDL cholesterol) were assayed on a Modular chemistry analyzer from Roche.

Health Literacy

During the recruitment call, all participants were assessed for health literacy using three items from the widely used S-TOFLA instrument that were identified as most sensitive [26].

Analyses

All data were entered and verified, and scores were calculated for multiple-item instruments according to previously established procedures. Descriptive statistics were computed to determine the nature of the data and to ensure that normality assumptions were met for the statistical tests employed. Participation rates were calculated based on differing numerator and denominator assumptions. Chi-square tests, one-way analyses of variance, and *t* tests were conducted, as appropriate, to determine group differences; where significant findings ($p < .05$) were obtained in three-group analyses, follow-up (Tukey or χ^2) tests were conducted to identify which groups differed.

Results

Participation Rates and Eligibility

To provide comparisons to previous research and to illustrate how different subgroups of potential participants impact participation rate calculations, we present several different participation rates in Table 1 and the rationale for each. The easiest to describe but least conservative rate is derived by dividing the number of persons agreeing to participate on the recruitment call by the number determined to be eligible, in this study 544 of 561, or 97%. A more conservative rate is calculated by dividing the number who completed baseline (463) by the number confirmed eligible on the recruitment screening call ("known eligibles"), in this study 463/(544 + 17), or 82% (Fig. 1 and Table 1).

Calculation of more conservative participation rates involves first determining an eligibility rate, which can

Table 1 Participation rate concepts, formulas, results, and citations

Concept	Formula (see Fig.1)	Participation rate
1. $\frac{\text{Agree on phone}}{\text{Known eligible}}$	$\frac{A}{A+B}$	96.9%
2. $\frac{\text{Baseline participants}}{\text{Known eligible}}$	$\frac{F}{A+B}$	82.5%
3. $\frac{\text{Baseline participants}}{\text{Assumed eligible phone}}$	$\frac{F}{A+B+ER(C)}$	49.7%
4. $\frac{\text{Baseline participants}}{\text{Attempt contact assumed eligible}}$	$\frac{F}{A+B+ER(C+D+G)}$	36.9%
5. $\frac{\text{Baseline participants}}{\text{Population}-\text{basedsample}}$	$\frac{F}{H}$	16.9%

A = confirmed eligible, agreed to participate; B = confirmed eligible, declined participation; C = declined to participate on phone before eligibility determined; D = unable to reach despite at least 6 attempts; E = determined to be ineligible during recruitment call; ER = eligibility rate defined as confirmed eligible/eligible + ineligible = A + B/(A + B + E + I) = 46.2%; F = participants who completed baseline; G = opted out of recruitment call by declining via opt-out postcard; H = members who met eligibility criteria that could be checked by EMR; I = determined to be ineligible by physician or research staff prior to mailing

then be applied to different subgroups. The eligibility rate is obtained by dividing the number of persons determined to be eligible on the telephone screening by this number plus the number of persons determined to be ineligible either prior to mailing or during the phone screening, in this study 561/(561 + 134 + 518), or 46%.

The widely used participation rate among "presumed eligible" from telephone screening applies the eligibility rate to those who declined participation on the telephone before eligibility could be determined, in this study 0.46 × 807= 371.2. This is the estimate of presumed eligibles on the telephone and can be used in turn to calculate the participation rate, dividing the number of participants by the number of known eligibles plus the number of presumed eligibles, in this study 463/(561 + 371.2), or 49.7%.

A more conservative participation rate is calculated based on all persons that the study attempted to contact. It applies the eligibility rate to individuals who were mailed materials but never reached, those who opted out via postcard, and those who declined on the telephone, in this study 473 + 229 + 807=1,509. This is the participation rate among all those "attempted to contact and assumed eligible," in this study 463/[(561 known eligible + .46 (1,509)]=36.9%. Finally, the most conservative participation rate is the number of baseline participants (463) divided by all individuals identified in the initial data pull from the EMR (463/2,745=16.9%).

The primary reasons for ineligibility were not having Internet access (n=304), living in the same household as someone already participating (n=67), no longer a KPCO member (n=45), participation in another diabetes intervention study (n=43), and no physician approval for moderate exercise (n=43). Among those declining during the recruitment call, the main reasons were "not interested" (n=458) and "too busy" (n=273).

Representativeness

Participants Versus Nonparticipants

We initially compared individuals agreeing to participate on the recruitment call with those declining participation. Participants and nonparticipants differed significantly on 6 of 11 comparisons, and some of these differences were substantial (Table 2). Compared with nonparticipants, participants were younger and less likely to be Latino,

Table 2 Characteristics of participants and nonparticipants

Characteristic	Participants[a] (n=544), mean (SD) or %	Nonparticipants[b] (n=1,534), mean (SD) or %	p
Age (y)	57.7 (9.4)	58.7 (10.2)	.041
% Female	50.4%	50.5%	.951
Race			.083
American Indian	7.4%	10.1%	
Asian	1.6%	0.8%	
Native Hawaiian	0%	0.8%	
Black/African-American	17.0%	16.9%	
White	69.2%	68.8%	
Latino Ethnicity	26.2%	35.6%	.002
Income			<.0001
<$30,000	19.1%	38.3%	
$30,000–$49,999	30.5%	29.6%	
$50,000–$69,999	22.6%	13.0%	
$70,000–$89,999	11.4%	7.9%	
$90,000 or more	16.5%	11.2%	
High school or less	21.0%	46.5%	<.0001
Smoke cigarettes	11.8%	19.2%	<.0001
BMI (kg/m^2)	34.6 (6.6)	34.1 (6.8)	.193
Systolic blood pressure (mm Hg)	128.3 (16.4)	130.1 (17.7)	.028
LDL (mg/dL)	94.4 (33.8)	93.4 (33.9)	.576
HbA1c (%)	8.2 (1.8)	8.3 (1.8)	.398

[a] Participants are defined as all those contacted by telephone, deemed eligible, and agreeing to participate

[b] Nonparticipants are defined as all those deemed eligible by telephone and declining participation, contacted by telephone but hanging up before determining eligibility, returning opt-out postcards, and unable to reach (excluding those whose recruitment letters were mailed back)

t tests and χ^2 tests, as appropriate

had higher incomes, were much more likely to have completed some post-high school education (79% vs. 53.5%) and much less likely to smoke (11.8% vs. 19.2%), and had lower systolic blood pressure.

The characteristics on which participants and nonparticipants did not differ were also informative. They were similar on gender, percentage of African-Americans and non-Hispanic whites, BMI, LDL cholesterol, and hemoglobin A1c levels. This pattern of results suggests that nonparticipants were of lower SES than participants, but given the important exception of smoking rate, not necessarily at higher medical risk.

Comparisons Among Subgroups of Participants

The recruitment procedures, sample size, and data availability in this study allowed us to compare subgroups within the broader groups of participants and nonparticipants. First, we summarize results comparing three subgroups of participants: proactive volunteers (n=135) who contacted the research team prior to being called, telephone recruits (n=328) who agreed to participate after receiving the recruitment call, and those who agreed to participate but did not show for the baseline visit (n=81). We found an almost linear pattern of results across these subgroups (Table 3), with the proactive volunteers and baseline no-shows being substantially different, and the telephone recruits being intermediate, on 9 of the 11 measures. We identified relatively large and significant differences among conditions on six characteristics and marginally significant results on one other variable (smoking status).

Proactive volunteers were older than the other two groups, most likely to be white, least likely to be Latino (16% vs. 24% and 52% for telephone recruits and baseline no-shows, respectively), and most likely to have some post-high school education. Importantly, they also differed on multiple clinical risk factors: proactive volunteers were least likely to smoke, had the lowest LDL levels, and had the lowest hemoglobin A1c levels. Cumulatively, the proactive volunteers were at lower risk and the baseline

Table 3 Characteristics of 3 subgroups of participants

Characteristic	Proactive volunteers (n=135), mean (SD) or %	Telephone recruits (n=328), mean (SD) or %	No-shows (n=81), mean (SD) or %	p
Age (y)	61.2 (8.2)[a,b]	57.2 (9.4)[a,c]	54.2 (9.7)[b,c]	<.0001
% Female	51.1%	49.2%	53.7%	.759
Race[b]				.009
American Indian	6.0%	7.0%	12.3%	
Asian	0%	2.3%	1.5%	
Native Hawaiian	0%	0%	0%	
Black/African American	10.4%	17.6%	27.7%	
White	79.9%	68.4%	50.8%	
Latino Ethnicity[b,c]	16.0%	24.2%	51.9%	<.0001
Income				.359
<$30,000	18.9%	16.9%	28.4%	
$30,000–$49,999	27.0%	31.0%	33.8%	
$50,000–$69,999	22.1%	23.3%	20.3%	
$70,000–$89,999	13.1%	11.8%	6.8%	
$90,000 or more	18.9%	16.9%	10.8%	
High school or less[b,c]	16.3%	20.2%	32.5%	.014
Smoke cigarettes[b]	8.1%	11.9%	17.1%	.140
BMI (kg/m^2)	34.4 (6.7)	34.5 (6.2)	35.2 (8.0)	.660
Systolic blood pressure (mm Hg)	128.9 (17.0)	127.5 (15.8)	130.2 (18.0)	.373
LDL (mg/dL)	86.3 (30.2)[a,b]	95.9 (34.3)[a]	101.4 (35.7)[b]	.003
HbA1c (%)	7.9 (1.4)[b]	8.2 (1.8)[c]	8.8 (1.9)[b,c]	.001

[a] In follow-up (Tukey or χ^2) test, group 1 significantly different from group 2

[b] In follow-up (Tukey or χ^2) test, group 1 significantly different from group 3

[c] In follow-up (Tukey or χ^2) test, group 2 significantly different from group 3

One-way analysis of variance and χ^2 tests, as appropriate

no-shows at higher risk than the telephone recruits. The baseline no-shows were especially likely to be Latino, to be younger, and to have elevated LDL and hemoglobin A1c levels. There were no significant differences on BMI or gender.

Comparisons Among Nonparticipant Subgroups

We compared three groups of nonparticipants: those who proactively contacted the project to decline participation (n=229), those who declined at some point during the recruitment call (n=824), and those we were unable to contact (n=473). Limited information was available on nonparticipants (Table 4). The pattern of results shows that those who proactively opted out were most different from the group that could not be contacted, and those who declined during the recruitment call fell between the other two subgroups on most measures. We obtained significant differences on four of the seven measures on which we were able to compare nonparticipant subgroups. The group that we were unable to contact was considerably younger and had the highest LDL and hemoglobin A1c levels but the lowest systolic blood pressure level. We found no differences between conditions on gender or BMI.

Discussion

This study addressed content as well as methodological and ethical issues related to recruitment to Internet-based and other behavioral medicine interventions. The first issue addressed was participation rate. We illustrated how different numerators and denominators for participants and target population can produce a wide range of participation rates, from 17% to 97%. Various methods for calculating participation rate have been employed in published research [1, 12, 13, 15], and there is clearly a need for standardization in this area.

We recommend that Internet and other intervention studies standardly report (a) the eligibility or exclusion rate, along with reasons for exclusion, and (b) the participation rate among all attempted to recruit and presumed eligible—option 4 in Table 1. This eligibility information will allow readers to judge the percent of patients for whom the intervention may not be appropriate. The recommended participation rate is closest to the widely recommended intent-to-treat analysis procedures for testing intervention results and is relatively robust to study idiosyncrasies, such as how many potential participants remain on the telephone to provide eligibility information.

By the recommended definition, our participation rate of 37% is reasonable in terms of potential population impact and exceeds that often found for face-to-face diabetes self-management programs [1, 27, 28]. Our data on identifying reasons for declining participation were not particularly informative. It would be instructive to know how many of those who declined did not want an Internet intervention, did not want to participate in research, or had other reasons.

In addition to exclusion and participation rates, we recommend reporting on the representativeness of participants. The strongest comparisons are between participants and those who decline when invited to participate. When data are unavailable for nonparticipants, we recommend the alternative of comparing participants to those in the most directly comparable health plan, diabetes registry, or community or state database (using Behavioral Risk Factor Surveillance System or other national survey data).

Although our overall participation rate was moderately encouraging, representativeness analyses revealed several concerns. Differences between participants and nonparticipants on income, age, Latino ethnicity, education, smoking rate, and some clinical indicators (blood pressure, but, interestingly, not hemoglobin A1c or BMI) suggest that the present intervention may not reach those who most need it and may not help to reduce health disparities related to SES [1]. Since so few studies have access to the substantial (de-identified) information on nonparticipants available in this study, it is impossible to know whether the results presented here are unique to this project, characteristic of Internet interventions, or applicable to research trials in general. Despite differences between participants and nonparticipants, we were able to enroll a higher percentage of Latinos than in the overall health maintenance organization population, due to offering the program in Spanish as well as English, and targeting clinics serving high proportions of Latino patients.

Investigation of subgroups within the broad categories of participants and nonparticipants produced several interesting findings. The most compelling results were the differences between the proactive volunteer group—which represents samples typically recruited from notices, public service announcements, or advertisements—and other participants. Despite speculation that such samples are likely nonrepresentative of the general population [11], this is, to our knowledge, the first empirical demonstration of the phenomenon. Replications are needed, but these findings suggest that more research should recruit from well-defined groups, such as patients in a diabetes registry, so that participation differences can be made transparent [29]. Ethical issues are involved, in that recruitment procedures limiting enrollment to those who proactively opt in, as required by some institutional review boards, may inadvertently prevent many individuals from participating, and especially those who are socioeconomically and clinically at higher risk of disease complications.

Table 4 Characteristics of 3 subgroups of nonparticipants

Characteristic	Proactive decliners (n=229), mean (SD) or %	Telephone decliners (n=824), mean (SD) or %	Unable to contact (excluding incorrect address) (n=473), mean (SD) or %	p
Age (y)	63.0 (8.6)[a,b]	60.3 (9.7)[a,c]	54.0 (10.1)[b,c]	<.0001
% Female	52.8%	51.2%	48.0%	.395
Race				
American Indian	Unknown	10.0%	Unknown	
Asian	Unknown	0.9%	Unknown	
Native Hawaiian	Unknown	0.9%	Unknown	
Black/African American	Unknown	17.2%	Unknown	
White	Unknown	68.5%	Unknown	
Latino Ethnicity	Unknown	35.6%	Unknown	
Income				
<$30,000	Unknown	38.1%	Unknown	
$30,000–$49,999	Unknown	29.5%	Unknown	
$50,000–$69,999	Unknown	13.1%	Unknown	
$70,000–$89,999	Unknown	8.1%	Unknown	
$90,000 or more	Unknown	11.2%	Unknown	
High school or less	Unknown	46.4%	Unknown	
Smoke cigarettes	16.6%	19.5%	19.9%	.548
BMI (kg/m^2)	33.9 (7.0)	34.2 (6.7)	34.1 (6.8)	.871
Systolic blood pressure (mm Hg)	132.2 (17.7)[b]	130.7 (17.9)[c]	128.2 (17.0)[b,c]	.009
LDL (mg/dL)	86.2 (30.9)[b]	91.5 (33.5)[c]	100.2 (34.7)[b,c]	<.0001
HbA1c (%)	7.9 (1.4)[b]	8.8 (2.1)[b,c]	8.8 (2.1)[b,c]	<.0001

[a] In follow-up (Tukey or χ^2) test, group 1 significantly different from group 2

[b] In follow-up (Tukey or χ^2) test, group 1 significantly different from group 3

[c] In follow-up (Tukey or χ^2) test, group 2 significantly different from group 3

One-way analysis of variance and χ^2 tests, as appropriate

This study also presents results from a relatively under-reported group, that is, those individuals who agree to participate in research but do not follow through. This category may be more common than reported [30]. Future research on the frequency of such "no-shows" is needed, as are efforts to minimize the occurrence of no-shows. Persons who "no-show" appear to be at high disease risk in terms of being almost twice as likely to smoke, having higher LDL and hemoglobin A1c, and being less educated. This group also is extremely expensive in terms of staff time.

Persons of Latino ethnicity were especially likely to "no-show," even after controlling for a host of potential confounding variables. Low levels of participation in research studies by ethnic and racial minority groups in the past have been attributed to inadequate outreach to such individuals, a reluctance to participate in research for fear of exploitation, and personal circumstances linked to lower SES that make it logistically difficult to participate [4, 6]. Our study had adequate outreach to Latinos, and we found no association between income and failure to attend the initial assessment. Is there something unique to Latino ethnicity that can explain this finding? Cultural norms, such as "simpatía," the tendency to want to please authority figures, can be proposed as a potential explanation for this finding [31]. However, given the diversity within Latinos, especially with regard to acculturation, it is difficult to make this conclusion. This finding also goes counter to a systematic review that found no overall differences in study consent rates for ethnic minorities [6]. Nevertheless, there remains a need to increase minority participation in research [4, 5]. Care must be taken to further investigate the no-show phenomenon while avoiding stigmatization of certain groups.

This study was limited to one health care organization and a single sample of diabetes patients. Also, some information that might be desired, such as the status of nonparticipants on factors such as health literacy and numeracy, self-management behaviors, and motivation to change, was unavailable. Despite these limitations, the study presents unusually comprehensive comparisons of demographic and clinical information among participant and nonparticipant groups, and the initial population-based sample was reasonably large and heterogeneous.

Conclusion

Our results illustrate the impact of differing definitions of participation rate and of different recruitment approaches on number and characteristics of participants recruited. The finding that recruitment restricted to proactive volunteers results in samples that are less diverse and at lower risk than population-based outreach recruitment has important methodological and ethical implications. Based on these results and the existing literature, we provide recommendations for reporting of eligibility rate, participation rate, and representativeness analyses in future research.

Acknowledgements This research was supported by Grant 2 R01 DK035524-21 from the National Institute of Diabetes and Digestive and Kidney Diseases. The authors have no relevant conflicts of interest to disclose.

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