ABSTRACT

Objective: To determine and quantify the unique characteristics of clinical trial participants in comparison to the general patient population.

Methods: Data were obtained from the U.S. National Health and Wellness Survey, an annual, nationally representative, Internet-based study of the healthcare attitudes and behaviors of non-institutionalized adults age 18+. The sample for analysis included 18,419 respondents who reported a diagnosis of hypertension, high cholesterol, or diabetes. Respondents reported ever participating in a clinical drug trial. They also provided information on demographics, healthcare attitudes, health habits, quality of life measured by the SF-8, and healthcare resource use in the past six months.

Results: Among respondents diagnosed with hypertension, high cholesterol, or diabetes, 7% (n=1333) have participated in a clinical drug trial. Clinical trial participants significantly differ from the general patient population in many key characteristics. Clinical trial participants are significantly older (mean age 60.5 versus 55.1, p<0.001) and more educated (college graduates 43% versus 36%, p<0.001). They experience worse physical well-being (SF-8 physical component summary score 43.1 versus 46.3, p<0.001), though they are more likely to maintain a healthy diet (50% versus 40%, p<0.001) and less likely to smoke (18% versus 23%, p<0.001).

Clinical trial participants are more willing to use alternative therapy such as acupuncture (49% versus 43%, p<0.001) and more likely to visit an alternative provider (96% versus 92%, p<0.001) and do so with greater frequency (visits 7.2 versus 6.6, p<0.001) than the general patient population.

Conclusion: Clinical trial participants are unique individuals who differ from those in the general patient population. Therefore, treatment experiences of clinical trial patients may not always be predictive of the treatment experiences of the general patient population.

INTRODUCTION

There has been much focus in the literature on barriers to participation in clinical trials, especially among cancer and HIV patients.1,2 Previous studies of clinical trial participation have reported a significantly lower likelihood of participation among patients from racial and ethnic minority groups and those with lower socioeconomic status including lower educational attainment, lower household income, and health insurance status.3,4 Disease progression, efficacy of current treatment, and co-morbid conditions also have been shown to affect patient willingness or ability to participate in a clinical trial and physician willingness or ability to suggest the possibility of participation.1

There is concern that these potential barriers to participation in a clinical trial may result in a sample that is unique and not representative of the total patient population.

OBJECTIVE

To determine and quantify the unique characteristics of clinical trial participants in comparison to the general patient population.

METHODS

Study Sampling Design and Data Collection

Data were obtained from the Consumer Health Sciences 2005 National Health and Wellness Survey (NHWS). NHWS is a comprehensive cross-sectional study of healthcare attitudes, behaviors, and treatment choices.

Data were collected through self-administered, Internet-based questionnaires in June 2005 from a nationally representative, community-based sample of U.S. adults.

Inclusion Criteria for Analysis

- ≥18 years of age
- Diagnosed by a physician with any of the following conditions: diabetes, high blood pressure, or high cholesterol

Operational Definitions

Clinical Trial Participation

Respondents to the NHWS were asked, “Have you ever participated in a clinical trial?”

Those answering “yes” are categorized as participating in a clinical trial, and those answering “no” are categorized as not participating in a clinical trial.

The therapeutic area of the trial was not specified.

Health-Related Quality of Life (HRQoL)

HRQoL in the past four weeks was assessed using the Medical Outcomes Study (MOS) 8-Item Short-Form Health Survey (SF-8).5 The SF-8 is a generic 8-item health-related quality of life measure designed to assess physical functioning, role limitations due to physical health problems, bodily pain, general health, vitality, social functioning, role limitations due to emotional problems, and mental health.6

The SF-8 yields physical and mental component summary scores that are normative to the U.S. population. The mean score for the U.S. population is 50 with a standard deviation of 10.7

Other Information Collected

Respondents also provided detailed information on demographics, healthcare and treatment attitudes, health habits, and traditional and alternative healthcare resource use in the past six months.

Statistical Analyses

Descriptive analyses were performed to compare respondents who participated in a clinical trial and those who did not participate in a clinical trial.

Significance testing was performed using chi-square for categorical variables and 2-tailed tests assuming equal variances for continuous variables.

RESULTS

Clinical Trial Participants (Figure 1)

18,419 respondents to the NHWS met the inclusion criteria for analysis. None (0%) have ever participated in a clinical trial; 17,088 (93%) never participated in a clinical trial.

Clinical Trial Participants are more likely to be male, older, unmarried, and to have a college degree than the general patient population.

Clinical trial participants are more likely to report drinking alcohol two or more times per week but are less likely to smoke cigarettes than the general patient population.

Patient Demographics and Health Habits (Table 1)

I would take an Rx every day for the rest of my life to

I am very satisfied with my healthcare (p=0.005)

Feel in control of health (p=0.028)

I would try acupuncture (p<0.001)

Friends consider me a good source of health information (p=0.002)

Doing all I can to maintain a healthy diet (p=0.002)

I would take a medication not approved by the FDA (p=0.014)

Table 1: Patient Demographics and Health Habits

<table>
<thead>
<tr>
<th>Variable</th>
<th>Did Not Participate in Clinical Trial (%)</th>
<th>Participated in Clinical Trial (%)</th>
<th>p-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (Mean ± SD)</td>
<td>60.46 ± 12.56</td>
<td>60.57 ± 12.56</td>
<td>0.29</td>
</tr>
<tr>
<td>% Non-White</td>
<td>90%</td>
<td>62%</td>
<td>0.005</td>
</tr>
<tr>
<td>% College Degree</td>
<td>36%</td>
<td>46%</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>% Smoke cigarettes</td>
<td>18%</td>
<td>23%</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>% reported ever participating in a clinical drug trial</td>
<td>45%</td>
<td>46%</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>% diagnosed with any of the following conditions: diabetes, high blood pressure, or high cholesterol</td>
<td>16%</td>
<td>15%</td>
<td>0.83</td>
</tr>
<tr>
<td>Visits (Mean ± SD)</td>
<td>7.16 ± 5.59</td>
<td>5.96 ± 4.97</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Hospitalization</td>
<td>13%</td>
<td>9%</td>
<td>0.005</td>
</tr>
<tr>
<td>Traditional Providers</td>
<td>96%</td>
<td>92%</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Alternative Providers</td>
<td>24%</td>
<td>28%</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

Health-Related Quality of Life (Figure 3)

Clinical trial participants experience poorer physical HRQoL than the general patient population.

Discussion & Conclusions

Clinical trial participants are unique individuals who differ from those in the general patient population demographically and attitudinally.

Patients who participate in clinical trials also differ in their HRQoL and healthcare resource use. Poorer physical well-being and greater resource use may increase the likelihood of a physician inviting the patient to participate in a trial. Conversely, resource use may increase due to monitoring during and after a clinical trial.

Because of these differences, the treatment experiences of clinical trial participants may not always be predictive of the treatment experiences of the general patient population.

To increase the representativeness of clinical trial samples, barriers to participation must be removed. Identification of these barriers should help in the development of strategies to maximize participation in trials.

REFERENCES


A Comparison of Clinical Trial Participants to the General Patient Population

Susan C. Bolge, PhD and Douglas L. Mills, MA MS

Consumer Health Sciences, Princeton, NJ

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