



Research Article

Demographic Silhouette Of Clinical Trial Participants: Refining The Efficiency Of Persuasive Recruitment

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ARTICLE INFO

ABSTRACT

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Background: Successfully recruiting participants for clinical trials is a challenge that crosses all medical disciplines. Slow enrollment to clinical trials delays the completion of clinical research studies.

Objectives: This study collected demographic data of current and past clinical trial subjects. Furthermore, it examined similarities and differences between clinical trial subjects, which provides deeper understandings of who subjects are and which may allow for improved education and recruitment of subjects.

Methods: 87 adults who had participated in at least one clinical research study were surveyed.

Findings:

- Healthcare represented the most common career at 27.6%.
- 93.1% received education beyond high school.
- 0% met the Investigator's definition for low socioeconomic status.
- 4.6% had healthcare coverage.

Conclusions: There does not appear to be any strong commonalities among clinical research subjects and the following demographics: career, education level, household income and health Insurance.

INTRODUCTION:

The majority (nearly 86%) of clinical trials conducted in the India fail to enroll subjects within the contract period¹⁻⁴. This failure rate is up from 80% of trials in the late 2005. These delays result in significant direct development costs for the study sponsor. Extended enrollment periods can also cause delays in new product introductions⁵.

A substantially higher cost that is due to missed market opportunity. Nearly two thirds of investigative sites argue that challenges of patient recruitment and retention are becoming more difficult⁶⁻⁹.

In a recent poll, 94% of people recognize the importance of participating in clinical research in order to assist in the advancement of medicinal science. Yet very few patients are even aware that they are eligible to participate in clinical trials¹⁰⁻¹¹. Seventy-five percent of the general public state that they have little to no knowledge about the clinical research enterprise and the anticipation process.

Where and how to recruit subjects for clinical trials depends on the demographics of the target populations and the conduction under investigation. Demographics are the characteristics of human populations and population segments. Psychographic information includes information regarding personality traits of individuals and/or groups¹². Accurate demographic data is the foundation of successful research, planning distribution and marketing strategies. Knowing exactly who your audience is provides critical data that is useful when developing educational and recruitment tools¹³.

Recruitment methods can be for a population sample or patients. Population recruitment includes telephone, letter, household, advertising, and the Web. Patient recruitment methods include clinics, hospitals, advertisements, referrals, and the Web¹⁴⁻¹⁵.

The lack of understanding of clinical trials deters participation in research studies. Recruitment tools and educational materials developed specially for specific target populations may help increase the percentage of the eligible population that enrolls in clinical trials and thus decrease enrollment delays¹⁶⁻¹⁷.

The National Institute of Health (NIH) requires that NIH-supported biomedical and behavioral research involving human subjects must report gender, race, and ethnicity information to ensure that all populations are offered the opportunity to participate (2008). Therefore, basic demographic data for clinical trial subjects are well tracked¹⁸⁻¹⁹.

Statement of the Problem

Despite well tracked basic demographics (gender, race, ethnicity), data representing the socioeconomic status and psychosocial characteristics of clinical research subjects are lacking. It is suspected that the lack of data available for the following demographics –career, education level, household income.

Historically, study sponsors have viewed these data as competitively sensitive information; therefore, it has been difficult to find and to aggregate the data. Sponsors have their own mechanism for gathering information and collected data that they consider proprietary. These individual methods for collection and collected data are not shared because it does not benefit their company to share. Benefiting another company actually causes damage to their own; Most professionals tend to think about the patients that they need for their specific studies and not about study subjects as a group.

Purpose of the Study

This research study acquired the following demographic and psychographic data from current and past clinical subject subjects: career, education level, household income. Hopefully, the data collected will enable professionals to develop more effective educational and recruitment tools for untapped subpopulations, facilitating partnerships with lay people predisposed to considering participating in trials. These relationships and better educational and recruitment tools may help studies meet their enrollment goals in a timelier manner, which would decrease the amount of extra costs incurred due to enrollment delays and potentially speed the approval process of effective drugs, biologic, or devices.

Significance

Acquiring the following demographic and psychographic data -career, education level, household income, religious affiliation, political affiliation, and musical affiliation of current and past clinical research subjects- will inform research professionals, policymakers, politicians, and regulatory agencies with a deeper understanding of who (demographic and psychographic data) subjects are. The data collected will hopefully enable professionals to improve the process of recruiting and retaining subjects for clinical trials.

Research Questions

This study addressed the following research questions:

- Do clinical research subjects who have participated in three or more trials have more socioeconomic and psychosocial characteristics in common than those who participated in two or fewer trials?
- Do clinical research subjects have minimal education (high school education or less)?
- Are there are commonalities between certain careers and being a research volunteer?
- Do the majority of clinical research subjects come from a low socioeconomic status (meet the following three criteria: highest level of education –high school education or less; healthcare coverage –none; and household income –below Rs 10,000)?
- Do the majority of clinical research subjects have healthcare coverage?

RESEARCH DESIGN AND METHODOLOGY

Sample Selection

The target population for this study consisted of adults who have participated in ≥ 1 clinical trial.

Human Subjects Protection

All potential study participants were informed of the study purpose and procedures by means of an email bulletin.

All potential participants had the right to refuse participation or withdraw from the study prior to completing the survey. Filling out the survey constituted the subject's agreement to participate in this study. Submission (completion) of the survey represented informed consent.

In addition, all data collected for this study were anonymous and confidential. Participants were instructed via bulletin email that their answers were confidential and could not be traced back to them.

Data Collection

Following Ethics Committee approval, subjects were informed to complete eight multiple choice questions, the participant was directed to click the "submit" button, which submitted their anonymous survey answers to the Investigator.

RESULT

One hundred and thirty-seven participants submitted surveys to the Investigator, which equates to a 43.2% response rate. Fifty participants did not meet the eligibility criteria (participated in < 1 clinical trial); as a result, their data were excluded from analysis. Thus, a final sample of 87 subjects participated in this study.

Question #1

Number of clinical trials participated in?

Survey participants chose from the following four options: a.) 1, b.) 2, c.) 3, or d.) ≥ 4 .

The objectives of this question were to: 1.) Ensure that participants had indeed participated in at least one clinical trial and 2.) To assist in the assessment if clinical research subjects who have participated in three or more trials have more socioeconomic and psychosocial characteristics in common than those who participated in two or fewer trials.

Subject Trial Participation

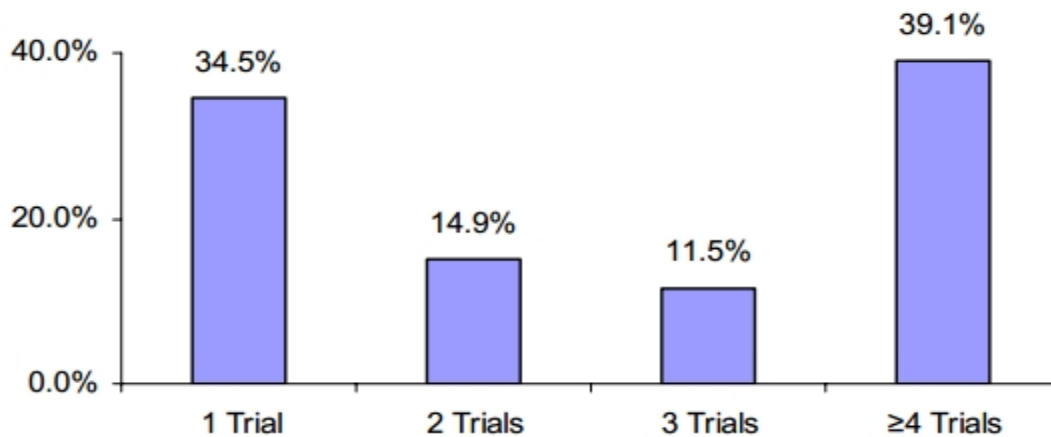


Figure 1: Number of Trials Subjects

Of the 87 survey participants, 44 (50.6%) had participated in three or more clinical trials, while 43 (49.4%) had participated in two or fewer clinical trials.

Survey participants chose from the following five options: a.) High School or less, b.) Professional Course, c.) College, d.) College Graduate). The objective of this question was to assess if the majority of clinical research subjects have minimal education (high school education or less).

Question #2

Highest level of education?

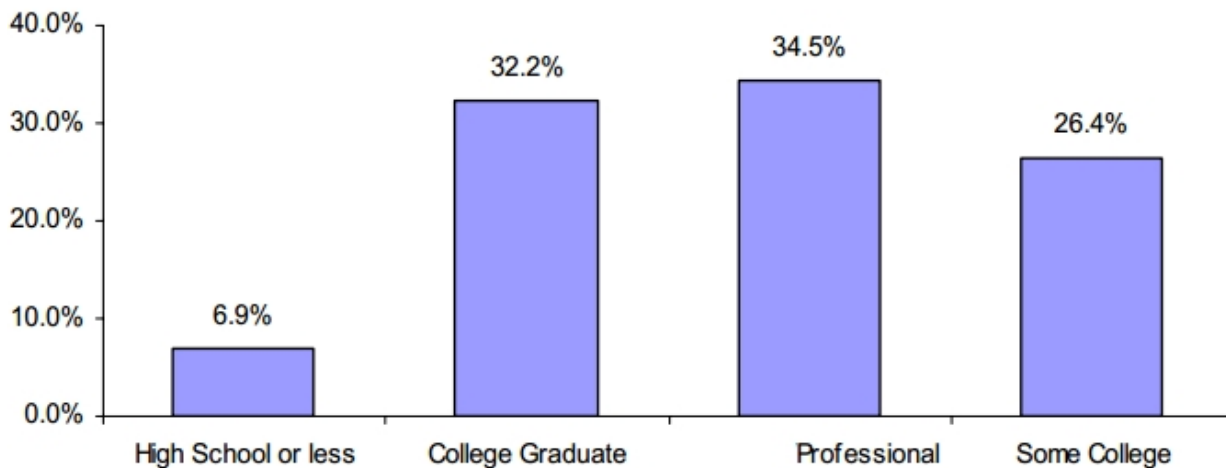


Figure 2a: Level of Education (all survey responses 1 - ≥4 trials participated)

Six survey participants answered that their highest level of education was high school or less. Eighty-one survey participants answered that they had received education beyond high school. These

data do not support the hypothesis that clinical research subjects have minimal education (high school education or less).

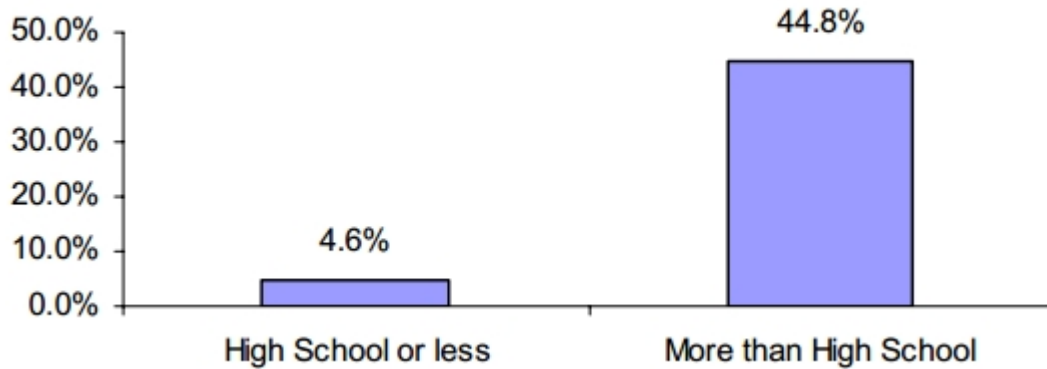


Figure 2b: Education: ≤ 2 studies participated

Four of the six survey participants (66.7%) whose highest level of education was high school or less had participated in two or fewer clinical studies.

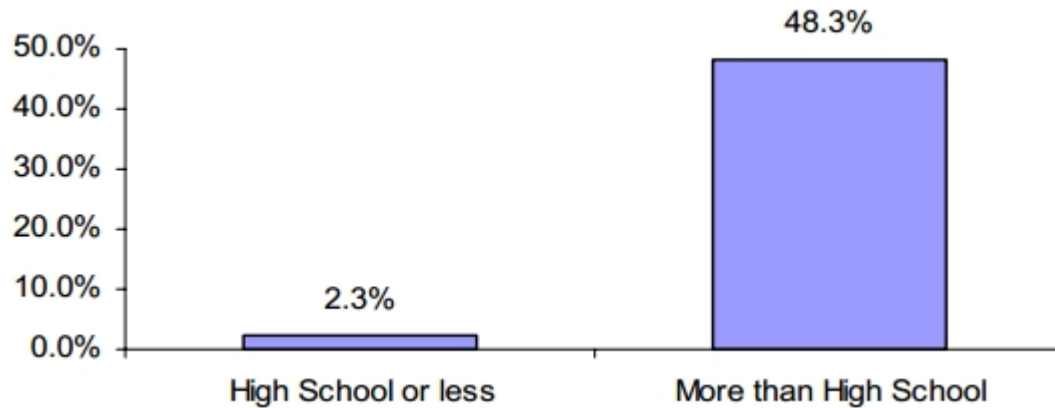


Figure 2c: Education: ≥ 3 studies participated

Two of the six survey participants (33.3%) whose highest level of education was high school or less had participated in three or more clinical studies.

Question #3

Career/profession?

Survey participants chose from the following eight options: a.) Arts, b.) Business, c.)

Education, d.) Health, e.) Technology, f.) Trade, g.) Unemployed or h.) Other.

The objective of this question was to assess if there were commonalities between certain careers and being a research volunteer.

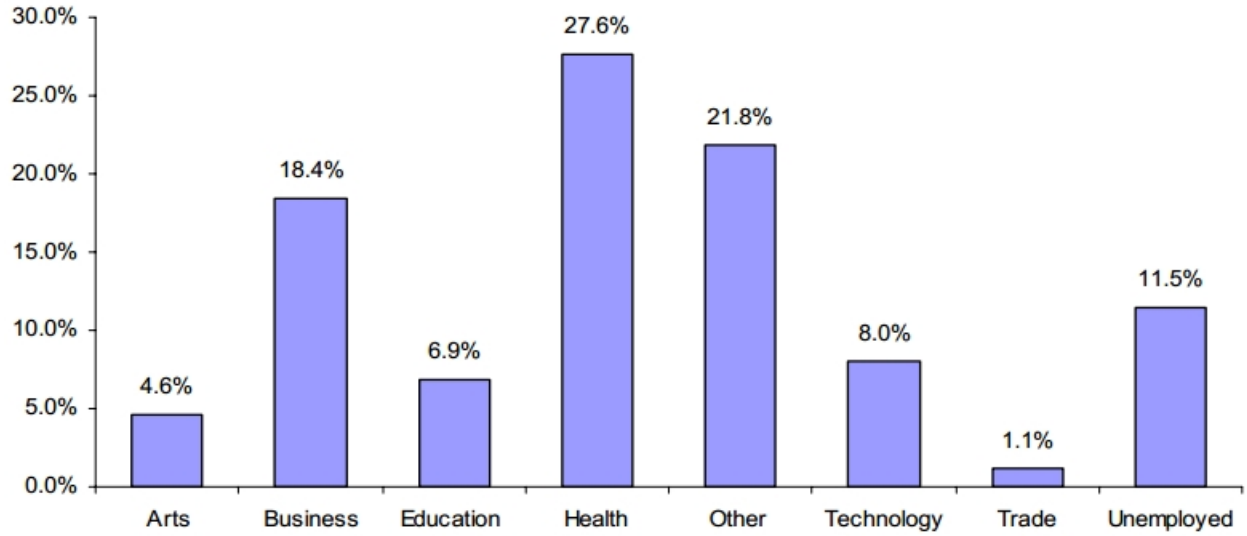


Figure 3a: Career (all survey responses 1 - >4 trials participated)

The career with the highest representation was healthcare; 24 of the 87 survey participants selected that they worked in healthcare. It was

interesting to find that the most underrepresented career was the trade's profession, 1 of 87 survey participants.

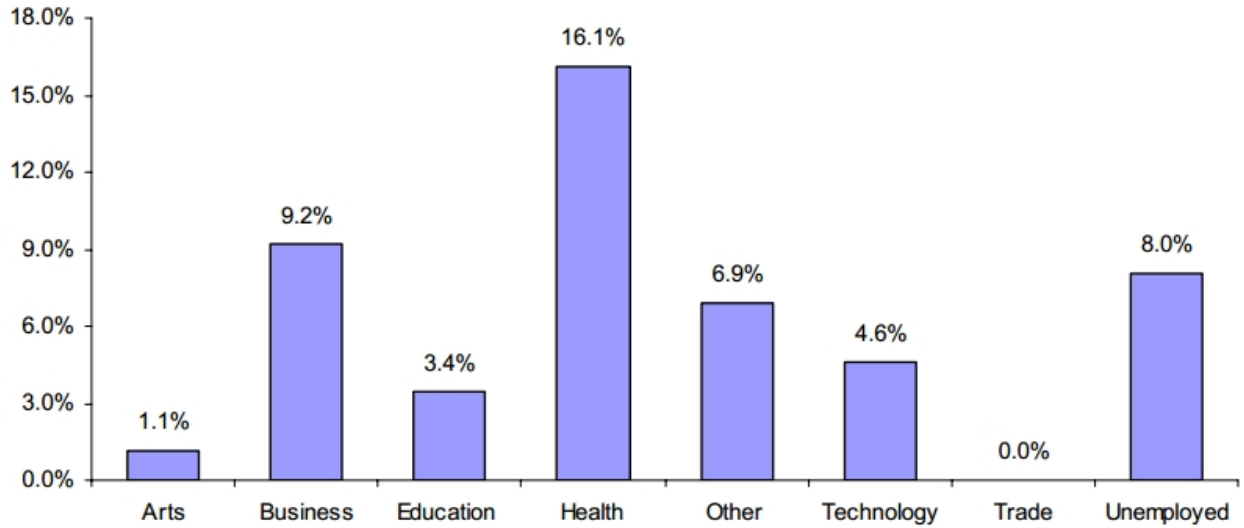


Figure 3b: Career: <=2 studies participated

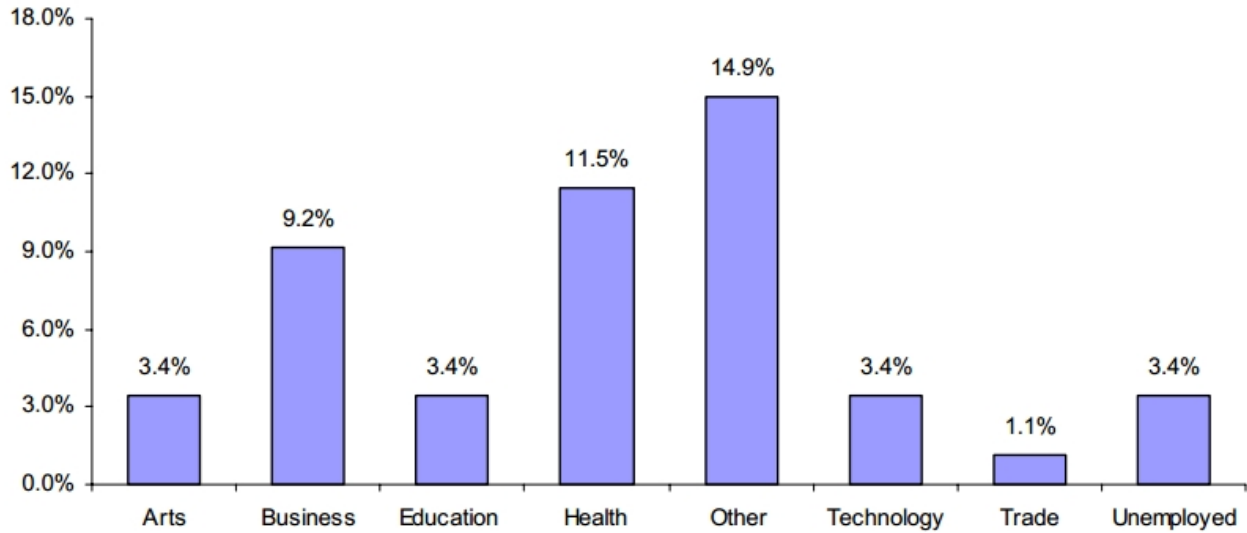


Figure 3c: Career: ≥3 studies participated

The data do not show any commonalities between a profession and the number of clinical trials participated.

Question #4.

Household income?

Survey participants chose from the following four options: a.) Below Rs 40,000, b.) Rs 40,000

- Rs 75,000, c.) Rs 75,001 – Rs100,000, d.) Over Rs 100,001.

The objective of this question was to assess if the majority of clinical research subjects come from a low socioeconomic status (meet the following three criteria: highest level of education –high school education or less, healthcare coverage –none, and household income –below Rs 40,000.)

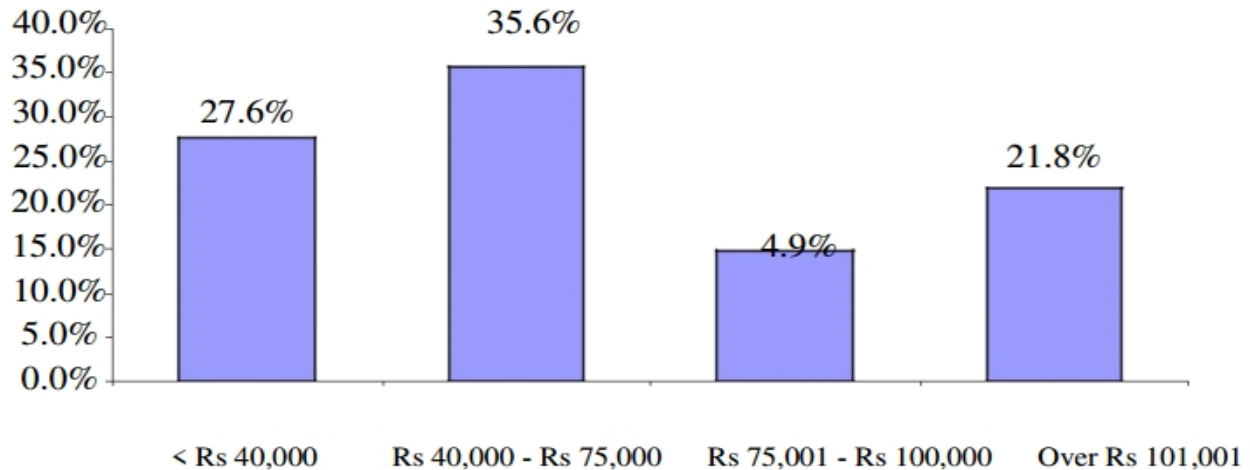


Figure 4a: Household Income (all survey responses 1 - ≥4 trials participated)

Twenty-four of the survey participants answered that their household income was less than Rs 40,000.00. Of these 24 survey participants, one did not have health insurance but had education beyond high school, and four of the survey participants disclosed that the highest level of education they

received was high school or less but they did not have health insurance. Therefore, of the subjects who participated in this study, none (0%) met all three criteria listed in the Investigator's definition for low socioeconomic status.

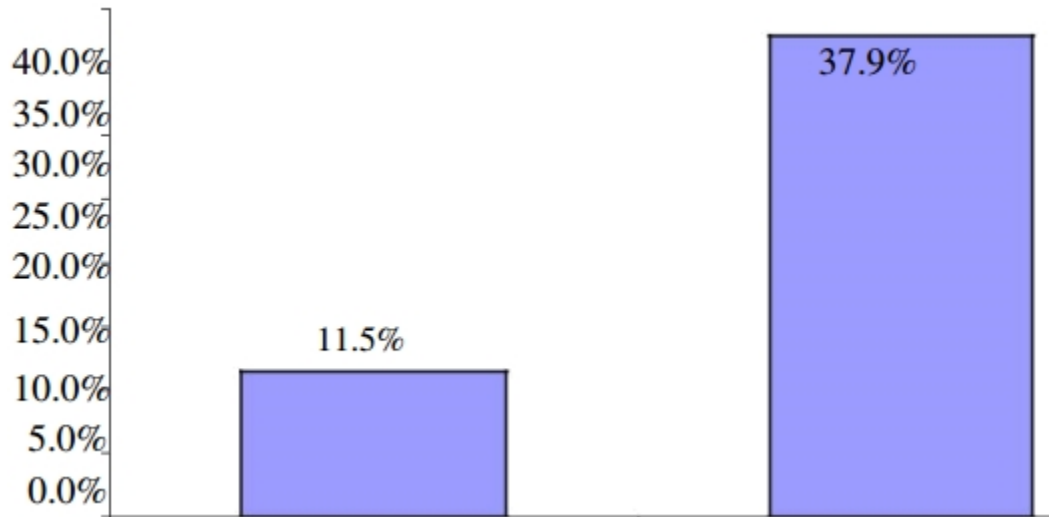


Figure 4b: Household Income: ≤ 2 studies participated

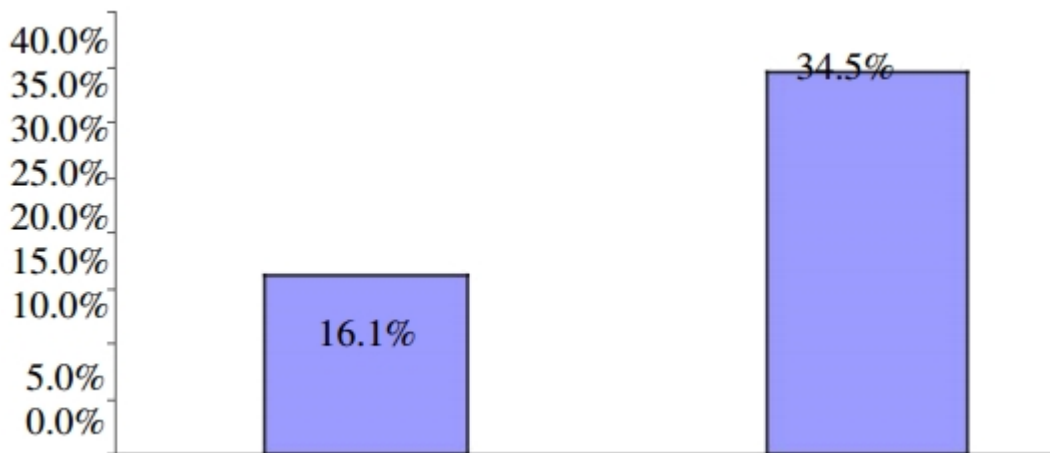


Figure 4c: Household Income: ≥ 3 studies participated

The data do not show that the number of clinical trials participated in (≤ 2 or ≥ 3) affected the $< \text{Rs}40,000$ household income population.

Question #5

Healthcare coverage?

Survey participants chose from the following options:
a.) yes or b.) no.

The objective of this question was to assess whether the majority of clinical research subjects have healthcare coverage.

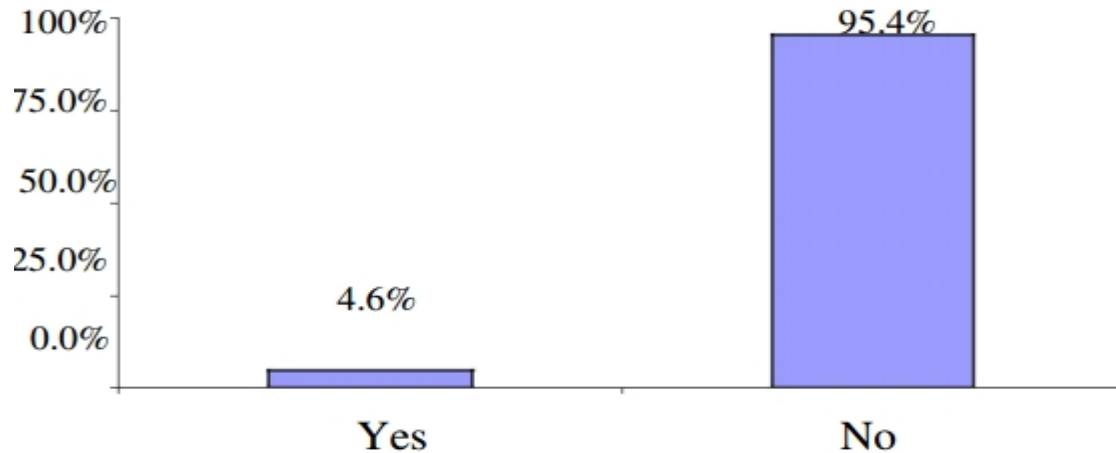


Figure 5a: Healthcare Coverage (all survey responses 1 - ≥ 4 trials participated)

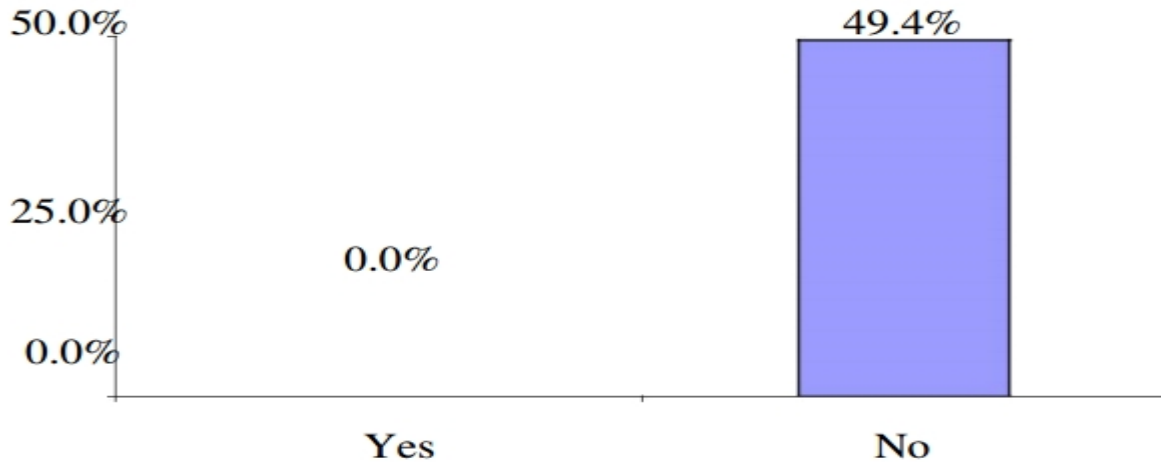


Figure 5b: Healthcare Coverage: ≤ 2 studies participated

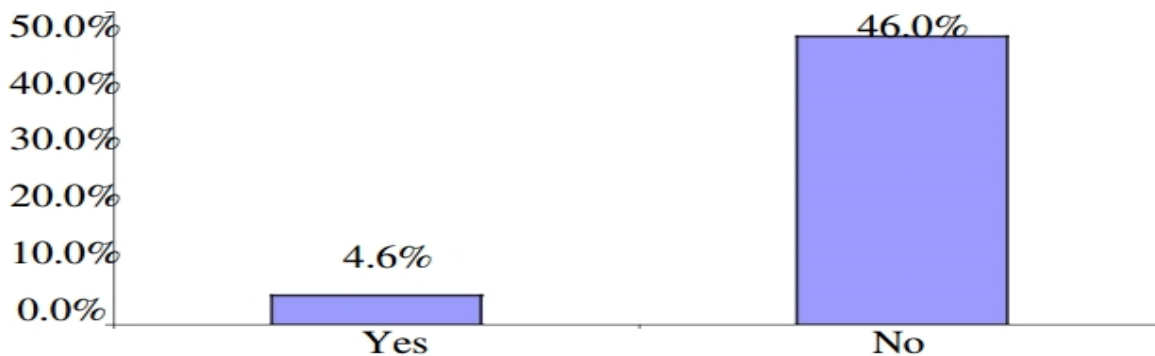


Figure 5c: Healthcare Coverage: ≥ 3 studies participated

Only four of the study participants had healthcare coverage. It was interesting to find that 100% of these four participants had participated in three or more clinical trials. These data coincide with current beliefs that people without insurance volunteer for clinical research studies for access to healthcare

and/or to assist with healthcare costs; however, the Investigator does not feel that she can support these beliefs with data from four subjects (4.6% of the survey population).

CONCLUSION

The Investigator was hoping to find psychographic commonalities among the survey participants and even more commonalities among those participants who had participated in three or more clinical trials. The data collected did not provide this as the number of trials that a subject had participated in did not appear to indicate any other similarities.

The Investigator was able to disprove the common belief that clinical research subjects have minimal education (high school education or less). However, the population this survey was sent to may have played a factor in these results.

The Investigator hypothesized that household income does not correlate with volunteering for clinical studies. The study data collected support this theory. The Investigator also hypothesized that the current belief that subjects come from low socioeconomic lifestyles would be disproved.

Many people believe that people who volunteer for clinic trials do so because they do not have any form of healthcare coverage and volunteering for a clinical study is a way to have part of their medical care and/or medication covered by research funds. The data collected in this study proved this current belief.

Recommendations for Further Research

To confirm the results of this study, future investigators should replicate this research in a larger population. Since this study used an online survey, participants required access to the internet. The assessment of low socioeconomic may be skewed since this population may not have internet access. In addition, this survey was sent to subjects of selected population. A broader population would most likely provide a wider spectrum of answers.

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