Contemporary Clinical Trials Communications 2 (2016) 85–90

Contents lists available at ScienceDirect

Contemporary Clinical Trials Communications

journal homepage: www.elsevier.com/locate/conctc

Attitudes and motivations regarding willingness to participate in dental clinical trials

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ARTICLE INFO

Article history:
Received 25 September 2015
Accepted 30 December 2015
Available online 12 January 2016

Keywords:
Recruitment for research
Clinical trials
Volunteering
Motivation
Research participation
Dental research

ABSTRACT

Background: This study examined attitudes about research, knowledge of the research process, reasons for and satisfaction with participation in a dental clinical trial as a function of demographic characteristics.
Materials and methods: 180 adults were invited to complete a 47-item survey at the completion of a 10-week dental product study at a Midwestern academic dental center. Seven demographic items included gender, race/ethnicity, age, education, household income, location of usual dental care, and dental insurance. Forty items assessed: attitudes about research; knowledge of the research process; perception of the study team; perceived risks/benefits; health perceptions; and general satisfaction with the study.
Results: 176 participants completed the questionnaire for a 98% response rate. African Americans were more likely to attribute Fate/God as more important to their health and their willingness to participate in research than whites, and more likely to report non-supportive social norms when compared to whites and other groups. Individuals in the 45–59 age group were less likely to attribute financial reimbursement as a motivator for their participation in research compared to all other age groups. Individuals with less education rated Fate/God attitudes as important to their research participation, reported lower autonomy for participation, and reported less supportive social norms compared to those with some college education. Participants in the four income categories showed significant differences in reasons for participation and desire for free care.
Conclusion: Motivations for participation of a Midwestern population of research subjects are dependent on age, ethnicity, belief in Fate/God, education, social norms and income.

1. Introduction

A goal of health research is to develop new, safe and effective treatment options for health conditions through rigorous testing in clinical trials. To ensure that findings are meaningful and generalizable, clinical trials must enroll and retain a diverse and representative group of research subjects. In 2009, there were 10,974 actively recruiting interventional trials with at least one center located in the United States [1]. These studies sought to enroll 2.8 million subjects [1]. One factor that consistently threatens the success of clinical trials is problems with subject accrual. In the United States, 17% of investigators failed to enroll any subjects, 56% failed to enroll the targeted number of subjects, and 90% of all clinical trials worldwide failed to enroll subjects in the targeted time frame [1]. Inadequate accrual can reduce power and threaten the external validity of findings. It is important for researchers to understand the subject-level factors that impact an individual's decision to participate in clinical trials.

Knowledge of research participants' motivations for agreeing to be in clinical trials, perception of the research team and the research process, and awareness of risks and benefits of research trial involvement all provide insight into improving subject recruitment. Subjects' decisions to volunteer for research studies

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http://dx.doi.org/10.1016/j.conctc.2015.12.011

are often multi-faceted and may be impacted by their age, motivations, cultural norms and other internal and external factors. In therapeutic research, the benefits of participating in research may be highly motivating and a key factor for participating in the study. However, in studies that offer no real benefit to the participant, other factors may influence someone to accept or decline participation. Several studies report altruistic motivations or personal benefit as one of the primary motivating factors for trial participation [2–4]. In a review of the literature, financial compensation was found to be the primary motivator for study participation of healthy volunteers; however, money was not the sole motivation [5]. Volunteers were also motivated by curiosity, contribution to scientific knowledge, and possible health benefits [5]. Also, healthy volunteers often weigh a range of concerns including risks, benefits, study goals, inconvenience, time commitment, and the possibility of contributing to scientific knowledge before making a decision on whether to participate [5]. To date, most of the published research involves patients who are enrolled in medical research, with only one study investigating the motivation of patients involved in dental research [6]. There is a need to evaluate how subjects understand and experience their participation in dental clinical trials, to help define the factors that determine their willingness to partake in these research studies.

This study examined the subjects' knowledge of the research purpose, randomization and placebo; their attitudes about research; their satisfaction with participation; volunteerism; perceived risk and expected personal benefit; the subjects' health/illness perceptions; their reason for participation; and issues related to the subjects' awareness of the informed consent process as a function of demographic characteristics in a population of individuals currently enrolled in a dental clinical trial at a Midwestern academic institution.

2. Methodology

2.1. Subjects

This study (IRB Protocol #07-78e) was approved by the University of Missouri – Kansas City (UMKC) Adult Health Science IRB. A convenience sample of 180 adult volunteers who were enrolled in a ten week dental product study were invited to complete the 47 item survey. For this previous study, participants had been recruited using various strategies: radio advertisements, flyers, billboard advertisement, and direct contact of previous research participants. For the survey, participants were informed about the survey at their final clinical evaluation appointment. They were told that their participation was entirely voluntary and, if they were interested, were provided with a survey and a plain manila envelope in which to place the completed survey following completion of all study procedures. They completed the survey in a private area, out of site of the research staff. To ensure anonymity, no identifiers were used and the participants who completed the survey were asked to deposit the completed survey in the envelope provided, and then into a locked collection box in the waiting room of the Clinical Research Center. One hundred and seventy-six participants completed the survey for a 98% response rate.

2.2. Survey development and description

A survey previously developed for use in medical research was adapted for this dental study [7]. The survey, comprised of seven general demographic items and forty items, designed to assess participants' attitudes and perspectives on participating in clinical research. The demographic items included gender, race/ethnicity, age group, educational category, household income category, location of usual dental care, and dental insurance (yes or no). The remainder of the forty items elicited information on: general attitudes about research, knowledge of the research process, perception of working with the study team, perceived risks and perceived benefits, health perceptions, and general satisfaction with the study. Modifications in language were made to adapt the 40 items to “dental” versus “medical” research while maintaining the core application to attitudes, knowledge, working with study team, perceptions of risk/benefit and general satisfaction. A five-point Likert response scale was used where 1 represented “strongly disagree” and 5 represented “strongly agree”. A description of the survey development and validation methodology is presented elsewhere [7].

3. Data analysis

Questionnaire data were coded and entered into SPSS (version 21) for analysis. In order to examine the underlying factor structure of the forty attitudinal and perception items, principal components analysis with Varimax rotation was used. Based on item loadings, subscales were identified and items that cross-loaded or had factor loadings <0.4 were eliminated, based on a time-honored rule of thumb that 0.40 or higher is an acceptable correlation between item and factor. Internal consistency estimates of reliability (Cronbach α) were evaluated to ensure subscale reliability and mean scores computed for each subscale for subsequent analysis [8].

Simple descriptive statistics were computed to characterize respondents' demographics and mean (standard deviation [SD]) and median (semi-interquartile range [SIQ]) values obtained on the identified subscales. The distributional characteristics of these subscales were explored and determined to meet the underlying assumptions for parametric analysis. Additionally, non-parametric analysis (Mann-Whitney) was also run to confirm our statistical decisions. In all cases, the statistical decisions were consistent between non-parametric and parametric analysis and results from the ANOVA reported. Subsequently, cross-sectional analyses were explored as a function of participant characteristics using the F test via ANOVA. Where the omnibus test showed significant results, post hoc analyses were conducted using the Least Significant Difference test (pairwise comparisons of three groups) or the Ryan-Einot-Gabriel-Welch Range test (pairwise comparisons of four groups) [9]. The level of statistical significance was set at alpha = 0.05 and tests were not adjusted for multiplicity.

4. Results

A total of 176 participants completed the questionnaire, for a response rate of 98%. Table 1 shows the demographic characteristics of the respondents. Women comprised the majority of participants (67.1%) and the race/ethnicity distribution was as follows: 59.8% were White, 25.0% were African American, 7.9% were Hispanic and 6.1% reported as Other. The vast majority of participants were in the 30 to 59 age range (74.4%). The educational characteristics were skewed to a higher level of attainment, with 54.4% having college degrees. Only 1.2% reported having “some high school” (Some HS) so, for subsequent analyses, this category was combined with those having a high school diploma (HS Grad) and analyzed as a single category (Some HS/HS Grad). A large majority reported having private dental insurance (70.5%), receiving dental care in a private dental office (62.1%), and having an income greater than $50,000 annually (47.4%).

Principal components factor analysis with Varimax rotation was used to explore the underlying factor structure of the 40 items designed to elicit information on attitudes and perception about