



# Attitudes and motivations regarding willingness to participate in dental clinical trials



Lynn Roosa Friesen <sup>a,\*</sup>, Karen B. Williams <sup>b</sup>

<sup>a</sup> Director of Corporate Clinical Research, Department of Research and Graduate Programs, University of Missouri – Kansas City School of Dentistry, 650 E. 25th St, Kansas City, MO 64108, United States

<sup>b</sup> Department of Biomedical and Health Informatics, University of Missouri– Kansas City School of Medicine, 1000 E. 24th St, Kansas City, MO 64108, United States

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## 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.

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## 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

\* Corresponding author. University of Missouri – Kansas City School of Dentistry, 650 E. 25th Street, Room 101-O, Kansas City, MO 64108, United States.

E-mail addresses: [friesenl@umkc.edu](mailto:friesenl@umkc.edu) (L.R. Friesen), [williamsk@umkc.edu](mailto:williamsk@umkc.edu) (K.B. Williams).

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  $\alpha$ ) 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

**Table 1**  
Demographics characteristics of respondents.

Characteristic	Summary data N (%)
<b>Gender</b>	
Women	112 (67.1%)
Men	55 (32.9%)
<b>Race/Ethnicity</b>	
White	100 (59.9%)
African American	41 (24.6%)
Hispanic	13 (7.8%)
Other	10 (6.0%)
Not reported	3 (1.8%)
<b>Age group</b>	
18–29	26 (15.6%)
30–44	61 (37.2%)
45–59	61 (37.2%)
>60	16 (9.6%)
Not reported	3 (1.8%)
<b>Education</b>	
High school/Graduate	29 (17.4%)
Some college education	47 (28.1%)
College graduate	91 (54.4%)
<b>Dental care</b>	
University clinic	57 (34.1%)
Private dental office	100 (59.9%)
Health department/Community clinic	4 (2.4%)
Not reported	6 (3.6%)
<b>Yearly income</b>	
<\$20,000	12 (7.2%)
\$20,000–29,999	27 (16.2%)
\$30,000–49,999	42 (25.1%)
>\$50,000	73 (43.7%)
Not reported	13 (7.8%)
<b>Dental insurance</b>	
Yes	117 (70.1%)
No	49 (29.3%)
Not reported	1 (0.6%)

research. Twelve factors were identified based on factor loadings  $\geq 0.4$  (Table 2). These twelve factors explained 70.7% of the variance in items, with a Kaiser-Meyer-Olkin Measure (KMO) = 0.77. The KMO statistic is a measure of the degree of factorability (e.g. degree of inter-correlation among items); values greater than 0.7 are considered acceptable [10]. Two factors had only a single item load and these were retained for analysis. Six items either cross-loaded or had loadings  $< 0.4$  on any of the twelve factors and these items were eliminated from subscale scoring. Where items loaded negatively on the factor, items were reverse scored and a mean subscale score computed for subsequent analyses. Internal consistency estimates of reliability were computed for each of the composite subscales (Table 2).

Table 3 displays the descriptive statistics on overall scores for attitudes and perception subscale scores. Areas where participants agreed relatively strongly were in their perceptions of Satisfaction with Study Participation, Autonomy for Participation, Attitudes about Study Consent and Communication, and the Need for Dental Research. Similarly, the overall group reported general disagreement for statements related to Participating for Dental Care, Perception of Negative Effects, Negative Social Norms and Worry about Health. Areas where there were less clear perceptions included perceptions about the Influence of Fate/God and Participating for Financial Reasons.

Cross-sectional analyses of subscales scores by participant characteristics as a function of group are shown in Table 4. With respect to gender, only the Health Worry subscale scores differed significantly ( $p = 0.024$ ) with women reporting a higher level of Health Worry than men. Comparison of subscales between ethnicity groups showed that African Americans were more likely to attribute Fate or God as important to health and their participation

in research than were Whites ( $p = 0.001$ ). No other pairwise contrasts were significantly different. Similarly, African Americans were significantly more likely to rate that their Social Norms do not support being involved in research when compared to Whites and Other groups ( $p = 0.004$ ).

Comparisons among the four Age Categories showed that the Financial Subscale was the only one that was different as a function of age. Individuals in the 45–59 age group were less likely to attribute Financial Reasons for their participation in research compared to all other groups ( $p = .001$ ). However, when education groups were compared, three subscales emerged as being significantly different. Those with less education rated higher Fate/God attitudes related to research participation and health compared to college graduates ( $p = .001$ ), lower level of Autonomy for Participation ( $p = .001$ ) and were more likely to cite non-supportive Social Norms compared to those with some college education ( $p = .001$ ). As expected, participants in the four annual income categories showed differences in the Purpose and Free Care Subscales.

## 5. Discussion

Recruitment and retention is a vital part of the clinical research process. Most previous studies have evaluated subjects enrolling in medical studies which cannot be extrapolated directly to understand factors regarding enrollment in dental studies. There are general differences between medical studies enrolling healthy individuals, medical studies enrolling individuals with a particular medical diagnosis, and dental studies. It is hard to compare the study designs, enrollment criteria, baseline characteristics and analysis strategies of these differing studies as the aims and criteria are so varied. To date, there has been only one study that has reported on the motivations of subjects to enroll in a dental study.

The current study provides insight into the sources of motivation for participating in dental clinical research. The only other study that has evaluated the motivations of dental patients concerning their participation in research was conducted in Jordan and published in 2014 [6]. The make-up of their sample was similar to ours with a majority of participants being women (60.8% and 67.1%, respectively) and the majority of both groups reporting some college education or a university degree (81.7% and 82.5%, respectively) [6]. In the previous study, those subjects who had previously participated in research reported their primary motivation for participation was altruistic (to help others and advance science) with participation for free dental care and financial incentives being rarely cited [6]. In the current study, we found that motivation for participation in dental research differs significantly as a function of the participant's ethnicity, belief in Fate/God, education, social norms, age, and income.

In our study, we did not find any gender differences with regard to factors directly related to motivation to participate in dental research. Previous studies have reported mixed results with regard to the impact of gender on willingness to volunteer for medical research with one study reporting that women were more likely to volunteer, another reporting that men were more likely to volunteer, and a third finding no differences by gender [11–13]. For example, Trauth et al. conducted a random digit dial telephone survey and determined that gender did not affect willingness to participate [13]. In contrast, Jenkins et al. found in a large sample of cancer patients that men were more likely to participate [12]. It is likely that one's motivation to participate in clinical trials with significant morbidity and mortality outcomes differ dramatically from dental clinical trials.

Other research has shown that general attitudes about health differ between sexes. Almeida et al. found that women may have a greater concern and focus regarding their physical health [14],

**Table 2**  
Results from the principal components analysis with varimax rotation.

Factors/Items (Cronbach $\alpha$ ) for subscale loadings	Factor loadings
<b>Study satisfaction (<math>\alpha = 0.91</math>)</b>	
My decision to do the study was easy.	0.809
I was given enough information about the research study before I decided to join.	0.717
The study team did a good job explaining the study to me.	0.731
It was easy for me to ask the study team questions.	0.582
The study team cared about my health and safety.	0.693
The study team treated me with respect.	0.872
I felt the study team cared about keeping my health information confidential.	0.769
I got good care from the study team.	0.554
Overall, I am very happy with the study.	0.612
<b>Fate/God factor (<math>\alpha = 0.73</math>)</b>	
I believe that fate, destiny or God's will make me get the right treatment.	0.784
No matter what I do or don't do, God is in control of my health.	0.775
I feel connected to God, my Creator, or some other higher power.	0.812
<b>Social norms (<math>\alpha = 0.73</math>)</b>	
People in my community or my family usually don't trust dentists.	0.761
People in my community or my family usually don't trust research.	0.769
My people, culture or religion does not support my participating in research.	0.730
<b>Pain (<math>\alpha = 0.61</math>)</b>	
I suffer daily from unhappy thoughts, sadness or nervousness.	0.850
I suffer from physical/dental pain every day.	0.765
<b>Purpose (<math>\alpha = 0.70</math>)</b>	
I wanted to do the study so I could help others.	0.503
The reason for the study is to answer questions about new treatments.	0.816
I think I got the treatment that I wanted.	0.783
<b>Negative Attitudes (<math>\alpha = 0.53</math>)</b>	
The study took much more time than I thought it would.	0.690
I had bad side effects during the study.	0.648
<b>Dental care (<math>\alpha = 0.48</math>)</b>	
I thought the study was going to cure me.	0.727
I did the study because I wanted free dental care.	0.701
I worried about my safety during the study.	0.491
<b>Study consent (<math>\alpha = 0.62</math>)</b>	
I knew the possible risks of the study before I joined.	0.517
I was told I could quit the study any time.	0.729
I got a copy of the consent form.	0.667
<b>Financial Issues (<math>\alpha = 0.54</math>)</b>	
I probably would NOT have done the study if they hadn't paid me to do it.	0.782
I did the study because I needed the money.	0.750
<b>Autonomy (<math>\alpha = 0.61</math>)</b>	
I only did the study because someone else wanted me to do it.	-0.831
It was my choice and my choice alone to do the study.	0.591
<b>Health worries (Single item)</b>	
I worry about my health every day.	0.647
<b>Need for dental research (Single item)</b>	
Dental studies are needed to find new and better ways to treat or prevent disease	-0.793

**Table 3**  
Overall descriptive data for subscale domains.

Domain	Mean (SD) <sup>a</sup>	Median (SIQ) <sup>b</sup>
Study satisfaction	4.6 (0.5)	4.8 (0.3)
Fate/God	3.1 (1.2)	3.0 (0.8)
Social normative behavior	1.9 (0.8)	2.0 (0.5)
Pain	1.5 (0.7)	1.0 (0.5)
Personal purpose	4.1 (0.7)	4.0 (0.5)
Negative effects	1.6 (0.7)	1.5 (1.0)
Need dental care	1.7 (0.6)	1.7 (0.8)
Study consent and communication	4.3 (0.8)	4.3 (0.5)
Financial issues	2.7 (1.1)	3.0 (0.8)
Autonomy	4.6 (0.7)	5.0 (0.3)
Health worries	2.0 (1.0)	2.0 (0.5)
Need for dental research	4.7 (0.8)	5.0 (0.5)

<sup>a</sup> Standard deviation.

<sup>b</sup> Semi-interquartile range.

which may extend to a greater concern and focus concerning their oral health. Women also perceive oral health as having a greater impact on their quality of life in general than men [15]. We found that the women who participated in our research study reported a

higher degree of worry or focus of attention on their health than men; however, this was not associated with any other factor differences from men.

Our study found African Americans and those with less education were also more influenced by their Fate/God attitudes in determining their research participation and their health condition compared to those with some college education. Additionally, those with less education were more likely to cite non-supportive social norms concerning research participation compared to those with a college education. However, Green et al. reported the opposite findings from a population of church goers in Alabama [16]. He found that people with more education (college or postgraduate) believed in fate and destiny significantly more than high school graduates or dropouts [16]. Additionally, he found that respondents who made more in annual income were more likely to believe in fate and destiny than people who made less [16]. The Fate/God attitudes of subjects concerning research may differ depending on geographic region.

The influence of social norms on participants who are deciding on whether to partake in clinical research cannot be ignored. Our study supports the finding that those with a lower level of

**Table 4**  
Statistically significant subscale score comparisons as a function of group.

Variable				
<b>Gender</b>	<b>Men</b>	<b>Women</b>	<b>p</b>	
Health worry	1.9 (0.9)	2.2 (0.9)	0.024	
<b>Ethnicity groups</b>	<b>African-American</b>	<b>White</b>	<b>Hispanic</b>	<b>Other</b>
Fate/God	3.8 (1.0)*	2.8 (1.1)	3.3 (1.3)	3.0 (1.2)
Social norms	2.3 (1.0)**	1.8 (0.7)	2.0 (0.8)	1.6 (0.7)
<b>Age groups</b>	<b>18–29</b>	<b>30–44</b>	<b>45–59</b>	<b>&gt;60</b>
Financial	3.2 (1.2)	2.8 (1.0)	2.3 (1.0) <sup>€</sup>	2.9 (1.2)
<b>Education groups</b>	<b>Some HS/HS grad</b>	<b>Some college</b>	<b>College grad</b>	
Fate/God	3.7 (1.0)	3.2 (1.2)	2.8 (1.1) <sup>€€</sup>	
Autonomy	4.3 (1.1)	4.5 (0.7)	4.8 (0.5) <sup>¥</sup>	
Social norms	2.1 (0.8)	2.1 (0.9)	1.8 (0.7) <sup>¥¥</sup>	
<b>Income</b>	<b>&lt;\$20K</b>	<b>\$20K–29,999</b>	<b>\$30K–49,999</b>	<b>&gt;\$50K</b>
Purpose	4.1 (0.5)	4.4 (0.6)	4.3 (0.5)	4.0 (0.8) <sup>β</sup>
Free care	2.3 (0.7) <sup>ββ</sup>	1.6 (0.6)	1.8 (0.6)	1.6 (0.6)

\* Significantly different  $p < 0.05$  from White only.

\*\* Significantly different  $p = 0.004$  than White and Other, only.

€€ Significantly different  $p = 0.001$  from all other groups.

€ Significantly different  $p = 0.001$  from Some HS and HS Grad, only.

¥ Significantly different  $p = 0.001$  from other 2 groups.

¥¥ Significantly different  $p = 0.001$  from Some College only.

β Significantly different  $p = 0.001$  from \$ 20,000–29,999 group only.

ββ Significantly different  $p = 0.001$  from all other income groups.

education and lower level of autonomy are more likely to cite non-supportive social norms for participation in research studies. Discussing whether you should participate in a clinical trial is encouraged as a way to help subjects make a decision on whether to accept or decline participation. Ensuring that recruitment materials and study personnel reflect a socially diverse group may facilitate decisions to participate in those with strong social norms or less autonomy. Almeida et al. found that 88.2% of people approached about participating in a clinical trial consulted other people (family/partner, friend or physician) prior to volunteering to participate [4]. Interestingly, Almeida et al. also found that only 20% of the people consulted recommended the subject take part in the clinical study [4]. Braunstein et al. found that racial differences in willingness to participate were most attributable to higher levels of distrust in clinical research among African Americans, even when taking into account other factors such as age, sex, and socioeconomic status [17]. This distrust may stem from the influence of the Tuskegee Study (of untreated syphilis in black men in Alabama) on public attitudes towards research participation especially among African Americans [18]. Several studies have found that distrust in clinical research is the most commonly cited contributor to lower willingness to participate in clinical research by African Americans [18]. Wendler et al. evaluated research enrollment in relation to the subject's race and found that individuals from minority groups are more willing to enroll in some studies and non-Hispanic whites are more willing to enroll in others, which suggests that the willingness to enroll is more a function of the characteristics of the individual study rather than a function of racial or ethnic identity [19]. Durant et al. found that when evaluating populations previously exposed to clinical research, African Americans are no less willing to participate in clinical trials when compared to whites [20].

Previous studies have generally reported that young patients are more willing to participate in research when compared to older patients and that the motivation for participation varies by age [12,13,21]. van Gelderen et al. found that young healthy volunteers were more likely to be motivated by financial reward than older individuals who were more motivated by receiving a medical evaluation and helping mankind [22]. However, our study found

that individuals in the 45–49 year age group were less likely to attribute financial reimbursement as a motivator for their participation in research compared to all other age groups. There were no other differences by age group.

Trauth et al. found that as the level of income increased so did willingness to participate with 42% of those earning less than twenty thousand willing to participate versus 52% of those earning greater than forty thousand [13]. In our study, lower income participants were more likely to state that they participated in the research study to have access to free dental care. However, it was also reported in our study that a high percentage of subjects had dental insurance (70.5%) and 97.5% of the subjects reported receiving care in either a university dental clinic or a private dental office. So it is not surprising that the subjects surveyed in our study with incomes over twenty thousand per year did not report that free dental care motivated their decision for participation. Almeida et al. reported that financial rewards were the most important motivation and were most valued by subjects with a lower monthly income [4]. In contrast, Al-Amad et al. reported that lower income participants were more likely than higher income participants to consider the benefit to the community over financial reward [6].

The high response rate to our questionnaire is probably due to the fact that the subjects were able to fill out the questionnaire during the last visit of a clinical study in which they were already enrolled in and their participation did not involve any extra time or visits. The volunteers in our study may also have been motivated to fill out the questionnaire because they saw it as a means to improve our research procedures. However, the sample of subjects who agreed to participate in this dental clinical trial may not fully represent the potential subjects that would be recruited for a dental clinical trial, as it included only those who had agreed to participate and not those who refused participation. Additionally, when compared to medical research, dental research probably poses less risk to the subjects enrolled in their studies; however, one must be aware of the variables that motivate patients to participate, to make sure that they are a good cross-section of patients represented by various age groups, gender, race, and ethnicity.

While this study provides evidence to support differential impact of constructs assessed and characteristics of the sample, one must consider the results in context to the psychometric integrity of the instrument. Most of the subscales in which differences were observed had the greatest internal consistency, whereas no differences were observed in subscales with lower internal reliability, such as pain, negative attitudes, dental care, and study consent. Whether this lack of differences for these domains resulted from psychometric problems or true lack of effect is unknown. Future studies are planned to further refine the instrument to improve psychometric characteristics of the instruments in these domains.

## 6. Conclusions

Subjects' motivations for participation in dental clinical trials in a Midwestern population of research vary and are dependent on age, ethnicity, belief in Fate/God, education, social norms and income. These results have implications for effective recruiting and retention strategies in dental clinical trials.

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## Conflict of interest

None of the authors have a conflict of interest related to the contents of this manuscript.

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