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Positive attitudes toward clinical trials among military Veterans leaves unanswered questions about poor trial accrual

Grace Clarke Hillyer^{a,b}, Yeun-Hee Anna Park^{c,d}, Ta-Chueh Hsu Rosenberg^c, Prabhjot Mundi^{c,d}, Imtiaz Patel^c, Susan E. Bates^{b,c,d}

^aDepartment of Epidemiology, Mailman School of Public Health, Columbia University, New York, NY, USA

^bHerbert Irving Comprehensive Cancer Center, Columbia University, New York, NY, USA

^cJames J. Peters Veterans Affairs Medical Center, Bronx, NY, USA

^dColumbia University Vagelos College of Physicians and Surgeons, New York, NY, USA.

Abstract

Background: Participation in clinical trials is essential to bringing novel and innovative cancer treatments to the bedside but trials that specifically enroll Veterans are relatively few. Given the inherent differences between Veterans and the general U.S. population, we sought to investigate awareness of and attitudes toward clinical trials among Veterans diagnosed with cancer at a large, urban Veterans Administration Medical Center in Bronx, New York.

Methods: The survey was administered in 2018-2019. Questions assessed sociodemographic characteristics, health literacy, and general attitudes about clinical trials. Based on key informant interviews, we also inquired about military-specific attitudes. Univariable analyses were conducted to evaluate differences in attitudes by age (<65 vs. ≥65 years) and race/ethnicity (non-Hispanic black vs. other).

CORRESPONDING AUTHOR: Grace Clarke Hillyer, EdD, MPH, Assistant Professor of Epidemiology, Department of Epidemiology, Mailman School of Public Health, Columbia University, 722 W. 168th Street, Room 1611, New York, NY 10032, gah28@cumc.columbia.edu, Tel: 212-342-1658.
Credit Author Statement

Grace C. Hillyer	Conceptualization, Formal analysis, Funding Acquisition, Methodology, Writing - Original Draft, Writing - Review and Editing
Yeun-Hee Anna Park	Conceptualization, Funding Acquisition, Methodology, Writing – Review and Editing
Ta-Chueh Hsu Rosenberg	Data Curation, Funding Acquisition, Methodology, Project Administration, Writing – Review and Editing
Prabhjot Mundi	Conceptualization, Methodology, Writing -Review and Editing
Imtiaz Patel	Conceptualization, Methodology, Writing -Review and Editing
Susan E. Bates	Conceptualization, Funding Acquisition, Methodology, Supervision, Writing – Original Draft, Writing – Review and Editing

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Results: Of 115 Veterans approached, 67 (58.3%) completed the survey. Approximately 95% of participants were male, 59.7% were 65 years old, and 41.8% were non-Hispanic black. Only 58.2% reported knowing what a clinical trial is but 78.5% of Veterans stated that they trust doctors who do medical research and 87.5% reported they would strongly consider joining a trial if their VA primary care physician recommended it. Many stated that they would be part of a clinical trial if it would help fellow Veterans in the future (93.8%) and would help scientists learn how to treat other Veterans with the same disease (93.8%). Among non-Hispanic black participants, 62.5% agreed that the government has a history of using Veterans in experiments without their knowledge compared to 34.2% of Veterans of other race/ethnicity ($p = 0.03$).

Conclusions: Clearly Veterans in our study were amenable to joining clinical trials. While many are aware of past misconduct in the treatment of military personnel in research, overall attitudes toward clinical trials were favorable and were especially positive when the possibility of improving cancer care for fellow Veterans was considered. In approaching Veterans regarding participation in a clinical trial we recommend education aligned with the literacy level of the Veteran, involvement of the VA primary care provider in clinical trial decisions, and awareness of a Veteran's altruism to help others.

Keywords

Clinical trials; Veterans; Military personnel; Cancer; Attitudes; Survey

INTRODUCTION

Clinical trials are essential to the generation of scientific evidence to inform clinical oncology practice and improve cancer outcomes. Critically important to the financial, ethical, and scientific success of cancer clinical trials is the voluntary participation of patients. A significant number of trials, however, fail to reach completion, close early or are terminated because of the inability to meet minimum accrual goals. Closure or termination due to poor accrual rates has been estimated at 8.5% for immune checkpoint inhibitor trials to as high as 37.9% for phase III trials [1-4].

In the United States, enrollment of eligible patients to cancer clinical trials is reported to be about 8% in the community [5] and 14.0% to 15.9% at academic centers [5-7]. (Table 1) Provider barriers to clinical trial enrollment can be categorized as systems-related, clinical, and attitudinal [5]. Systems level provider barriers typically include factors such as lack of awareness of trials and insufficient system support [8], whereas clinical factors involve the potential impact of restrictive eligibility criteria and competing comorbidities on trial toxicities. Finally, provider attitudes about the patient's ability to comply with complex study protocols, their own personal values and beliefs about clinical trials [8, 9], and misperceptions related to the patient's willingness to participate [10] all impact trial enrollment.

Since patients ultimately decide whether or not to participate in clinical trials, much research has been devoted to understanding patient-level barriers. Low socioeconomic status of patients limits access to both health care and to high-volume cancer centers where most clinical trials are conducted [11-13]. Financial barriers such as inadequate health insurance

coverage [8], additional expenses associated with participation [8, 14], and logistic factors and family issues including transportation, childcare [14-17] and required time off from work for research visits and procedures [9] disproportionately impact the willingness of many patients to enroll in a clinical trial. Many patients are also faced with language and cultural barriers [16] in the medical system, lack of awareness or knowledge about clinical trials [8, 14] and fears surrounding study design (e.g., randomization, placebo, adverse effects) [16, 18, 19]. Additionally, strict trial eligibility criteria [16, 20] more often excludes minority patients from clinical trial consideration who are more likely than non-Hispanic Whites to live with chronic comorbidities.

Patient attitudinal and cognitive barriers also impact clinical trial enrollment. Past cases in which the rights of participants were abused still linger in the minds of many and contribute to feelings of mistrust of the medical system, particularly amongst historically targeted groups such as the African American population [9, 14, 15]. Attitudes that research is not beneficial to the patient, and negative beliefs about the purpose and intention of research (e.g., being treated like a guinea pig) [8, 21] are often reported by patients as barriers to trial enrollment.

Clinical trials that enroll specifically military service members and Veterans are relatively few, and most studies do not track whether a trial participant is a Veteran or not. In 2016, a review of the 2,475 U.S. clinical trials registered in clinicaltrials.gov between 2005 and 2014 found that U.S. service members participated in a meaningful proportion in 512 studies (20.7%). That is, enrollment of military service members met a threshold of at least 30, or, in larger trials a minimum of 10% in studies comprising both military and non-military participants. Of these 512 trials, only 120 were open to military participants exclusively [22] and none focused on patients with cancer.

Veterans are a special population with characteristics that differ from those of the general U.S. population. The majority of Veterans today are predominantly male who tend to have higher levels of education and income than the average American [23]. Further, Veterans who use the Veteran Administration (VA) medical system are considered to be a highly selected group within this special population. Users of VA medical benefits include individuals who were honorably discharged and priority care is provided for Veterans with service-related disability, who were prisoners of war or who meet specific financial criteria [23]. A study among 3,152 Veterans enrolled in the National Health and Resilience of Veterans Study in 2011, found that individuals seeking healthcare at VA medical facilities reported greater prevalence of psychopathology, more suicidal ideation, and higher levels of enduring trauma – further distinguishing Veterans from the general U.S. population [24].

The overwhelming majority of knowledge related to clinical trial enrollment and barriers to trial participation has been learned from civilian populations. Little is known about differences between the general population and military personnel with regard to willingness to participate in clinical trials and barriers that are specific to these individuals (Table 2). Cook and Doorenbos reported that among clinical trials seeking to enroll large numbers of military participants (25% or more of all enrollees), 12% were withdrawn, terminated, or suspended due to low rates of enrollment or funding issues [25]. No differences were

identified, however, in the difficulty to recruit and enroll service members vs. other research participants. Another study investigated the impact of financial reimbursement on trial retention among 666 active duty service members from six U.S. military treatment facilities and concluded that reimbursement for trial participation was modestly associated with retention rates [26]. Conversely, Campbell et al. reported that among Veterans, there was a strong aspect of ‘paying back’ people who treated them as important while financial compensation was less important [27]. This altruism toward fellow Veterans was also observed in a qualitative evaluation of motivations to participate in clinical trials among military Veterans in five U.S. cities where adequate compensation, desire to help fellow Veterans, and the significance and relevance of the research topic all played important roles in the decision to participate in a clinical trial. Additional factors such as trust, respect, and transparent communication were also highly ranked conditions of trial participation among Veterans [28].

Given the inherent differences between military service members and Veterans and the general U.S. population, we hypothesized that attitudes toward clinical trials that underly receptivity and motivation to participate in trials would similarly differ from barriers commonly reported among civilian Americans. Therefore, the purpose of this study was to investigate attitudes about clinical trials and clinical trial participation among a group of military Veterans diagnosed with cancer at a large, urban Veterans Administration Medical Center in Bronx, New York.

MATERIALS AND METHODS

Development of the patient survey

We conducted in-depth interviews among three key informants including a psychiatrist, an infectious disease physician, and a social worker; all had prior experience implementing clinical trials in their respective clinical areas among Veteran patients at the Veterans Administration Medical Center in Bronx, New York. Several important themes emerged from these discussions including the importance of building patient trust and leveraging existing trusted relationships to encourage clinical trial participation (e.g., involving the primary care physician in discussions surrounding clinical trial participation); embedding clinical trials into the culture of the clinical area and eliciting staff buy-in; emphasizing the importance of research and appealing to altruism toward other Veterans; and offering compensation for trial participation to cover transportation and other expenses. Barriers identified by the key informants also encompassed costs associated with trial participation (e.g., time off from work and transportation costs), lack of rapport with the research investigative team, and general attitudes of suspicion and distrust regarding clinical research. These concepts were then integrated into the design of the quantitative survey that was administered to Veterans.

Patient survey

All procedures were conducted at the James J. Peters Department of Veterans Affairs Medical Center (Bronx VA), the oldest VA facility in New York City located in the borough of the Bronx. Using a convenience sampling strategy, we approached adult patients with

cancer in the waiting room of a large VA oncology clinic. Participants included adult patients, 18 years of age or older, who were diagnosed with cancer, were under the care of a VA medical oncologist, and were not currently enrolled in a clinical trial. Excluded were patients not yet diagnosed with cancer. With the permission of the attending physician, an oncology research nurse or a clinical trials navigator approached potential participants, introduced the study, and determined participation interest. Written informed consent from interested patients was obtained and the survey was administered in English in a private area in the clinic. Responses were recorded in Qualtrics and uploaded to a dedicated VA server via secure internet lines.

From each participant we collected clinical information including type of cancer and year diagnosed. Sociodemographic information included sex, race/ethnicity (non-Hispanic black vs. other race/ethnicity), age (<65 years vs. ≥65 years), highest educational level (high school, some college/trade/technical school, and college or graduate degree), and marital status. We also evaluated social support using the eight-item modified Medical Outcomes Study (MOS) Social Support Survey that encompasses tangible support and emotional support [29] and quality of life using the FACT-G7 capturing physical well-being [30]. Using a brief screening measure, we assessed health literacy [31]. Participants were asked if they possessed a cell/mobile phone and if they used that phone to connect to the internet. We also inquired about health seeking behavior on the internet.

Knowledge of clinical trials was evaluated by asking a single question “Do you know what a clinical trial is?” with binary responses (‘Yes’ vs. ‘No’). To assess attitudes toward clinical trials, we asked participants to rate feelings toward clinical trials as ‘very negative’ through ‘very positive.’ Willingness to participate in a clinical trial today if asked was assessed and responses included “Yes, I definitely would,” “I might, not sure, it depends,” and “No, I definitely would not.” We further asked participants to indicate level of agreement (‘strongly agree’ through ‘strongly disagree’) with a series of questions about clinical trials that were positive or negative in nature [32]. Based on the key informant interviews, we constructed eight clinical trial attitude questions specific to Veterans that queried participants about the extent to which they agreed or disagreed with each statement (for example, “Being part of a clinical trial that could help my fellow Veterans in the future is important to me”).

Data analysis

Descriptive analyses including frequency distributions for categorical variables and mean, standard deviation, median, and range for continuous variables were computed. Univariable analyses using the Chi square test and Fisher’s Exact test were performed to assess response differences by race ethnicity (non-Hispanic black vs. other race and ethnicity) for categorical type questions and Analysis of Variance (ANOVA) for continuous variables. The social support measure was scored according to published instructions [33] which generated a value on a scale of 0-100. The quality of life measure was scored by summing response values and calculating the mean score, ranging from 0-28 [34]. For attitude measures, Likert scale responses were recoded as “agree” vs. “disagree.” Differences in characteristics and attitudes toward clinical trials was examined by age and race/ethnicity. P values <0.05 were considered statistically significant. Analyses were performed using IBM SPSS (version 27)

[35]. All procedures were approved by the Bronx VA Medical Center Institutional Review Board.

RESULTS

Of 115 Veterans approached, 67 (58.3%) completed the survey. The majority of participants were male (95.5%), had some college education (69.2%) and were unmarried (63.6%) (Table 3). For social support, the mean score was slightly above the mid-point of the scale at 57.3 [SD 28.7] (scale range 0.0 to 100.0) and the mean score for quality of life was 19.2 [SD 3.3] (scale range 9-27). When asked about comprehension of information from their doctor, 62.2% reported being able to understand information ‘all the time’; however, 41.8% stated that they needed some type of assistance with written information or instructions from the doctor or pharmacy. Approximately two-thirds of participants reported that they used the internet (64.2%) and, of those, 65% stated that they use the internet to seek health information. When stratified by age (<65 years vs. ≥65 years), older participants had a lower quality of life score (18.3 [SD 3.2] vs. 20.4 [3.2], $p = 0.008$) and more often reported needing help with instructions and information from the doctor or pharmacy “all the time” (12.5% vs. 0.0%, $p = 0.04$) than their younger counterparts. There were no statistically significant differences in sociodemographic characteristics by race/ethnicity.

Only 58.2% reported knowing what a clinical trial is (Table 4). When asked about feelings toward clinical trials, 68.2% had ‘somewhat’ or ‘very’ positive feelings. When queried about willingness to join a trial today if asked, 42.4% stated “Yes, I definitely would” but this response differed significantly by age with younger participants (<65 years) twice as often stating willingness compared to older participants (59.3% vs. 30.8%, $p = 0.02$).

All respondents agreed that clinical trials help doctors to improve treatment for patients in the future; other commonly reported positive attitudes toward clinical trials included “It is safe to be in a medical research study” (82.8%) and “I completely trust doctors who do medical research” (78.5%) (Figure 1). Although few participants held negative beliefs regarding clinical trials, there was a single item - “There are some things about medical research that I do not trust at all,” to which nearly half of the participants (47.6%) responded with agreement. Many held positive attitudes about clinical trials as they specifically relate to Veterans. Nearly all (98.5%) stated that they believe the VA oncologist has their best interests at heart and 95.4% felt that VA doctors who conduct clinical trials want to improve care for Veterans. Most stated “being part of a clinical trial that could help my fellow Veterans in the future is important to me” (93.8%) and that joining a clinical trial would help scientists learn how to treat other Veterans with their disease in the future (93.8%). Lastly, 87.5% said they would strongly consider joining a trial if their VA primary care provider recommended doing so.

Older participants (≥65 years), relative to younger participants, felt more often that being part of a clinical trial would help them be more in control of their disease and treatment (89.5% vs. 56.0%, $p = 0.002$), would provide the best treatment available for their disease (73.7% vs. 48.0%, $p = 0.04$), and that the benefits of trial participation outweighed the harms or risks (71.1% vs. 46.2%, $p = 0.045$) (Table 5). Military-specific attitudes did not

differ by age of the participant, but when compared to participants of the other races and ethnicities, non-Hispanic black participants nearly twice as often agreed that the government has a history of using Veterans in experiments without their knowledge (62.5% vs. 34.2%, $p = 0.03$) and more often stated that they would consider clinical trial participation if there was reimbursement for their time, effort, and transportation (69.2% vs. 43.2%, $p = 0.04$).

DISCUSSION

This study is one of very few focused on Veterans' attitudes toward health research [36] and the only one we know of in the past decade focused on VA cancer-specific research. Our findings indicate that among a racially diverse sample of Veterans seeking care at a large urban VA medical center, none reported "very negative" attitudes and only 3.0% expressed "somewhat negative" feelings toward clinical trials. While a substantial proportion of Veterans (41.8%) were unaware of what a clinical trial is, 78.5% of Veterans stated that they trust doctors who do medical research and 87.5% reported they would strongly consider joining a trial if their VA primary care physician recommended it. Our study corroborates prior findings [37, 38] in that >93% of Veterans surveyed regardless of age or ethnicity felt that being part of a clinical trial that could help fellow Veterans in the future is important and appears to supersede concerns we detected among non-Hispanic black Veterans that the government has a history of using Veterans in experiments without their knowledge.

Our sample included a large proportion of non-Hispanic blacks and nearly exclusively comprised males (95.5%) similar to the reports of others [23, 24] but differed in that the population we studied was older (59.7% aged 65 years and older). We also found that a large proportion of Veteran participants required assistance with written materials provided by the doctor or pharmacy which may reflect the large number of participants with high school level education or less (75.6%). Limited literacy is an established barrier to clinical trial enrollment, particularly among racially and ethnically diverse populations [39]. It has been suggested that when confronted with a cancer diagnosis, patients with low or inadequate literacy struggle to understand and make decisions about treatment more so than among those with adequate literacy [39, 40]. Given the complexity of clinical trials, individuals with limited literacy can experience information overload which may result in fewer offers to participate from providers or the preference for standard treatment [10]. The influence of lower literacy may also account for the lack of awareness and knowledge of clinical trials in the current study and is an area that has not been previously evaluated and warrants further consideration.

What was most striking in our findings was the high proportion of participants who stated that they would be part of a clinical trial if it would help fellow Veterans in the future (93.8%) and would help scientists learn how to treat other Veterans with the same disease (93.8%). Commonly cited reasons for trial participation among non-military patients are to receive personal benefit from and improved access to better and more high-quality care. For members of the military, this motivation is less relevant as most Veterans have access to free high-quality care with few exceptions [36]. Instead, altruism toward fellow service members takes the fore [38].

This study was limited in that it was an observational study conducted among a relatively small number of Veterans at a large urban VA medical center. In addition, a large proportion of our study sample was non-Hispanic black and older in age which differs from reports of the typical characteristics of Veterans and may limit generalizability of our findings to other geographic areas and Veteran Administration facilities whose patient population differs in racial, ethnic, and age distribution. Additionally, 41.7% of those approached refused to participate in the survey. Those patients could have held more negative opinions of clinical trials than those who participated in the survey. That combined with the 41.8% of patients without knowledge of clinical trials suggests that there is much work to be done in the VA system to help Veterans understand the goals of clinical trials, particularly in cancer. Nonetheless, given the dearth of information about attitudes toward clinical trials among Veterans, this study provides insight to the strong sense of altruism existing in Veterans who likely struggle with infirmities of older-age as well as physical and mental issues related to their service decades in the past.

The VA system is the largest integrated health care system in the United States and boasts a history rich of adding to medical knowledge and furthering treatment options for patients with cancer [41]. In recent decades, there has been a paucity of medical data stemming from Veterans for a myriad of reasons, including the pivot in cancer research toward industry sponsored trials, increased concerns about privacy, and regulatory restrictions imposed on research conducted in the VA health care system. Our survey is an attempt to understand at least one factor – whether Veteran attitudes toward trials impact enrollment. To reverse recent trends, the VA has partnered with the NCI to boost Veteran enrollment [42] and is in the process of gaining deeper understanding of factors that limit Veteran accrual.

CONCLUSIONS

Clearly Veterans in our study were amenable to joining clinical trials. While many are aware of past misconduct in the treatment of military personnel in research, overall attitudes toward clinical trials were favorable and were especially positive when the possibility of improving cancer care for fellow Veterans was considered. Together, these findings illuminate potential interventions to increase Veteran clinical trial participation. In addition to expanding the number of clinical cancer trials that allow and encourage Veteran participation, providing access to cutting edge therapies, it also behooves us to better understand the motivations and hesitations of this population. Having trusted practitioners provide more education on the nature of clinical trials, increased transparency about every step in the research protocol, and a focus on the value that Veterans place in altruism may all contribute to improving cancer trials enrollment. Veterans with cancer are by in large an aging group with multiple comorbidities whose enrollment in future clinical trials can give them more rapid access to potentially helpful treatments while advancing therapeutic knowledge for the greater good. Ultimately, barriers at the systems level such as availability of trials to meet the special needs of Veterans and eligibility criteria that disproportionately exclude underrepresented racial and ethnic groups due to increased prevalence of comorbidities, also need to be addressed and are areas that are now receiving long overdue attention.

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ABBREVIATIONS:

U.S.	United States
VA	Veterans Administration
MOS	Medical Outcomes Study
ANOVA	Analysis of Variance

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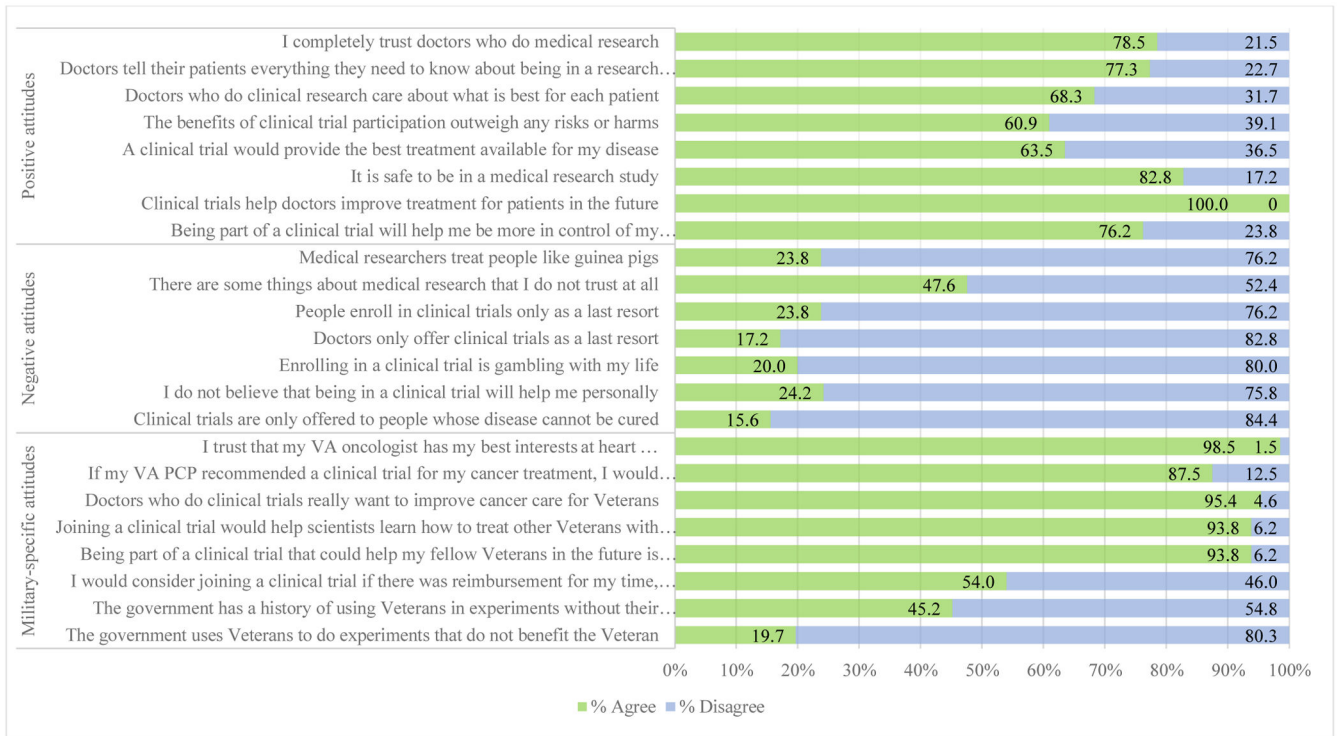


Figure 1: Overall positive, negative, and military-specific attitudes toward clinical trials among Veterans diagnosed with cancer at the Bronx Veterans Hospital (n = 67).

Grace C. Hillyer	Conceptualization, Formal analysis, Funding Acquisition, Methodology, Writing - Original Draft, Writing - Review and Editing
Yeun-Hee Anna Park	Conceptualization, Funding Acquisition, Methodology, Writing – Review and Editing
Ta-Chueh Hsu Rosenberg	Data Curation, Funding Acquisition, Methodology, Project Administration, Writing – Review and Editing
Prabhjot Mundi	Conceptualization, Methodology, Writing -Review and Editing
Imtiaz Patel	Conceptualization, Methodology, Writing -Review and Editing
Susan E. Bates	Conceptualization, Funding Acquisition, Methodology, Supervision, Writing – Original Draft, Writing – Review and Editing

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Table 1

Barriers to enrollment in clinical trials

		Provider barriers	
System-related barriers			
Unger, 2019 ⁵	Systematic review and meta-analysis including 13 studies (9 in academic and 4 in community settings) with 8883 patients	<ul style="list-style-type: none"> 55.6% (95%CI], 3.7-67.3%) - trial unavailable at patient’s institution 21.5% (95%CI, 10.9-34.6%) - ineligible for available trial 14.8% (95%CI 9.0-21.7%) eligible but did not enroll 8.1% (95%CI, 6.3-10.0%) eligible and enrolled 	<ul style="list-style-type: none"> Structural and clinical factors are reasons more than ¾ of patients with diagnosis of cancer (77.1%) did not participate in clinical trials - 55.6% because not available and 21.5% ineligible for available Rates of trial enrollment differed between academic and community settings, but not rates of trial unavailability, ineligibility, or non-enrollment Need to address structural and clinical barriers to trial participation, which combined make trial participation unachievable for more than three of four cancer patients.
Hamel, 2016 ⁸	<ul style="list-style-type: none"> Used a multilevel model as a framework to identify potential barriers to trial enrollment of racial and ethnic minorities at system, individual, and interpersonal levels Reviewed exactly how each level directly or indirectly contributes to doctor-patient communication 	<ul style="list-style-type: none"> Barriers at the level of health care systems and hospitals include limited number of available trials hospital infrastructures that lack resources to support trials; financial costs to hospitals; and restrictive study designs and eligibility criteria Health care professionals may not fully agree with or understand the scientific value of trials in general or the details of specific trials Some clinicians find it difficult to reconcile roles of physician and researcher, or are concerned about unduly influencing patient decisions about enrolling 	<ul style="list-style-type: none"> Barriers to enrolling a diverse population of patients in clinical trials are complex and multilevel Interventions focused on each level have been relatively successful, but multilevel interventions have the greatest potential for success Interventions to increase enrollment of racial and ethnic minorities in clinical trials, should address barriers at multiple levels Many barriers have disproportionate effect on minority enrollment because they receive care at under-resourced hospital systems
Provider attitudes			
Hamel, 2016 ⁸	<ul style="list-style-type: none"> Used a multilevel model as a framework to identify potential barriers to trial enrollment of 	<ul style="list-style-type: none"> Attitudes of health care professionals about trials and discussing such trials can affect quality of communication during discussions of clinical trials and impact recruitment 	<ul style="list-style-type: none"> Physician bias and its impact on decision to offer a clinical trial all impact enrollment but has not been fully investigated.

Provider barriers				
		racial and ethnic minorities at system, individual, and interpersonal levels	<ul style="list-style-type: none"> Health care professionals may not fully agree with/understand scientific value of trials in general or the details of specific trials, or may have concerns about practical issues such as strict protocol designs, patient inconvenience, and added work for the health care staff 	<ul style="list-style-type: none"> Differences in attitudes between providers and patients are important to understand in order to focus future initiatives to raise awareness about in congruency between each group and reduce implicit biases
Ibraheem, 2017 ⁹	<ul style="list-style-type: none"> Insight from Experts 		<ul style="list-style-type: none"> Some attitudinal factors are specific to enrollment of minority patients, such as concern about harming the therapeutic relationship 	
Hillyer, 2020 ¹⁰	<ul style="list-style-type: none"> Online survey of physicians and research staff involved in clinical research at a comprehensive cancer center and interviews of adult cancer patients not currently enrolled in a trial 		<ul style="list-style-type: none"> Conscious and unconscious implicit biases toward members of minority groups have an impact on clinical interactions with minority patients In one study¹⁰ as few as 20% of physicians and staff in one study agreed that clinical trials absolutely provide the best treatment available, and only 44% agreed benefits of clinical trial participation outweighed risks or harms. However, 57% felt participation in a clinical trial helps a patient be more in control of their disease and treatment 	
Patient Level Barriers				
Mills, 2006 ¹⁹	<ul style="list-style-type: none"> Systematic review to assess studies and estimated the frequency with which patients identified particular issues as barriers to participation in experimental and randomized trials 		<ul style="list-style-type: none"> Analyzed 12 qualitative (n=722) and 21 quantitative (n=5452) studies. Most common barriers included: <ul style="list-style-type: none"> Concerns with the trial setting Dislike of randomization General discomfort with research process Complexity and stringency of protocol Presence of placebo or no-treatment group Potential side-effects Unaware of trial opportunities Idea clinical trials not appropriate for serious diseases Fear trial involvement would have negative effect on relationship with physician Physician's attitudes towards trial Meta-analysis confirmed the findings of our systematic review 	<ul style="list-style-type: none"> Identified barriers to participation in clinical trials should help trialists develop strategies to attain maximum participation and cooperation in cancer trials, while informing and protecting participants

Provider barriers				
<p>Ford, 2008¹⁵</p>	<ul style="list-style-type: none"> Systematic review to determine barriers to participation of underrepresented populations in cancer-related trials 5257 studies cited; 65 eligible for inclusion Trials included: recruitment into cancer therapeutic trials (n=46), prevention trials (n=15), and both prevention and treatment trials (n=4) 	<ul style="list-style-type: none"> Numerous factors reported as barriers to participation in cancer-related trials. Only 20 studies reported statistically significant associations between hypothesized barriers and enrollment. Most articles reported an association between specific sociodemographic characteristics, such as older age, socioeconomic status, and racial/ethnic minority status, along with lack/inadequate health insurance and reduced enrollment Additional opportunity barriers include study design, namely, comorbid conditions and age-based exclusion, lack of provider referral, and the extent of managed care competition 	<ul style="list-style-type: none"> Underrepresented populations face numerous barriers to participation in cancer-related Racial and ethnic minorities, older adults, rural residents, and individuals of low socioeconomic status are underrepresented among participants in cancer-related trials. 	
<p>Meropol, 2007¹⁸</p>	<ul style="list-style-type: none"> Survey distributed to all medical oncologists in Pennsylvania and a subset of their patients to assess relevant background information and practical and psychosocial barriers to clinical trial participation 	<ul style="list-style-type: none"> 137 oncologists and 170 patients completed the surveys, 84% of patients aware of clinical trials Oncologists and patients generally agreed clinical trials important to improving cancer treatment. However, oncologists and patients more likely to consider clinical trials in advanced or refractory disease Random assignment and fear of receiving a placebo were ranked highly by both patients and oncologists as a barrier. Patients identified fear of side effects as the greatest barrier to clinical trial participation, whereas oncologists ranked this psychosocial barrier as least important to their patients 	<ul style="list-style-type: none"> Although oncologists and patients aware of clinical trials and have favorable attitudes, psychosocial barriers exist for patients that may impact participation in clinical trials Important discrepancies exist between perceptions of oncologists and patients regarding psychosocial barriers To optimize trial participation, need to characterize barriers perceived by oncologists and patients to help improve communication and decision making about enrollment 	
<p>Unger, 2019²⁰</p>	<ul style="list-style-type: none"> 5499 patients with a diagnosis of breast, lung, colorectal, or prostate cancer who made a treatment decision within the previous 3 months completed a national survey embedded within a web-based cancer treatment-decision tool accessible on multiple cancer-oriented websites 	<ul style="list-style-type: none"> 3420/5499 (62.6%) women and 2079/5499 (37.8%) were 3610/5499 (65.6%) 1 comorbidity Compared with the absence of comorbidities, 1 comorbidity associated with decreased risk of: <ul style="list-style-type: none"> Trial discussions (44.1% vs 37.2%; OR, 0.86; 95%CI, 0.75-0.97; P = .02) Trial offers (21.7% vs 15.7%; OR, 0.82; 95%CI, 0.70-0.96; P = .02). 	<ul style="list-style-type: none"> Independent of sociodemographic variables, the presence of comorbidities is adversely associated with trial discussions, trial offers, and trial participation itself. Updating trial eligibility criteria could lead to several thousand more patients with well-managed comorbidities participating in clinical trials each year 	

Provider barriers				
			<ul style="list-style-type: none"> • Trial participation (11.3% vs 7.8%; OR, 0.76; 95%CI, 0.61-0.94; P = .01) 	
Hamel, 2016 ⁸	<ul style="list-style-type: none"> • Used a multilevel model as a framework to identify potential barriers to trial enrollment of racial and ethnic minorities at system, individual, and interpersonal levels 		<ul style="list-style-type: none"> • Lack of transportation, inadequate insurance, lack of childcare, and poor access to health care amongst patient-level barriers to the enrollment of racial and ethnic minorities in clinical trials 	<ul style="list-style-type: none"> • Future interventions have to address barriers at multiple levels
Unger, 2013 ¹¹	<ul style="list-style-type: none"> • Internet-based treatment decision tool used to assess clinical trial participation patterns according to important income, education and demographic factors 		<ul style="list-style-type: none"> • In univariate models, older patients (P = .002) and patients with lower income (P = .001) and education (P = .02) were less likely to participate in clinical trials. In a multivariable model, income remained a statistically significant predictor of clinical trial participation (OR, 0.73; 95%CI 0.57-0.94; P = .01) • Even in patients age ≥ 65 years, with access to Medicare, lower income predicted lower trial participation. Cost concerns much more evident among lower-income patients (P < .001) 	<ul style="list-style-type: none"> • Lower-income patients were less likely to participate in clinical trials, even when considering age group • A better understanding of why income is a barrier may help identify ways to make clinical trials better available to all patients and would increase the generalizability of clinical trial results across all income levels.
Gross, 2005 ¹²	<ul style="list-style-type: none"> • Case-control study comparing women 65 who were participants in National Cancer Institute cooperative group breast cancer trials (cases) with a population-based sample of breast cancer patients (controls) obtained from the linked SEER Medicare database 		<ul style="list-style-type: none"> • Trial participants significantly less likely than community cancer patients to reside in high-poverty zip codes (20.9% vs. 24.9%, respectively; P<.001) or to have Medicaid insurance (2.0% vs. 10.0%; P<.0001). After adjusting for race, age, and county, trial participation remained inversely related to <ul style="list-style-type: none"> - Residing in areas with high poverty (OR vs. residents of remaining counties, 0.78; 95%CI, 0.62-0.98) - High unemployment rates (OR vs. residents of counties in the lowest quartile, 0.50; 95%CI, 0.35-0.71) - Having Medicaid insurance (OR vs. women without Medicaid, 0.22; 95%CI 0.13-0.37) • Black race was not found to be related to trial participation (OR for black vs. white, 1.0; 95% CI, 0.67-1.47) 	<ul style="list-style-type: none"> • Low socioeconomic status was associated inversely with trial enrollment for older women with breast cancer and appeared to account for the enrollment disparities between black patients and white patients.
Avin, 2017 ¹³	<ul style="list-style-type: none"> • Opinion 		<ul style="list-style-type: none"> • While the NIH Revitalization Act in 1993 requires that medical research paid for by the NIH include women and minorities, 	<ul style="list-style-type: none"> • Additional financial barriers also exist, including transportation

Provider barriers				
			<ul style="list-style-type: none"> it does not provide adequate instruction on minority enrollment. Only ~6% of clinical trials in the US are funded by the NIH, so that majority of trials do not abide by this requirement 	<ul style="list-style-type: none"> and/or lodging costs, and limited sick leave. Minority patients may have less access to clinical trials, as minorities are more likely to rely on under-resourced hospitals for care
Williams, 2018 ¹⁴	<ul style="list-style-type: none"> Opinion 		<ul style="list-style-type: none"> Logistics can include issues surrounding costs associated with participation, transportation, and convenience 	<ul style="list-style-type: none"> Possible solutions to issues concerning cost include ensuring studies are appropriately budgeted to account for time and commitment expectations and providing travel or meal vouchers that may ease the financial burden
Byrne, 2014 ¹⁶	<ul style="list-style-type: none"> 1100 White, Hispanic, and Black participants with a diagnosis of breast, lung, colorectal, or prostate cancer were obtained through the Florida cancer registry. Participants were surveyed via telephone to obtain demographic information, past participation, and willingness to participate in clinical trials, as well as barriers and facilitators to participation. 	<ul style="list-style-type: none"> 36.5% were willing to participate in a clinical trial In multivariate models, blacks and Hispanics equally willing as whites to participate in cancer trials, but Hispanics less likely to have participated, especially non-English-speaking Hispanics compared with English-speaking Hispanics Notable barriers across race/ethnicity were mistrust and lack of knowledge of clinical trials. There were racial differences in participation rates but not in willingness to participate 	<ul style="list-style-type: none"> 36.5% willingness to participate rate not very high felt to be due to being uninformed about participating, particularly in non-English-speaking Hispanics. Barriers and facilitators to participation vary by race. Improved understanding of cultural differences that can be addressed by physicians may restore faith, comprehension, and acceptability of clinical trials by all patients. 	
BeLue, 2006 ²¹	<ul style="list-style-type: none"> African American participated in focus groups by gender All focus groups were audio-taped and transcribed verbatim 	<ul style="list-style-type: none"> Different themes emerged for men versus women: <ul style="list-style-type: none"> Men desired to know information on funding issues, financial benefit and impact of the research Women desired to be treated respectfully and as an individual as opposed to just a study subject Researcher-participant relationship one of strongest themes related to potential female participation 	<ul style="list-style-type: none"> African American men and women present different preferences, beliefs and barriers to participation Integrating gender preferences into researcher-participant interactions, advertisement, informed consent delivery and advertisement of research studies may lead to increased participation rates Discussing and presenting relevant information on clinical research funding mechanisms, and the business of clinical research with potential participants may be helpful in building trust 	

Provider barriers

- Creating a process for information exchange and minimizing power imbalance between the researcher and participant may build trust
-

Abbreviations: CI, confidence interval; OR, odds ratio; SEER, Surveillance, Epidemiology, and End Results

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Table 2 –

Issues in Participating in Clinical Trials Amongst Veterans and Military Personnel

<p>Novak, 2019²⁶</p>	<ul style="list-style-type: none"> • Study enrolled 666 active-duty Service members from six U.S. military treatment facilities in a collaborative care study and completed assessments at baseline, 3-, 6-, and 12-months. • Data analyzed focused on study assessment completion rates at 3- and 6-months 	<ul style="list-style-type: none"> • Survey completion rates at both time-points points were 82% in both reimbursement status groups • Participants who received reimbursement were significantly more likely to complete follow-up assessments • Participants who received reimbursement were significantly more likely to complete study assessments at both 3- and 6-month time-points, controlling for gender, education, and race/ethnicity ($p < 0.01$) • Survey completion was 5% (98% vs 93%) and 4% (95% vs 91%) greater among participants offered reimbursement at three- and six-month time-points, respectively 	<ul style="list-style-type: none"> • Results suggest providing Service members reimbursement for research participation is associated with modest increases in retention rates in clinical trials. • Important to note this was not disease oriented
<p>Campbell, 2007²⁷</p>	<ul style="list-style-type: none"> • People in two outpatient waiting rooms were approached. The questionnaire assessed motivation toward trial involvement through use of five-point Likert-type scales and hypothetical trial scenarios; it also analyzed reasons for participation through subject ranking of reasons. 	<ul style="list-style-type: none"> • Veterans' likelihood of participation was only significantly different than non veterans' in relation to one clinical trial scenario - a clinical trial where all subjects were randomized to receive a new medication or placebo for research about a chronic disease for which there was no usual treatment such as Alzheimer's ($p = 0.011$) • Veterans had different reasons for trial participation than non veterans: <ul style="list-style-type: none"> – To help mankind and further improve medical care for others [altruism] ($P = 0.024$) – Paying back" the people who have treated them ($p = 0.003$) • Acquiring money for volunteering less important to Veterans ($p < 0.001$) • Comparing Veterans with armed conflict and inexperienced counterparts: 	<ul style="list-style-type: none"> • Knowledge of the varying reasons for participation could potentially aid recruitment efforts.

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- Reasons for participation similar
- Veterans with combat experience valued financial compensation less, and altruism, and contributing to medical research based on the care received more

Littman, 2018 ²⁸	<ul style="list-style-type: none"> • 10 focus groups in a purposive sample of 89 OEF/OIF Veterans in five US cities • Key topics included: • Reasons for participating or declining to participate in health-related research • Logistics around study • Recruitment and conduct • Compensation • Written materials • Information sharing preferences for study results 	<ul style="list-style-type: none"> • Key determinants of participating in health-related research were: <ul style="list-style-type: none"> - Receipt of adequate compensation - <i>“Duty, honor, and doing the right thing ”</i>-- a desire to fulfill an obligation to help other Veterans - Perception of the research topic as relevant and important. • For many, <i>both</i> sufficient compensation and a sense that the study would help other Veterans were critical. • Important potential deterrents to participating in a research study included considerations regarding the relative costs (e.g., inconvenience, time away from work and family) and risks related to privacy and information security, losing VA benefits, and study participation (e.g., experimental drugs) were • Before considering participation, Veterans needed assurance that the study was legitimate and not a <i>“scam”</i>. • Interacting with study personnel who were professional, courteous, knowledgeable was also noted as being helpful • Importance of transparency a key theme 	<ul style="list-style-type: none"> • Veterans described trust, transparent communication, and respect as essential characteristics of research in which they would be willing to participate.
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- Vague language about study aims or procedures engendered distrust.
- Desire for studies to communicate results of their specific health tests, as well as overall study findings, back to research participants

Hillyer, 2021 ^{current study}	<ul style="list-style-type: none"> • Survey assessing sociodemographic characteristics, health literacy, and general attitudes about clinical trials • Univariable analyses were conducted to evaluate differences in attitudes by age (<65 vs. 65 years) and race/ethnicity (non-Hispanic black vs. other). 	<ul style="list-style-type: none"> • 67/115 (58.3%) Veterans approached completed survey • 58.2% reported knowing what a clinical trial is • 78.5% stated that they trust doctors who do medical research • 87.5% would strongly consider joining a trial if recommended by VA primary care physician • 93.8% would participate in a clinical trial if it would help fellow Veterans in the future (• 93.8% would participate in a clinical trial if it would help scientists learn how to treat other Veterans with the same disease • 62.5% of non-Hispanic black participants agreed government has a history of using Veterans in experiments without their knowledge compared to 34.2% of Veterans of other race/ethnicity ($p = 0.03$). 	<ul style="list-style-type: none"> • Overall attitudes toward clinical trials were favorable especially when possibility of improving cancer care for fellow Veterans was considered • In approaching Veterans regarding participation in a clinical trial recommend: <ul style="list-style-type: none"> – Education aligned with the literacy level of the Veteran – Involvement of the VA primary care provider in clinical trial decisions – Awareness of a Veteran's altruism to help others/information
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Abbreviations: OEF, Operation Enduring Freedom; OIF, Operation Iraqi Freedom

Table 3:

Sociodemographic characteristics of Veterans diagnosed with cancer at the Bronx Veterans Hospital (n = 67) by age and race/ethnicity

SCREENING INFORMATION	Age				Race		
	Total (n = 67)	<65 (n = 27, 40.3%)	65 (n = 40, 59.7%)	p-value	Non-Hispanic African American (n = 28, 41.8%)	Other race and ethnicity (n = 39, 58.2%)	p-value
DEMOGRAPHICS							
Sex							
Male	64 (95.5)	24 (88.9)	40 (100.0)	0.06	25 (89.3)	39 (100.0)	0.07
Female	3 (4.5)	3 (11.1)	0 (0.0)		3 (10.7)	0 (0.0)	
Race/ethnicity							
Non-Hispanic Black	28 (41.8)	15 (55.6)	13 (32.5)	0.06	--	--	--
Other race/ethnicity	39 (58.2)	12 (44.4)	27 (67.5)		--	--	
Age							
<65 years	27 (40.0)	--	--	--	15 (53.6)	12 (30.8)	0.06
65 years	40 (59.7)	--	--		13 (46.4)	27 (69.2)	
Education							
High school	20 (30.8)	6 (23.1)	14 (35.9)	0.13	7 (25.9)	13 (34.2)	0.71
Some college, trade or technical school	30 (44.8)	16 (61.5)	14 (35.9)		14 (51.9)	16 (42.1)	
College or graduate degree	15 (24.4)	4 (15.4)	11 (28.2)		6 (22.2)	9 (23.7)	
Marital status							
Married/living as married	24 (36.4)	10 (37.0)	14 (35.9)	0.93	18 (64.3)	24 (63.2)	0.93
Not married	42 (63.6)	17 (63.0)	25 (64.1)		10 (35.7)	14 (36.8)	
SOCIAL SUPPORT							
Mean [SD]	57.3 [28.7]	62.1 [23.9]	53.9 [31.6]	0.26	52.9 [28.2]	60.4 [29.0]	0.94
Actual range	0.0-100.0	0.0-100.0	0.0-100.0		0.0-100.0	0.0-100.0	
QUALITY OF LIFE							
Mean [SD]	19.2 [3.3]	20.4 [3.2]	18.3 [3.2]	0.008	19.1 [3.8]	19.2 [3.0]	0.45
Actual range	9-27	16-27	9-24		9-26	13-27	
HEALTH LITERACY							
How often do you understand information from doctor							
Never	0 (0.0)	0 (0.0)	0 (0.0)	0.79	0 (0.0)	0 (0.0)	0.15
Almost never	0 (0.0)	0 (0.0)	0 (0.0)		0 (0.0)	0 (0.0)	
Sometimes	26 (38.8)	11 (40.7)	15 (37.5)		8 (28.6)	18 (46.2)	
All the time	41 (61.2)	16 (59.3)	25 (62.5)		20 (71.4)	21 (53.8)	
How often do you need help with instructions and information from the doctor or pharmacy							
Never	39 (58.2)	20 (74.1)	19 (47.5)	0.04	18 (64.3)	21 (53.8)	0.6
Almost never	11 (16.4)	3 (11.1)	8 (20.0)		5 (17.9)	6 (15.4)	

SCREENING INFORMATION	Age			Race			
	Total (n = 67)	<65 (n = 27, 40.3%)	65 (n = 40, 59.7%)	p-value	Non-Hispanic African American (n = 28, 41.8%)	Other race and ethnicity (n = 39, 58.2%)	p-value
Sometimes	12 (17.9)	4 (14.8)	8 (20.0)		3 (10.7)	9 (23.1)	
All the time	5 (7.5)	0 (0.0)	5 (12.5)		2 (7.1)	3 (7.7)	
HEALTH INFORMATION SEEKING							
Have a cell/mobile phone	61 (91.0)	26 (96.3)	35 (87.5)	0.39	27 (96.4)	34 (87.2)	0.39
Connect to internet via cell phone	36 (53.7)	18 (66.7)	18 (45.0)	0.08	15 (53.6)	21 (53.8)	0.98
Use the internet	43 (64.2)	20 (74.1)	23 (57.5)	0.17	19 (67.9)	24 (61.5)	0.60
Seek health information on the internet	29 (65.1)	13 (65.0)	15 (65.2)	0.99	13 (46.4)	16 (41.0)	0.66

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Table 4:

Clinical trials knowledge, attitudes, and beliefs among Veterans diagnosed with cancer at the Bronx Veterans Hospital (n = 67) by age and race/ethnicity

	Age			p-value	Race/ethnicity		p-value
	Total (n = 67)	<65 (n = 26, 38.8%)	65 (n = 40, 59.7%)		Non-Hispanic African American (n = 28, 41.8%)	Other race and ethnicity (n = 39, 58.2%)	
CLINICAL TRIALS KNOWLEDGE - Know what a clinical trial is							
Yes	39 (58.2)	18 (66.7)	21 (52.5)	0.25	15 (53.6)	24 (61.5)	0.51
No	28 (41.8)	9 (33.3)	19 (47.5)		13 (46.4)	15 (38.5)	
FEELINGS TOWARD CLINICAL TRIALS							
Very negative	0 (0.0)	0 (0.0)	0 (0.0)	0.90	0 (0.0)	0 (0.0)	0.80
Somewhat negative	2 (3.0)	1 (3.7)	1 (2.6)		1 (3.7)	1 (2.6)	
Neutral	19 (28.8)	9 (33.3)	10 (25.6)		9 (33.3)	10 (25.6)	
Somewhat positive	21 (31.8)	8 (29.6)	13 (33.3)		9 (33.3)	12 (30.8)	
Very positive	24 (36.4)	9 (33.3)	15 (38.5)		8 (29.6)	16 (41.0)	
WILLINGNESS TO JOIN A CLINICAL TRIAL							
If you were asked to participate in a clinical trial today, would you participate							
Yes, I definitely would	28 (42.4)	16 (59.3)	12 (30.8)	0.02	15 (53.6)	13 (34.2)	0.14
I might, not sure, it depends,	28 (42.4)	6 (22.2)	22 (56.4)		8 (28.6)	20 (52.6)	
No, I definitely would not	10 (15.2)	5 (18.5)	5 (12.8)		5 (17.9)	5 (13.2)	

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Table 5:

Attitudes toward clinical trials among Veterans diagnosed with cancer at the Bronx Veterans Hospital (n = 67) by age and race/ethnicity.

CLINICAL TRIAL ATTITUDES	Age			Race/ethnicity		p-value
	<65 (n = 26, 38.8%)	65 (n = 40, 59.7%)	p-value	Non-Hispanic African American (n = 28, 41.8%)	Other race and ethnicity (n = 39, 58.2%)	
<i>Positive attitudes</i>						
Being part of a clinical trial will help me be more in control of my condition/disease and treatment	14 (56.0)	34 (89.5)	0.002	20 (76.9)	28 (75.7)	0.91
Clinical trials help doctors improve treatment for patients in the future	27 (100.0)	40 (100.0)	--	28 (100.0)	39 (100.0)	--
It is safe to be in a medical research study	19 (73.1)	34 (89.5)	0.10	22 (84.6)	31 (81.6)	1.00
A clinical trial would provide the best treatment available for my disease	12 (48.0)	28 (73.7)	0.04	17 (65.4)	23 (62.2)	0.79
The benefits of clinical trial participation outweigh any risks or harms	12 (46.2)	27 (71.1)	0.045	14 (53.8)	25 (65.8)	0.34
Doctors who do clinical research care about what is best for each patient	16 (64.0)	27 (71.1)	0.56	17 (65.4)	26 (70.3)	0.68
Doctors tell their patients everything they need to know about being in a research study	19 (73.1)	32 (80.0)	0.51	20 (74.1)	31 (79.5)	0.61
I completely trust doctors who do medical research	19 (76.0)	32 (80.0)	0.70	20 (74.1)	31 (81.6)	0.47
<i>Negative attitudes</i>						
Clinical trials are only offered to people whose disease cannot be cured	6 (23.1)	4 (10.5)	0.29	4 (14.8)	6 (16.2)	1.00
I do not believe that being in a clinical trial will help me personally	4 (15.4)	12 (30.0)	0.18	6 (22.2)	10 (25.6)	0.75
Enrolling in a clinical trial is gambling with my life	3 (11.5)	10 (25.6)	0.16	6 (22.2)	7 (18.4)	0.71
Doctors only offer clinical trials as a last resort	3 (12.0)	8 (20.5)	0.51	5 (18.5)	6 (16.2)	1.00
People enroll in clinical trials only as a last resort	5 (19.2)	10 (27.0)	0.47	4 (15.4)	11 (29.7)	0.19
There are some things about medical research that I do not trust at all	14 (53.8)	16 (43.2)	0.41	12 (44.4)	18 (50.0)	0.66
Medical researchers treat people like guinea pigs	6 (24.0)	9 (23.7)	0.98	5 (19.2)	10 (27.0)	0.47
<i>Military-specific attitudes</i> *						
The government uses Veterans to do experiments that do not benefit the Veteran	7 (28.0)	5 (13.9)	0.20	8 (30.8)	4 (11.4)	0.06
The government has a history of using Veterans in experiments without their knowledge	12 (50.0)	16 (42.1)	0.54	15 (62.5)	13 (34.2)	0.03
I would consider joining a clinical trial if there was reimbursement for my time, effort and travel costs	16 (66.7)	18 (46.2)	0.11	18 (69.2)	16 (43.2)	0.04
Being part of a clinical trial that could help my fellow Veterans in the future is important to me	26 (100.0)	34 (89.5)	0.14	26 (96.3)	34 (91.9)	0.63
Joining a clinical trial would help scientists learn how to treat other Veterans with my disease in the future	25 (96.2)	36 (92.3)	0.64	26 (92.9)	35 (94.6)	1.00
Doctors who do clinical trials really want to improve cancer care for Veterans	27 (100.0)	35 (92.1)	0.26	28 (100.0)	34 (91.9)	0.25

CLINICAL TRIAL ATTITUDES	Age			Race/ethnicity		
	<65 (n = 26, 38.8%)	65 (n = 40, 59.7%)	p-value	Non-Hispanic African American (n = 28, 41.8%)	Other race and ethnicity (n = 39, 58.2%)	p-value
If my VA PCP recommended that I join a clinical trial for my cancer treatment, I would strongly consider doing it	21 (80.8)	35 (92.1)	0.25	23 (85.2)	33 (89.2)	0.71
I trust that my VA oncologist has my best interests at heart and is recommending the best treatment for my cancer	26 (100.0)	38 (97.4)	1.00	27 (100.0)	37 (97.4)	1.00

* Agreement with each statement

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