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Prevalence and correlates of invitation to participate in clinical trials among US adults

Aurora Occa^{a,b,*}, Allison Leip^{b,c}, Allison S. Merritt^d, Jerod L. Stapleton^{b,d}

^a Department of Communication, University of Kentucky College of Communication and Information, 277 Blazer Dining, 343 S. Martin Luther King Blvd, Lexington, KY 40526-0012, USA

^b Markey Cancer Center, University of Kentucky, 800 Rose St., Lexington, KY 40536, USA

^c Department of Family Sciences, University of Kentucky College of Agriculture, Food, and Environment, S123 Ag Science – North Lexington, KY 40546-0091, USA

^d Department of Health, Behavior & Society, University of Kentucky College of Public Health, 111 Washington Ave, Lexington, KY 40536, USA

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ABSTRACT

Clinical trials are essential to modern medicine, but several barriers, including poor communication, hamper their successful completion. We examined the prevalence and correlates of invitation to participate in clinical trials among a nationally-representative sample of US adults using survey responses from the 2020 HINTS (Cycle 5). Analyses were conducted in 2021.

Overall, 9% of respondents reported being invited to a clinical trial, a prevalence that is nearly half of previously reported rates in convenience samples recruited from health care settings. Compared to non-Hispanic Whites, Black respondents reported the higher prevalence of invitation (16.0%) whereas Asian respondents reported the lowest (2%). Prevalence of clinical trial invitation was significantly higher for the 65–74 age and the 75 + age groups. Prevalence of invitation was significantly higher among college graduates (12.0%) and lower for those residing in rural areas/small towns compared to metropolitan areas. Invitation was significantly higher among cancer patients/survivors (16.0%), patients with diabetes (11.7%) and with chronic lung disease (16.7%). Provider and patient factors there were associated with higher invitation rates included using web devices to communicate with providers or to aid health-related discussions, having a specific medical provider, and looking for health information online.

This study establishes a population-based prevalence of clinical trial communication that can be monitored as health care providers/organizations increase their focus on enrollment activities. Targeted interventions to improve communication about clinical trials are needed to address socio-demographic disparities and are particularly important for Asian patients, patients with lower income, and those living in rural areas.

1. Introduction

Clinical trials are fundamental to modern medicine and have produced new treatments and procedures to improve patients' quality of life and prevent diseases (NIH, 2021). Despite their importance, many clinical trials are compromised because of failure to enroll the number of participants required to examine treatment efficacy and safety. Barriers to the successful enrollment and retention of participants in clinical trials operate at multiple levels including: systemic, contextual, individual, and interpersonal (Unger et al., 2019; Hamel et al., 2016). Systemic and contextual barriers, such as inadequate infrastructures, trial unavailability, lack of funding and potential costs for participants, geographical location, and stringent inclusion criteria (Siembida et al., 2020; Unger et al., 2019; Djurisic et al., 2017; Wallington et al., 2016; Levy et al., 2006), are particularly challenging to address and may require coordinated efforts to produce complicated organizational changes (Morgan et al., 2020; Margitić et al., 1999). When organizations make clinical trials available to patients, individual and interpersonal barriers of healthcare providers and patients may impact success as well (Morgan et al., 2017). Such factors include negative attitudes towards clinical trials, mistrust, the time necessary to participate or reach the research hospital, limited understanding of medical research, and lack of discussion about clinical trials available opportunities between physicians and patients (Anderson et al., 2018; Hamel et al., 2016). A lack of

E-mail address: aurora.occa@uky.edu (A. Occa).

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^{*} Corresponding author at: Department of Communication, University of Kentucky College of Communication and Information, 277 Blazer Dining, 343 S. Martin Luther King Blvd, Lexington, KY 40526-0012, USA.

discussion is of critical relevance for the successful and informed recruitment of patients and there is evidence that although most patients would like to receive clinical trial information from their healthcare providers, clinical trials are discussed in only about 20% of physician-patient interactions (Albrecht et al., 2008; Anderson et al., 2018). When such discussions happen, data indicates that the physician's invite to join a clinical trial can increase participants' enrollment significantly (Eggly et al., 2008). Researchers have also begun to document socio-demographic differences in clinical trial perceptions and participation for members of under-represented groups, older individuals, and patients in rural communities (Kim et al., 2014; Levy et al., 2006; Sedrak et al., 2021; Stevens et al., 2016; Wallington et al., 2016).

The purpose of this study is to expand knowledge related to clinical trials by reporting the prevalence and correlates of invitation to participate in clinical trials among a nationally representative sample of US adults. We utilized data gathered in the 2020 Health Information National Trends Survey 5 (HINTS 5) which included new questions about participants' experiences with clinical trials. Our study objectives are to 1) provide unique national estimates of clinical trial availability to patients that extends prior studies by capturing whether discussions about clinical trials between physicians and patients have occurred and 2) add new information regarding whether the prevalence of these discussions differs based on patient demographic characteristics and provider and patients-related communication behaviors. This study has implications for identifying audiences that healthcare providers need to better include in clinical trial conversations and informing physician-led efforts and interventions to reduce disparities and bias in the clinical trial recruitment process.

2. Methods

We analyzed data from the Health Information National Trends Survey 5 (HINTS 5) Cycle 4 (2020), a cross-sectional, nationally representative survey administered by the National Cancer Institute, to civilian, non-institutionalized U.S. adults aged at least 18 years (Westat, 2020). The HINTS survey questions are designed to gather data on health communication, information, and behaviors and was active between February through June 2020. Participants completed the selfadministered mailed questionnaire in English or Spanish. The response rate was 37% with a total of 3,865 respondents returned completed surveys.

Invitation to clinical trials was measured using one item (Have you ever been invited to participate in a clinical trial?) with response options of yes, no, or I don't know/ I don't remember. Consistent with the goal of the study to identify the prevalence of participants who had been invited to clinical trials in the past, the small number of "I don't know/I don't remember" responses (n = 120, 3.2% of the total sample) were combined with the "no" responses to create a single "not invited" category. Socio-demographic correlates were gender, race/ethnicity, age, education, household income, geographic location, and medical history (diagnoses of cancer, diabetes, chronic lung diseases). For the geographic location variable (RUCA code), small town and rural were combined into a single category given a small number of "rural" responses (combined n = 478, 12.4% of the total sample). Other correlates included whether patients used any technologies to communicate with their providers, to aid discussions, whether there was a specific healthcare provider they visited most often, and whether they looked for cancer information (in this study, a proxy of whether patients looked for health information).

Prevalence estimates and analyses were weighted to correct for nonresponse and noncoverage biases using Complex Samples in SPSS Version 26 (Westat, 2020). Associations between each correlate and trial invitation were first examined with unadjusted (bivariable) logistic regression models. An additional adjusted (multivariable) model was conducted with all the correlates included as independent variables. The analysis of this publicly available data was approved by the University of Kentucky Medical Internal Review Board (IRB # 67898).

3. Results

In total, 3809 participants responded to the question regarding their invitation to clinical trials (56 missing responses, 1.4% of the total sample) with 9.0% reporting an invitation to a clinical trial. A similar number of males (8.4%) and females (9.0%) were invited to clinical trials. There was evidence of racial and ethnic and differences with, compared to non-Hispanic Whites (8.7%), higher prevalence of invitation among Blacks (16.0%) (unadjusted OR = 2.00; adjusted OR = 1.94) and lower prevalence among Asians (unadjusted OR = 0.22; adjusted OR = 0.21). The odds of clinical trial invitation were significantly higher for the 65–74 age and the 75 + age groups compared to individuals between 18 and 34 in the unadjusted model and for all age categories in the adjusted model. Prevalence of invitation was significantly higher among college graduates (12.0%) compared to those with less than a high school education (5.0%) (unadjusted OR = 2.59; adjusted OR =4.26). Considering income, looking at the adjusted model (OR = 0.40), significant differences in invitation rates were observed for individuals in the highest bracket (7.8%), who were invited less compared to individuals in the lowest bracket (12%). The odds of invitation were significantly lower for individuals residing in rural areas or small towns compared to metropolitan areas (unadjusted OR = 3.41; adjusted OR =4.68). Invitation rates were higher among those with certain health conditions including a cancer history (16.0%), chronic lung disease (16.7%), and diabetes (11.7%). In univariate analyses, the odds of invitation were significantly higher for those respondents who reported using web devices to communicate with providers (OR = 1.62) or to aid health-related discussions (OR = 2.16), who report having a particular medical provider they used regularly (OR = 2.54), and looking for health information online (OR = 2.28) (Table 1).

4. Discussion

In this study, we examined the prevalence and correlates of invitation to participate in clinical trials among US adults who were surveyed in the HINTS 2020. Our findings are consistent with Williams et al. (2021) and expanded to include patients' and healthcare providers' behaviors. Across all participants in this sample, 9.0% recalled ever being invited to a clinical trial, which is a unique documentation of national prevalence. This prevalence is lower than other studies that document approximately 20% of patients are invited to join clinical trials (Albrecht et al., 2008; Anderson et al., 2018). Prior studies have been conducted in convenience samples from health care settings or among participants with interest in receiving health care information and may have inflated rates relative to population-based studies. This finding may indicate miscomprehensions during clinical consultations between patients and their healthcare providers, for example due to the complex jargon used to describe medical research or due to differences in expectations. Discrepancies in prevalence of invitation may also be due to differences in the socio-demographic characteristics of study samples since this study with national data shows important differences within socio-demographic factors. Considering race and ethnicity, we observed that Asian individuals reported the lowest prevalence of invitation to join clinical trials (2%), with no or little improvement to what observed in previous studies (Guerrero et al., 2018; Pang et al., 2016). This low prevalence may be attributed to the limited efforts dedicated to recruiting Asians specifically. Also, the umbrella term "Asian" include individuals with different cultures, religions, and preferences, which may not be adequately addressed when recruiting (Hussain-Gambles et al., 2006). Asian and Hispanic individuals may also be invited less often due to possible language barriers that limit conversations between them and their healthcare providers. Black individuals reported the highest prevalence of invites compared to the other groups. This finding of higher rates of invitation was surprising, considering that Black

Table 1

Weighted percentages and odds ratios of invitation to a clinical trial among U.S. a

Table 1 (continued)

lults, HINTS 5 Cycle 4 (Clinical Trial			
	Ever Invited to Clinical Trial		Tests of Associations			No ^a	Yes	Yes compared to No	
	No ^a	Yes	Yes compared to No			% (95% CI)	% (95% CI)	Unadjusted OR (95% CI)	Adjusted OR (95%
	% (95% CI)	% (95% CI)	Unadjusted OR (95% CI)	Adjusted OR (95%					CI)
		-	OR (93% CI)	CI)	20–35	91.2 (85.9,	8.8 (5.3, 14.1)	0.70 (0.39, 1.28)	0.75 (0.33) 1.72)
Total	91.0 (89.4,	9.0 (7.5, 10.6)	-	-	35–50	94.7) 92.7	7.3 (4.3,	0.58 (0.28,	0.79 (0.31
	(89.4, 92.5)	10.0)				(87.9, 95.7)	12.1)	1.21)	2.02)
Com lan					50–75	91.6	8.4 (5.7,	0.67 (0.35,	0.66 (0.28
Gender Male	91.6	8.4 (6.3,	Ref	Ref		(87.8,	12.2)	1.27)	1.54)
	(88.9,	11.1)			75+	94.3) 92.2	7.8 (5.9,	0.62 (0.37,	0.43* (0.2
	93.7)					(89.7,	10.3)	1.05)	0.97)
Female	91.0	9.0 (7.3,	1.09 (0.73,	1.11 (0.74,		94.1)			
	(88.8, 92.7)	11.2)	1.62)	1.6)					
					Urban-Rural				
Race/ethnicity					Small town/rural	97.0	3.0 (1.2,	Ref	Ref
Non-Hispanic White	91.3	8.7 (7.0,	Ref	Ref		(92.7, 98.8)	7.3)		
-	(89.2,	10.8)			Micropolitan	94.1	5.9 (2.5,	2.01 (0.54,	1.74 (0.35
	93.0)				-	(86.9,	13.1)	7.48)	8.73)
Non-Hispanic Black	84.0	16.0	2.00** (1.25,	1.87* (1.08,		97.5)			
	(77.6, 88.8)	(11.2, 22.4)	3.21)	3.23)	Metropolitan	90.4	9.6 (8.1,	3.41** (1.39, 8.39)	4.00* (1.0)
Hispanic	93.6	6.4 (3.9,	0.72 (0.41,	0.11 (0.53,		(88.7, 91.9)	11.3)	8.39)	15.46)
-r -	(89.5,	10.5)	1.29)	2.35)		,,,,,			
	96.1)				Concor History				
Non-Hispanic Asian	98.0	2.0 (0.7,	0.22** (0.07,	0.22* (0.06,	Cancer History No	92.0	8.0 (6.6,	Ref	Ref
	(94.0, 99.3)	6.0)	0.68)	0.74)	10	(90.3,	9.7)	iter	iter
Non-Hispanic Other	87.1	12.9	1.55 (0.69,	1.74 (0.76,		93.4)			
	(74.8,	(6.1,	3.49)	3.98)	Yes	84.0	16.0	2.18*** (1.43,	1.43 (0.92
	93.9)	25.2)				(78.6, 88.3)	(11.7, 21.4)	3.30)	2.20)
Age (years)									
18–34	94.5	5.5 (3.4,	Ref	Ref	Chronic Lunch Disease	92.3	77(6)	Def	Def
	(91.1,	8.9)			No	92.3 (90.6,	7.7 (6.3, 9.4)	Ref	Ref
35-49	96.6) 90.8	9.2 (6.6,	1.73 (0.96,	1.51 (0.77,		93.7)	5.1)		
	(87.3,	12.7)	3.10)	2.97)	Yes	83.3	16.7	2.40*** (1.51,	1.82* (1.14
	93.4)					(76.7,	(11.7,	3.82)	2.90)
50–64	90.9	9.1 (7.1,	1.72 (0.97,	1.47 (0.82,		88.3)	23.3)		
	(88.3,	11.7)	3.05)	2.62)					
65–74	92.9) 86.7	13.3	2.61*** (1.47,	2.90***	Diabetes				
	(83.2,	(10.4,	4.63)	(1.53, 5.52)	No	91.6 (89.7,	8.4 (6.8, 10.3)	Ref	Ref
	89.6)	16.8)				93.2)	10.3)		
75+	89.8	10.2	1.95* (1.14,	1.90 (0.82,	Yes	88.3	11.7	1.45* (1.00,	1.52* (1.03
	(84.9,	(6.8, 15.1)	3.31)	4.38)		(84.8,	(8.9,	2.10)	2.28)
	93.2)	15.1)				91.1)	15.2)		
Education					Use smart device,				
Less than High School	95.0	5.0 (2.8,	Ref	Ref	internet or email to				
	(91.1,	8.9)			communicate with				
High School Graduate	97.2) 93.9	6.1 (4.0,	1.23 (0.64,	1.14 (0.44,	doctor				
High School Graduate	(90.0,	9.1)	2.36)	2.99)	No	93.0 (90.9,	7.0 (5.4, 9.1)	Ref	Ref
	96.0)					(90.9, 94.6)	9.1)		
Some College	91.1	8.9 (6.8,	1.85 (0.94,	1.97 (0.79,	Yes	89.1	10.9	1.62*** (1.15,	1.18 (0.77
	(88.5,	11.5)	3.63)	4.91)		(86.6,	(8.8,	2.28)	1.82)
Coll. graduate or more	93.2) 88.0	12.0	2.59** (1.34,	4.60**		91.2)	13.4)		
	(85.0,	(9.6,	5.02)	(1.61,					
	90.4)	15.0)	-	13.16)	Has smart device helped in discussions with				
Income (in thousands)					provider No	93.5	6.5 (5.0,	Ref	Ref
Less than \$20	88.0	12.0	Ref	Ref	110	93.3 (91.6,	8.4)	1001	1101
	(82.5,	(8.1,				95.0)	~		
	91.9)	17.5)						(continued	

Table 1 (continued)

	Ever Invit Clinical Tr		Tests of Associations			
	No ^a	Yes	Yes compared to No			
	% (95% CI)	% (95% CI)	Unadjusted OR (95% CI)	Adjusted OR (95% CI)		
Yes	87.0 (83.7, 89.7)	13.0 (10.3, 16.3)	2.16*** (1.48, 3.16)	1.56* (1.02, 2.37)		
Is there a particular health care provider you see often						
No	95.1 (93.0, 96.6)	4.9 (3.4, 7.0)	Ref	Ref		
Yes	88.5 (86.1, 90.6)	11.5 (9.4, 13.9)	2.54*** (1.63, 3.95)	1.27 (0.72, 2.25)		
Seek Cancer Info any Source						
No	94.1 (92.3, 95.5)	5.9 (4.5, 7.7)	Ref	Ref		
Yes	87.4 (84.5, 89.8)	12.6 (10.2, 15.5)	2.28*** (1.59, 3.26)	1.70* (1.05, 2.76)		

Note. CI, confidence interval; OR, odds ratio; Ref, reference category. ***= p < 0.001; **= p < 0.01; *= p < 0.05.

^aRespondents who reported "no" or "I don't know/I don't remember".

patients are under-represented within clinical trial patients, with only 4% of all patients enrolled in clinical trials (U.S. Food and Drug Administration Snapshots Summary in Nazha et al., 2019) compared to their representation in the population, equal to 13.4% in 2019 (US Census Bureau, 2021). It is possible that the higher invite rates for Black patients are due to the realization that this population has been historically under-represented. However, the documented low rate of actual enrollment may suggest that invitations to Black patients do not consider their specific needs and preferences, for example, the inclusion of family and friends (Graham et al., 2018). This finding may also be explained by the presence of systemic barriers affecting Black patients, such as restrictive inclusion criteria that do not account for the higher presence of comorbidities in this population (Nazha et al., 2019), and by the lack of a support system (Graham et al., 2018). Another factor that may have influenced this data is the higher incidence of chronic diseases African Americans suffer from compared to White Americans (CDC, 2021). It is essential to continue the efforts to increase the representation of patients from all historically marginalized groups into clinical trials by engaging them in dedicated discussions and by designing clinical trials that take into considerations their specific needs and characteristics.

We observed significant difference in the prevalence of invitations by age with a higher prevalence among older participants. Younger adults tend to require less medical assistance than older adults, and thus to visit their healthcare providers less often. They tend to be healthier than older adults, and thus they may perceive the importance of medical research as less pressing. Also, younger adults may have full-time jobs that allow for less flexibility and thus less time to participate in clinical trials. However, age discrepancies in clinical trial enrollment are concerning for several reasons. First, the current enrollment rates of adolescents and young adults in clinical trials are significantly lower than the enrollment rates of pediatric patients (Parsons et al., 2019), hampering the identification of optimal treatment regimens (Siembida et al., 2020). Second, several clinical trials evaluate prevention or early screening treatments that are open to healthy younger adults, and the number of these clinical trials is likely increasing over time (ClinicalTrials.gov, 2021; Gresham et al., 2020). Third, the significantly lower prevalence of invites for younger adults represents a missed opportunity. Starting clinical trial-related conversations early on may help to reduce negative attitudes and improve patients' education about the medical research process, which have shown to be barriers to clinical trial accrual.

College graduates tended to be invited more compared to individuals with a lower education level. It is possible that college graduates have jobs that allow for a greater time flexibility, and thus greater time to participate in clinical trials. It is also possible that exposure to scientific or health concepts that most college students receive influenced their engagement in the conversations with their healthcare providers, as observed for discussions about cancer screening (Bao et al., 2007). This finding points to the importance of improving the organization of clinical trials by making data collection strategies more flexible when possible. For example, researchers may activate mobile units to collect data, thus reducing temporal and geographical barriers (Beck et al., 2020). In addition, this finding highlights the importance of providing education and support materials about clinical trials that can be understood and appreciated by individuals who have not been exposed to such information.

Individuals with lower income tended to be invited more often than individuals with a higher income. This data seemed to be in contrast with the one about education. However, it is possible that individuals with more limited economic resources are invited to join clinical trial as a strategy to receive care for free or to at a more controlled cost as part of the trial's incentives.

Consistent with previous research (Kim et al., 2014), we observed rural–urban differences such that the odds of invitation were more than 3 times higher for urban participants compared to participants from rural areas or small towns. As Kim and colleagues (2014) suggest, physicians from rural areas may be less aware of existing open clinical trials or citizens from rural areas or small towns may live so far away from research facilities and hospitals that it could be inconvenient for them to participate in clinical trials. To reduce this disparity, researchers should make specific efforts to engage individuals from these disadvantaged areas in their clinical trials. These efforts could be directed to inform and update local healthcare providers about clinical trial opportunities and to provide resources for patients to reach the research facility, or e-health provision and monitoring.

Importantly, we observed specific provider and patient communication factors that may impact conversations with healthcare providers and thus the likelihood of being invited to join a clinical trial. In particular, using technological devices and web resources was associated with higher odds of invitation. Patients who are more technologically savvy may be advantaged to retrieve relevant information about clinical trials useful during discussions with healthcare providers. This finding, along with the fact that patients who look for health-related information online are more likely to be invited, points to the importance of media literacy as a factor to consider when designing interventions about clinical trials. Another relevant behavior was the frequency of visits, which is in line with previous research that indicates the importance of relationship building to support clinical trials-related discussions (Morgan et al., 2017).

Lastly, individuals with a history of cancer, diabetes, or chronic lung disease diagnosis were more likely to have been invited to join clinical trials compared to other individuals. While this finding is a positive sign for patients' focused research, the low accrual rates to these clinical trials indicate that it is important to continue improving these conversations. In addition, this finding highlights the necessity of working on multiple levels to sustain existing and future cancer-related trials. Ultimately, this finding reinforces the importance of offering individuals the opportunity to join clinical trials during their routine medical appointments, not only when satisfactory alternatives may not be available. Table 2 summarizes several possible communication interventions that Table 2

Communication interventions to aid clinical-trial related discussions.

Target audience	Intervention
Healthcare providers	Communication training programs for providing verbal and nonverbal skills to interact with patients. Interventions and resources to support the adoption of telemedicine. Development of inter-organizations programs to inform providers outside metropolitan areas about the availability of trials and facilitate remote enrollment. Training programs to reduce unconscious bias.
Patients	Educational interventions in hospitals and healthcare facilities about clinical trials, their purpose, their processes (in multiple languages). National campaigns to inform about the importance of medical research leveraging online resources. Media literacy training programs to help patients navigate health-related information online. Decision aids to support patients' decision-making process.

could be developed and tested to aid clinical-trial related discussions.

5. Limitations

Limitations include the use of self-reported data that may be subject to reporting or recall bias. Second, the year 2020 has brought several challenges to providing healthcare services, including conducting and recruiting for clinical trials. Therefore, some of the differences observed between groups may have been exacerbated by the Covid-19 crisis. Third, it was not possible to analyze actual participation in clinical trials or to examine the possible relationship between invitation and participation in clinical trials because of the low number of individuals participating in clinical trials within the sample. Future studies should be designed to address these limitations and include prevalence and correlates of actual participation following an invite. Future studies should also focus on examining other potentially relevant factors, such as for example the role and type of providers associated with clinical trial invite.

6. Conclusions

This study analyzed the HINTS 2020 to examine the prevalence and correlates of invitation to participate in clinical trials among US adults. Findings indicated disparities by race/ethnicity, age, education, geographical location, and cancer history. We hope the findings from this study will encourage researchers and healthcare providers to better target their conversations about clinical trials with potential participants, for example, by addressing the concerns and needs of each specific group. We recommend healthcare providers to increase direct invitations to join clinical trials to patients. To support healthcare providers and personnel in their recruitment efforts, and increase access to clinical trials, we encourage research facilities and hospitals to partner with communication experts and social scientists to develop training programs aimed at reducing biases and improving the communication about clinical trials with potential participant. We also advocate for developing interventions to support the information and communication needs of the critical audiences identified through this study, and to facilitate the conversations between healthcare providers and patients.

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Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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