

Clinical trial participation in America: The roles of eHealth engagement and patient–provider communication

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Abstract

Objective: Public participation in a clinical trial is the foundation of clinical research and the cornerstone for the discovery of new treatment and improving health outcomes. This study aims to examine how eHealth engagement, patient–provider communication, and clinical trial knowledge are associated with clinical trial participation in the United States.

Methods: Data were drawn from the Health Information National Trends Survey Iteration 5 Cycle 4 conducted in 2020. The sample included 3865 American adults aged 18 years and above. Path analysis using structural equation modeling and hierarchical linear regression was performed to examine the effects of eHealth engagement and patient–provider communication on clinical trial participation.

Results: About 5% of American adults have ever participated in a clinical trial. Younger adults, males, minorities, and people with lower education, less clinical trial knowledge, and less eHealth engagement were less likely to participate. After controlling for demographic variables, we found that more eHealth engagement led to a better knowledge of clinical trials, which was strongly associated with participation. Further, patient-centered communication did not directly lead to clinical trial participation; instead, it positively moderated the relationship between clinical trial knowledge and participation.

Conclusions: The national survey data indicate that American participation in clinical trials remains low and a significant disparity exists. Within the context of the eHealth movement, it is critical to implement targeted interventions to improve clinical trial knowledge, address the digital divide, and enhance patient-centered communication.

Keywords

clinical trial participation, health disparities, digital divide, eHealth engagement, patient-centered communication

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Introduction

Public participation in a clinical trial is the foundation of clinical research and the cornerstone for the discovery of new treatment and improving health outcomes. Data are limited in terms of Americans' participation in clinical trials. It is estimated that 2% to 3% of cancer patients have ever participated in a clinical trial, even though most Americans view clinical trial participation favorably.^{1,2} The gap between the willingness to participate and the actual participation rate suggests the barriers; more research is needed to identify the modifiable barriers.

The low rates of clinical trial participation reflect significant demographic and socioeconomic disparities.

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Literature documents lower clinical trial participation rates among minority and underserved populations,³ which are linked to their poor knowledge of clinical trials, mistrust of the health care system, and the associated clinical trial opportunities.⁴ Discrepancies in participation in clinical trials may exacerbate known health disparities among underserved populations, while broad and diverse inclusion of all population subgroups can help advance clinical research and improve quality of life for all patients.⁵ It is important to note that most of these previous studies were based on a small sample size of cancer patients; data are rather limited from the general population-based national representative sample. It remains unclear whether the demographic and socioeconomic disparities in clinical trial participation exist among the general population in a broader health context, not limited to cancer care.

The internet has fundamentally transformed how people seek health information; the eHealth movement is changing people's health behaviors and reshaping the landscape of health care delivery.⁶ E-Health engagement (i.e. using the internet or mobile devices for health purposes) is found to be associated with improved health knowledge and better health outcomes, including active participation in health care.⁷ E-Health also has the potential to enhance clinical trial participation. For example, internet use for health information has been found to increase clinical trial awareness.⁸ According to a systematic review, no knowledge of clinical trial opportunities is one major barrier to participation in clinical trials.⁹ Health care organizations have also increasingly utilized social media for health education and community outreach for clinical trial recruitment.¹⁰ Despite these benefits of eHealth engagement, it is still unclear if an individual's eHealth engagement would affect one's clinical trial knowledge and participation.

The patient-provider relationship is crucial in patients' clinical decision-making. The literature suggests that patient-centered communication (PCC) is a strong predictor of patient engagement and empowerment.¹¹ It is also a key factor in clinical trial recruitment and can explain the disparities in clinical trial participation.⁵ For example, a study that analyzed video recordings of patient-provider communication about clinical trials found that PCC facilitated clinical trial recruitment. Specifically, patients were more likely to participate if their providers conveyed the assurance of support, communicated in a way that patients and family members could understand, and helped build an alliance.¹² Another study, on the other hand, found that mistrust of health care providers was the main cause in African American cancer patients' lower rates of clinical trial participation.¹³ Despite the documented effect of PCC on clinical trial participation, how PCC takes effect (i.e. via direct effect or moderating effect) in the context of eHealth engagement is understudied.

Taken together, the goal of the study is to examine the key factors associated with clinical trial participation in

this eHealth movement. Specifically, we hypothesized that (1) disparities exist in clinical trial participation with underserved populations less likely to participate; (2) after controlling for potential confounders, knowledge of clinical trial, eHealth engagement, and PCC have direct effects on participation; and (3) PCC moderates the relationship between knowledge and participation, such that patients who perceive higher levels of PCC from their doctors are more likely to participate in clinical trials compared to their counterparts with the same level of knowledge.

Methods

Data source

Data were drawn from the Health Information National Trends Survey (HINTS) Iteration 5 Cycle 4. The HINTS collects nationally representative data annually to understand American public's information use and health behaviors.¹⁴ The HINTS 5 Cycle 4, conducted in 2020, is the most recent iteration and includes a sample size of 3865 American adults aged 18 years and above. All the 3865 respondents were included in our study for data analysis.

Measures

The outcome variable is *clinical trial participation*, which was assessed with a binary item (0 = no, 1 = yes). The independent variables include *clinical trial knowledge*, which was measured with a 3-point scale on self-rating of one's level of knowledge about clinical trials. This measure has been used in a prior study to assess patients' self-reported health knowledge.¹⁵ *E-Health engagement* was measured by 12 items about how one uses the internet and mobile technologies for health purposes such as looking for health information online, communicating with doctors online, using mobile devices to track progress on health-related goals, using social media for health information sharing, and seeking online social support.¹³ A summative index was created with a higher score indicating more eHealth engagement. *PCC* was measured by 7 items drawn from the core functions of patient-provider communication proposed by Epstein and Street.¹¹ Participants were asked to report if their doctors would spend enough time with them, give them the chance to ask questions, give them enough attention, make sure to understand them, explain things to them, and help them deal with feelings of uncertainty. The responses were a 4-point scale ranging from 1 = never to 4 = always; the scores were averaged with a higher score indicating better PCC (Cronbach's alpha = 0.93). *Demographic variables* included age, gender, education, household income, race (1 = non-Hispanic White, 0 = other), and self-rated health status (ranging from 1 = poor to 5 = excellent).

Data analysis

First, we conducted a descriptive analysis to understand the participant characteristics and their relationships with the outcome variable. Chi-square (for categorical variables) and *t*-test (for continuous variables) were used to compare the differences between clinical trial participants and non-participants. Second, we performed path analysis using structural equation modeling (SEM) to examine the direct and indirect effects of eHealth engagement, clinical trial knowledge, and PCC on clinical trial participation, controlling for demographic variables. In the covariance structure analysis, the maximum likelihood of estimation was adopted.¹⁶ Third, we conducted hierarchical regression to assess the moderating effect of PCC. An interaction term between clinical trial knowledge and PCC (after being mean-centered) was created and entered into the regression model. The significance of this interaction term indicated the moderation effect. To further examine the moderated mediation effect, we adopted a normal theory-based approach proposed by Preacher et al.¹⁷ This method was effective in testing conditional indirect effect at three values of the moderator, including low (mean $-1 \times$ standard deviation), medium (mean), and high (mean $+1 \times$ standard deviation). Stata 14 was used for data analysis.

Results

The sample characteristics are presented in Table 1. The average age was 57; 40% were male; 43% had some college education or above. The mean household income was about \$50,000. Around 60% were non-Hispanic White. The average self-reported health status was 3.39 (range 1–5) at the level of “good”. In total, 5.1% of the respondents have participated in clinical trials. The clinical trial knowledge was rather low, with 36.4% reporting “I don’t know anything about clinical trials,” and 52.1% indicating “I know a little bit about clinical trials.” Of the 12 eHealth activities, people on average engaged in 4 to 5 activities. The level of PCC was generally high with a mean score of 3.41 (ranging from 1 to 4).

As shown in Table 1, clinical trial participants were likely to be older, female, non-Hispanic White, having a higher level of education, better knowledge about the clinical trial, and more eHealth engagement than non-participants. We also noted that there was no difference in PCC between the two groups. Given the differences in sample size in these two groups, we conducted Levene’s test to check for the assumption of homogeneity of variance. We found that the two groups have equal variances, except age [$F(1,3863) = 6.289, p = 0.012$]. To compare groups with the heterogeneity of variance, prior research suggested the Brown–Forsythe test.¹⁸ The Brown–Forsythe test still supported our finding regarding the significant effect of age on clinical trial participation

[$F(1227) = 12.938, p < 0.001$]. This result demonstrated that disparities did exist in American adults’ clinical trial participation. Specifically, racial and ethnic minorities and people with lower socioeconomic status (SES) had a lower level of participation in clinical trials.

The results of the SEM modeling are shown in Figure 1. Our SEM model had a satisfactory fit: $\chi^2(2) = 13.227, p = 0.001$; root mean square error of approximation = 0.038 (90% confidence interval, 0.020–0.059); comparative fit index = 0.995; and standardized root mean squared residual = 0.007. The path analysis found that eHealth engagement had a positive and direct effect on clinical trial participation ($\beta = 0.10, p < 0.001$). Also, eHealth engagement was positively associated with clinical trial knowledge ($\beta = 0.22, p < 0.001$), which, in turn, increased participation ($\beta = 0.18, p < 0.001$). Thus, a partial mediation effect was supported. Also, PCC did not have a direct effect on clinical trial participation; instead, it positively moderated the relationship between clinical trial knowledge and participation (odds ratio = 1.15, $p < 0.05$). In other words, PCC strengthened the effect of knowledge on participation.

Table 2 also illustrates the moderated mediation effect in which PCC strengthened the indirect effect of eHealth engagement on clinical trial participation; that is, eHealth engagement exerted stronger indirect effects on clinical trial participation, through clinical trial knowledge, when patients had more PCC with their doctors. Finally, regardless of the level of PCC, clinical trial knowledge remained a significant mediator in the pathway linking eHealth engagement to clinical trial participation.

Discussion

This study represents one of the first to examine Americans’ participation in clinical trials based on a nationally representative survey; the critical constructs such as eHealth engagement and PCC were analyzed using SEM to illustrate the interrelationships. Only 5.1% of American adults have ever participated in a clinical trial, and significant disparities existed with racial/ethnic minorities, men, and people of low SES less likely to participate. These findings are consistent with the literature and echo the need for effective interventions to boost underserved populations’ participation in clinical trials.^{2,3} Our analyses have also identified some modifiable factors that can guide developing evidence-based interventions, explained as follows.

First, our data revealed that eHealth engagement had a direct effect on clinical trial participation, but the indirect effect through the mediator of clinical trial knowledge was stronger. Such a finding indicated that in the context of the eHealth movement, a higher level of eHealth engagement would lead to a better knowledge of clinical trial and a subsequently higher likelihood of participation. This finding has two implications for interventions. One, some underserved groups have not fully utilized widely available

Table 1. Demographic characteristics of sample by participation in clinical trial.

Variable	Total	Participants (5.15%)	Non-participants (94.85%)	t	Chi-square
Age (mean, SD)	57 (16.7)	60.69 (14.72)	56.81 (16.78)	3.20**	–
Gender				–	3.94*
Male	40.39%	33.67%	40.75%		
Female	59.61%	66.33%	59.25%		
Education				–	18.19***
High school or less	35.83%	22.61%	36.55%		
Some college	21.14%	21.61%	21.11%		
College or above	43.03%	55.78%	42.33%		
Income (mean, SD)	5.59 (2.13)	5.69 (2.02)	5.58 (2.14)	0.68	–
Race				–	4.93*
Non-Hispanic White	59.82%	67.34%	59.41%		
Minority	40.18%	32.66%	40.59%		
Health status				–	1.27
Poor or fair	16.22%	19.1%	16.07%		
Good or excellent	83.78%	80.9%	83.93%		
Clinical trial knowledge				–	165.5***
No knowledge	38.78%	7.54%	40.48%		
A little	49.94%	56.78%	49.56%		
A lot	11.28%	35.68%	9.96%		
PCC (mean, SD)	3.41 (0.59)	3.41 (0.56)	3.41 (0.60)	0.07	–
eHealth usage (Mean, SD)	4.61 (3.14)	6.11 (3.18)	4.53 (3.12)	6.95***	–

Note. Participants refer to people with previous clinical trial participation; Non-participants refer to people who have never participated in clinical trials. PCC=patient-centered communication; SD=standard deviation. * $p < 0.05$; ** $p < 0.01$; *** $p < 0.001$.

eHealth resources, thus targeted interventions are needed to bridge the digital health divide.^{8,19} For example, providing access to high-speed internet and targeted outreach to improve eHealth literacy.²⁰ Two, it is critical to make clinical trial information easily available to the public via the internet; such information also needs to be culturally tailored to the underserved groups, especially minority populations and people of lower SES.²¹

Second, our analysis showed that contradictory to our hypothesis, PCC had no direct effect on clinical trial

participation; instead, PCC acted as a moderator and “amplified” the effects of eHealth engagement and clinical trial knowledge on the outcome of clinical trial participation. This finding suggests that PCC can be integrated with eHealth engagement to maximize the benefits of online information exchange. Literature has documented that PCC in the traditional face-to-face setting is associated with better health outcomes and is critical for patients’ clinical decision-making.⁹ As our health care system is experiencing the digitalization revolution, it is also crucial to

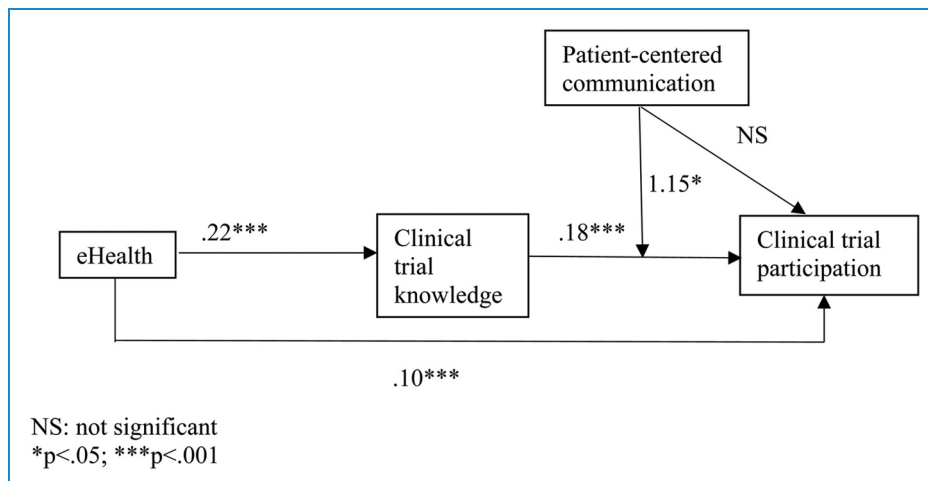


Figure 1. Structural equation model on factors associated with clinical trial participation.

promote PCC in the eHealth context. We call for more initiatives to increase doctors’ online PCC skills, such as

Table 2. Regression results for moderated mediation model.

Predictor	OR	SE	z	p
Block 1: Main predictors				
Clinical trial participation				
Clinical trial knowledge (CK)	4.02	0.48	11.76	0.000
PCC	0.95	0.12	0.41	0.685
Block 2: Interaction Terms				
CK	4.07	0.48	11.79	0.000
PCC	0.81	0.12	1.48	0.138
CK × PCC	1.15	0.80	1.96	0.049
Conditional indirect effect				
	β	SE	z	p
Clinical trial participation				
M – 1 SD	0.07	0.01	5.30	0.000
M	0.08	0.02	4.79	0.000
M + 1 SD	0.09	0.02	4.38	0.000

Note: Numbers in bold indicate significant effect. OR = odds ratio; CK = clinical trial knowledge; PCC = patient-centered communication; M = mean; SD = standard deviation; SE = standard error.

being more responsive to patients’ online messages, activating patients in online conversations, and respecting patients’ data security concerns.²² When making clinical trial information available to the public via the internet, PCC principles should be embedded in program development and dissemination. For example, doctors can build and maintain trusting healing relationships with patients via email and social media, where they can impart clinical trial knowledge and promote patient participation.

This study has the following limitations. First, clinical trial participation is a multistage process and involves complex decision-making with multiple stakeholders. In the current study based on a national survey, some major variables such as clinical trial participation and clinical trial knowledge were measured with a self-reported single item and might not capture the complexity of clinical trial participation. Second, in this study, we have focused on eHealth engagement and PCC, while other important factors associated with clinical trial participation might have been missed. Third, we found significant disparities in clinical trial participation, but measures of subgroups were limited. For example, the race was categorized into non-Hispanic Whites and minorities. Future research needs to further examine racial differences using more advanced measures of racial and SES groups. Fourth, the cross-sectional design of the study prohibits causal interpretation of the associations identified in the analyses.

To conclude, this study represents one of the first studies on American participation in a clinical trial using the latest national survey. We learned that significant disparities existed in participation in a clinical trial. To reduce these disparities and boost underserved populations’ participation in a clinical trial, our data suggested that targeted interventions to improve relevant knowledge, bridge the digital health divide, and enhance PCC are needed.

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