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Original Investigation | Diversity, Equity, and Inclusion

Association of Remote Technology Use and Other Decentralization Tools With Patient Likelihood to Enroll in Cancer Clinical Trials

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Abstract

IMPORTANCE Logistical challenges such as travel time and distance to a clinical trial site can be a barrier to patient participation. The association of remote technology use and other decentralization tools that can reduce these barriers with likelihood to enroll in cancer trials is not well understood.

OBJECTIVE To assess the association of remote technology and other decentralization tools used to reduce participation-related time and travel with the likelihood to enroll in cancer clinical trials.

DESIGN, SETTING, AND PARTICIPANTS Between July 6 and September 8, 2021, a 41-question, cross-sectional, internet-based survey was administered to patients with cancer and survivors of cancer in the US who had been diagnosed with or treated for cancer in the past 7 years.

MAIN OUTCOMES AND MEASURES Increase in self-reported likelihood to enroll in cancer clinical trials that use remote technology and other decentralization tools to decrease the need for travel to the trial site.

RESULTS There were 1183 survey respondents, with a mean (SD) age of 58.2 (12.5) years. Respondents self-reported their gender, race and ethnicity, cancer type, and treatment status. Of the 1183 respondents, 848 (72%) were female, 296 (25%) were male, 8 (1%) were other/nonbinary, and 31 (3%) declined to answer. With regard to race, 28 respondents (3%) were American Indian or Alaska Native, 25 (2%) were Asian, 234 (20%) were Black or African American, 20 (2%) were Native Hawaiian or Other Pacific Islander, 825 (70%) were White, and 51 (4%) declined to answer. With regard to ethnicity, 115 respondents (10%) were Hispanic, Latino/Latina, or of Spanish origin, whereas 1017 (86%) were not and 51 (4%) declined to answer. Regarding cancer type and treatment status, 483 respondents (41%) either had or had survived breast cancer and 325 (28%) were being treated for cancer during the survey period. Individuals older than 55 years were more likely to say that they would only participate in trials no farther from their home than their regular care health care practitioner compared with younger respondents (26% vs 16%, respectively; $P = .02$). Higher-income earners (ie, those in households earning >$125 000/y) were significantly more likely than lower-income earners (ie, those in households earning <$70 000/y) to say they would participate in trials requiring additional effort (62% vs 41%, respectively; $P = .03$). If given the opportunity to enroll in a cancer clinical trial that required travel farther than their regular care, a majority of respondents (range, 60%-85%) indicated that they would be more likely to participate if the trial used remote technology and other tools to decrease the need for travel to a trial site.

CONCLUSIONS AND RELEVANCE In this cross-sectional study, the survey findings suggest that cancer clinical trials leveraging remote technology and decentralization tools to reduce patient time and travel burden associated with participation may increase the patient consent rate.

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Key Points

Question What is the association of remote technology and other decentralization tools with patient likelihood to enroll in cancer clinical trials?

Findings In this cross-sectional survey study of 1183 patients with cancer and survivors of cancer, self-reported patient disposition toward enrollment in cancer clinical trials increased for modifications using remote technology and other decentralization tools. The majority of respondents (60%-85%) reported being more likely to enroll if the participation-related time and travel burden decreased as a result of these practices.

Meaning These findings suggest that greater adoption of practices that reduce patient time and travel burden associated with clinical trial participation could improve enrollment in cancer trials.

+ Supplemental content

Author affiliations and article information are listed at the end of this article.

Introduction

Adequate enrollment of participants in cancer clinical trials is essential for trial success and for advancing new standards of cancer care. Inadequate enrollment can lead to trial failure[1] or affect the interpretation of study results.[2] Even when recruitment is successful, cancer trials often do not reflect the diversity of the US population diagnosed with cancer,[3,4] which can limit the generalizability of results and lead to an unequal benefit in treatment advancements. The COVID-19 pandemic has disrupted all aspects of cancer clinical research, including enrollment in trials,[5] as many ongoing trials were suspended and the start of planned studies was delayed.[6] In an effort to reduce the risks of SARS-CoV-2 transmission to patients and research staff and to move research forward, the US Food and Drug Administration[7] and the National Cancer Institute[8,9] issued guidance for trial investigators on clinical trial conduct for the duration of the federal Coronavirus Disease 2019 Public Health Emergency (PHE). This guidance provided flexibility for the adoption of methods to facilitate trial decentralization through the remote collection of trial data[8,9] outside of a standard, in-person, centralized clinical trial assessment site. These methods included use of virtual clinic visits, delivery of investigational products to the home, and use of alternative laboratories or imaging centers.

Although most patients accept when offered to participate in cancer clinical trials,[10] logistical challenges such as travel time and distance to a trial site are often a barrier to patient enrollment.[11-13] Decentralization of clinical trials beyond the PHE could provide an opportunity to increase access to and enrollment in available trials by reducing the participant time and travel burden. The effects of remote technology and other decentralization tools on the likelihood to increase patient disposition toward participation in cancer clinical trials are not yet well understood. This study aimed to assess the association of remote technology and other decentralization tools used to reduce time and travel related to clinical trial participation with patient likelihood to enroll in cancer trials.

Methods

The cross-sectional survey study was deemed exempt by the Morehouse School of Medicine Institutional Review Board. Participant informed consent was obtained electronically. Participation was voluntary and could be withdrawn at any time. This study followed the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) reporting guideline for cross-sectional studies where applicable.

Participants were included from the American Cancer Society Cancer Action Network's Survivor Views panel and augmented with commercially available web survey panels. Panelists were aged 18 years or older, had been diagnosed with and/or treated for cancer within the past 7 years, and were US residents. A series of questions were designed regarding telehealth, remote care technologies, and willingness to participate in cancer clinical trials (eMethods in the Supplement). These questions were incorporated into the existing survey program and sent to 1269 Survivor Views participants between July 6 and September 8, 2021, and to an undefinable number of commercial web survey panelists who were contacted through a Dynata panel. A total of 591 Survivor Views responses were received for an estimated response rate of 46.5% from the panel. The response rate for the remaining 592 responses obtained via other sources was undefinable because it is unclear how many received the invitation to participate, owing to uncertainty of email delivery status. Socioeconomic data, including race and ethnicity defined by the investigator, were identified by self-report and were accessed to ascertain differential associations of trial decentralization by socioeconomic factors. We classified race into 6 categories: American Indian or Alaska Native, Asian, Black or African American, Native Hawaiian or Pacific Islander, White, or declined to answer. We classified ethnicity into 3 categories: Hispanic, Latino/Latina, or Spanish origin (yes or no) or declined to answer.

Statistical Analysis

For comparisons of statistical significance, we used independent *t* tests for means and independent *z* tests for percentages. Statistical significance was set at α = .05. All statistical analyses were performed with IBM SPSS, version 27.

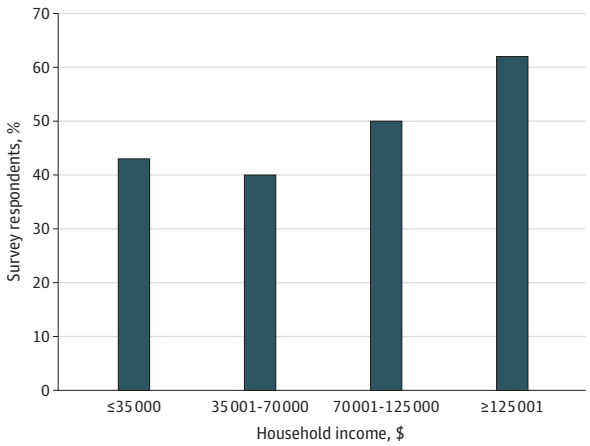
Results

The 1183 survey respondents had a mean (SD) age of 58.2 (12.5) years. Respondents self-reported their gender, race and ethnicity, cancer type, and treatment status. Of the 1183 respondents, 848 (72%) were female, 296 (25%) were male, 8 (1%) were other/nonbinary, and 31 (3%) declined to answer. With regard to race, 28 respondents (3%) were American Indian or Alaska Native, 25 (2%) were Asian, 234 (20%) were Black or African American, 20 (2%) were Native Hawaiian or Pacific Islander, 825 (70%) were White, and 51 (4%) declined to answer. With regard to ethnicity, 115 respondents (10%) were Hispanic, Latino/Latina, or of Spanish origin, whereas 1017 (86%) were not and 51 (4%) declined to answer. There were 483 patients (41%) who had breast cancer or were survivors of breast cancer and 325 (28%) were being treated for cancer at the time of the survey (eTables 1-15 in the Supplement provide additional demographic data).

Of the survey respondents, 217 (18%) had participated in a cancer clinical trial, and 73 (6%) looked for a trial on their own but did not find one. Only 88 respondents (7%) declined to participate in a trial they were told they qualified for, whereas 543 (46%) had never discussed trial participation with their health care practitioner. There were 909 respondents (77%) who said they would join a cancer clinical trial if it were at least as easy as their regular care in terms of distance and frequency of visits, and 557 (47%) said they would participate even if it required additional effort in terms of travel distance or frequency of visits. There were 353 respondents (30%) who said they would be willing to travel up to 90 minutes or more from their regular care to join a trial. Respondents older than 55 years were significantly more likely to say they would only participate in trials no farther from their home than their regular care compared with younger respondents (158 [26%] vs 39 [16%], respectively; *P* = .02). Individuals in higher-income households (>$125 000/y) were significantly more likely than those in lower-income households (<70 000/y) to say they would participate in trials requiring additional effort (147 [62%] vs 354 [41%], respectively; *P* = .03) (**Figure 1**).

Many respondents had already begun engaging in remote care outside of a clinical trial. For example, 520 (44%) had previously participated in a video visit with a health care practitioner for an issue related to their cancer for which they would have otherwise had to go into the office. These

Figure 1. Willingness of Surveyed Patients With Cancer or Survivors of Cancer to Participate in Trials Requiring Additional Effort, by Respondent Income

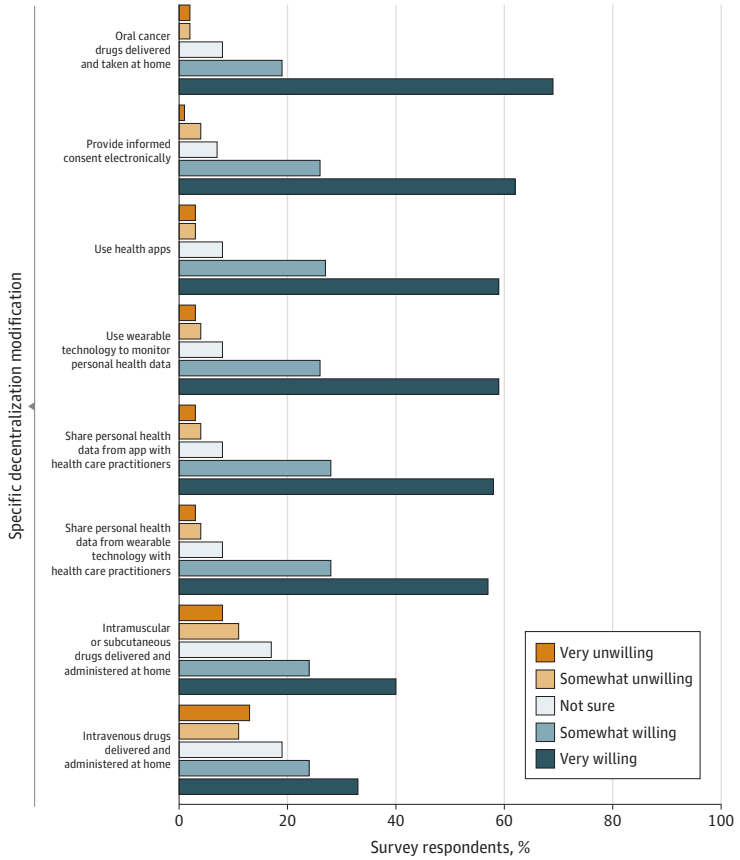


Additional effort is defined in terms of frequency of visits or travel to a more distant location to participate in a cancer clinical trial compared with the site where regular care is provided.

experiences were overwhelmingly positive, with 496 respondents (95%) reporting that their issues and questions were well addressed during the video visit.

Respondents were asked about their general willingness to adopt technologies and tools related to remote care not specifically within the clinical trial context. They were subsequently asked whether the adoption of these technologies and tools by a trial that would otherwise require more distant travel would make them more likely to enroll. More than 80% of respondents (range, 999-1033) expressed willingness to adopt the majority (6 of 8) of remote interventions (**Figure 2**); similarly, the use of these interventions was associated with an increase in self-reported likelihood to enroll in a trial among a majority of respondents (range, 60%-85%) (**Table**). The proposed modifications were associated with an increase in willingness to enroll by the greatest amount among respondents who expressed the highest interest in enrolling in a trial absent such modifications (range, 429-509 [77%-91%]), but increases in willingness were reported by all groups, even among those who initially reported that they would not join a clinical trial under any circumstances (range, 7-13 [26%-48%]) or unless there were extremely compelling reasons (range, 55-114 [34%-70%]) (Table). For each modification, a minority of respondents reported that the modification would decrease their willingness to participate. For example, "intravenous (IV) clinical trial medications delivered to and infused in the home by trial personnel" was the most notable, with 239 respondents (20%) indicating that the modification would make them less likely to participate (eTables 16-24 in the Supplement). Finally, 1015 respondents (86%) said it was important to have the option for in-person visits when desired if enrolled in a trial in which all trial-related activities could be done in their home.

Figure 2. Willingness of Surveyed Patients With Cancer or Survivors of Cancer to Adopt Remote Care Outside of a Clinical Trial



Discussion

The results of this cross-sectional survey study suggest that most patients with cancer and survivors of cancer are willing to participate in cancer clinical trials if recommended by their health care practitioner, even if participation requires additional effort in terms of frequency of visits or travel to a more distant location compared with their regular health care practitioner. However, willingness to participate in trials requiring additional effort varies by income and age, with lower-income earners and older respondents less likely to travel farther or attend more frequent visits. Previous research has established a higher travel burden experienced by patients living in low-income areas and enrolled in trials[14] and a positive correlation between patient income and their likelihood to participate in a trial.[15]

The COVID-19 pandemic and subsequent regulatory guidance on the conduct of clinical trials increased the adoption of decentralized clinical trials; however, many of the regulatory flexibilities permitted during the pandemic are set to expire at the conclusion of the PHE. Decentralization of trials through remote technology and other tools can alleviate travel burden associated with trial participation by delinking where a patient is evaluated and/or treated in respect to a trial and where a trial is hosted, potentially allowing for a larger and more diverse cohort of trial participants. Our data show that patients with cancer and survivors of cancer are receptive to these technologies and tools and use in the context of trials is associated with an increase in self-reported likelihood to consent if the technology or tool decreases the need to travel to a trial site. However, the degree to which respondents would be more likely to join a trial varied by approach, and the ability to have the option for in-person visits at a trial site when desired remained important.

Limitations

This study has some limitations. The survey questions assess hypothetical participation in cancer clinical trials and do not measure the extent to which stated participation intent corresponds to actual participation. The survey questions assessing willingness to participate in cancer clinical trials were not evaluated by clinical trial phase or by type of trial intervention. Each clinical trial phase has different goals, and cancer clinical trials range in terms of the intensity of the intervention that may be required (eg, an experimental drug vs an experimental drug plus a surgical intervention), which may affect an individual's willingness to participate in a cancer clinical trial. A potential source of bias inherent to the methodology is that respondents taking part in survey research may be more predisposed to research in general.

Table. Association of Decentralization Modifications With Self-reported Willingness to Enroll in a Trial, Cross-tabulated by Initial Reported Willingness to Participate in Trials

	Increased likelihood to enroll, No. of respondents (%)					
		Cross-tabulation by initial willingness to participate				
Decentralization modification	Total more willing to join trial if specific modifications were made available (N = 1183)	Would not join under any circumstance (n = 27)	Would join only for extremely compelling reasons (n = 163)	Would join only if easier than regular care (n = 84)	Would join only if no extra effort was required (n = 352)	Would join even if extra effort was required (n = 557)
Trial activities completed at local facility	1005 (85)	7 (26)	114 (70)	70 (83)	305 (87)	509 (91)
Wearable technology to capture trial data	967 (82)	12 (44)	112 (69)	64 (76)	294 (84)	485 (87)
Health apps to track trial data	956 (81)	13 (48)	105 (64)	63 (75)	287 (82)	488 (88)
Oral trial medications delivered and taken at home	954 (81)	9 (33)	104 (64)	64 (76)	287 (82)	490 (88)
Trial check-ins via video from home	912 (77)	8 (30)	100 (61)	62 (74)	269 (76)	473 (85)
Giving virtual informed consent	912 (77)	7 (26)	90 (55)	59 (70)	289 (82)	467 (84)
Trial activities via video from home	865 (73)	8 (30)	83 (51)	57 (68)	264 (75)	453 (81)
Injectable trial medications given at home by trial personnel	790 (67)	9 (33)	63 (39)	55 (66)	234 (67)	429 (77)
Intravenous trial medications given at home by trial personnel	715 (60)	9 (33)	55 (34)	49 (58)	215 (61)	387 (70)

Conclusions

In this cross-sectional study of patients with and survivors of cancer, most respondents expressed a strong willingness to participate in cancer clinical trials. However, willingness to participate in trials requiring additional effort in terms of the frequency of visits and travel distance, compared with regular care, varied by income and age. The use of remote technology and other decentralization tools that can decrease the need for travel to a trial site was associated with an increase in self-reported patient likelihood toward participation in cancer trials. Greater adoption of remote technology and other decentralization tools may alleviate patient barriers such as travel time and distance to a trial site, which in turn may increase patient consent rates.

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SUPPLEMENT.

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