ASPE ASSISTANT SECRETARY FOR PLANNING AND EVALUATION | OFFICE OF SCIENCE AND DATA POLICY

ISSUE BRIEF

January 16, 2025

Financial stress associated with oncology clinical trial participation

Allison Kolbe and Trinidad Beleche

KEY POINTS

- Clinical trials produce foundational evidence to support our understanding of human diseases and conditions and to develop treatments. However, clinical trial participants are not always representative of the populations most impacted by a disease or condition. Financial impacts are often cited as a barrier to trial participation, but little is known about the size and scope of the financial burden experienced by participants of clinical trials.
- In a survey of 112 recent oncology clinical trial participants, we found that 64.3% reported at least some financial stress associated with their clinical trial participation.
- Participants who reported financial stress tended to have spent more money during their clinical trial, traveled more frequently and at greater distances for their trial, and reported more significant impacts of financial stress. Participants reported dipping into savings, taking on credit card debt, and reduced spending on leisure activities, and some even reported difficulty paying for necessities such as food or rent.
- Compensation for participants' time and reimbursement for specific expenses such as parking was reported only by a minority of respondents. Compensation was generally nominal in comparison with reported expenditures.
- Financial stress had a significant impact on the financial well-being of the oncology clinical trial participants in this study. As shown in the literature, this burden may result in negative health outcomes and may be a barrier for individuals to participate.

BACKGROUND

Clinical trials are fundamental in the development of treatments and in enhancing the scientific understanding of human diseases and conditions. In some cases, such as cancer, clinical trials may also offer a critical opportunity to access cutting-edge treatments when all other treatment options have been exhausted. Furthermore, the generalizability and usability of clinical trial results relies upon the participants being representative of the U.S. population with the condition. Therefore, it is important to ensure equitable access for all people to participate in clinical trials, regardless of income, geography, or other factors. The U.S. Department of Health and Human Services (HHS) has taken a wide variety of actions to enhance diversity in clinical trial participation,[1] but gaps remain in our understanding of barriers to participation. Understanding the size and scope of costs experienced by clinical trial participants is a critical piece in identifying appropriate ways of reducing financial barriers to participation.

U.S. law requires payers to cover "routine care costs" for patients enrolled in clinical trials.[2] However, the definition of "routine care" can be unclear, leaving patients uncertain of which costs will be covered, and patients are still subject to cost-sharing such as coinsurance while participating in clinical trials. Patients may

also experience increased costs if the clinical trial is conducted at an out-of-network research center. Relatively little is known about the magnitude of the out-of-pocket medical expenses clinical trial participants may have. Studies quantifying the direct cost burden to patients participating in clinical trials have had mixed results, with some reporting clinical trial costs to be similar to costs of standard care,[3] while others reported higher out-of-pocket costs for clinical trial participants.[4,5] For cancer patients, many receiving standard care experience significant financial hardship,[6] which can make it challenging to separate the financial implications of standard cancer treatment from that received as part of a clinical trial.

Clinical trial participants may also face considerable indirect costs, such as lost wages and expenditures for travel and lodging. These types of costs are often cited as a barrier for participation in clinical trials, particularly among lower income and underinsured individuals.[7,8] Studies focusing on travel costs have found that clinical trial participation may cost from $200 to $1,000 per month depending on factors such as proximity to the trial site,[2] and can be a particular concern for individuals living in rural areas at greater distance to trial facilities.[9,10] One study reported that offering reimbursement for these types of indirect costs significantly increased the rate of recruitment.[8] However, patient-reported financial burden associated with trial participation is rarely measured as part of a clinical trial, limiting our understanding of the financial impacts to clinical trial participants.[11,12]

One approach to address financial burden for clinical trial participants may be to offer compensation, which can help to offset direct and indirect costs. However, determining an appropriate amount of compensation for a trial can be challenging and must be balanced with ethical considerations to avoid creating undue influence or coercion.[1,13] There are limited data available on the current use of compensation in clinical trials, although one systematic review of 73 cancer clinical trials found only two that provided compensation to participants.[11]

To further understand the size and impact of costs to clinical trial participants, the Office of the Assistant Secretary for Planning and Evaluation (ASPE) conducted an exploratory survey of 112 U.S. adults who participated in an oncology clinical trial between 2018-2024. Here, we describe the reported impact of clinical trial participation on their financial well-being, explore the reported characteristics of clinical trials associated with financial stress, and discuss areas of future work around the financial burden of clinical trial participation.

METHODS

The survey was developed by Mathematica under contract number HHSP233201500035I with ASPE. Mathematica partnered with the American Cancer Society Cancer Action Network (ACS CAN) to field the survey to their existing Survivor Views panel.[14] The Survivor Views panel is comprised of individuals who meet the following criteria:

- Diagnosed with and/or treated for cancer within the last seven years
- Over the age of 18 (parents of childhood cancer survivors were invited to participate on behalf of their minor children)
- Reside in the U.S. or U.S. territories

Survivor Views participants are invited to participate through email, direct mail, social media, and outreach to communities and partners engaged with cancer patients and survivors.

Survey Overview

The web-based survey "Clinical Trial Participation Costs" was fielded in English to Survivor Views panel members between July 9, 2024, and September 2, 2024, and took 15 to 20 minutes to complete. The survey content was informed by an environmental scan[2] and input from ASPE and other subject matter experts,

including ACS CAN. Mathematica and ACS CAN also pilot tested the survey with five Survivor Views members who had experience participating in clinical trials. People who completed the Clinical Trial Participation Costs Survey were eligible to receive a $25 gift card.

The survey included questions on cancer clinical trial participation, employment, trial location, travel and lodging needs during the trial, types of medical costs, compensation/reimbursement from the trial sponsor or other source, financial stressors, and demographic characteristics. The survey was deployed using ACS CAN's InMoment survey platform and optimized for computer, tablet, smartphone use and multiple browsers, including Chrome, Edge, and Safari. The full survey instrument and associated documentation is available upon request.

Institutional Review Board Review and Paperwork Reduction Act Clearance

The study protocol, including the survey and survey correspondence, received expedited approval from the institutional review board at Health Media Lab on May 20, 2024. The Office of Management and Budget approved the protocol and materials on July 1, 2024, as under ASPE's generic clearance package (0990-0421).

Population of Interest and Sample Frame

Survivor Views panel members who had participated in an oncology clinical trial between 2018 and 2024 (at the point the survey was fielded) and were 18 or older were eligible to complete the survey. ACS CAN Survivor Views staff identified 231 panel members who reported on prior Survivor Views surveys that they had participated in a clinical trial. These individuals served as the initial survey sample.

ACS CAN fielded an unrelated survey concurrent with the Clinical Trial Participation Costs Survey. The concurrent survey, sent to about 5,750 panel members, included a screener question about clinical trial participation between 2018 and 2024 (at the point the survey was fielded). This identified additional potentially eligible individuals who were not included in the initial survey sample.

By the end of the fielding period, 374 people had been invited to participate in the survey. The final eligible sample consisted of 313 people, after excluding 61 individuals (13 people under age 18 and 48 people who did not participate in clinical trials between 2018 and 2024). People answered screening questions about current age and clinical trial participation, and those deemed eligible proceeded to an informed consent form. Once the respondents consented to participate, they began the survey. Non-responders received weekly reminder emails. The final participation rate at the end of the fielding period was 35.8%.

Survey Data Analysis

At the end of the field period, ACS CAN provided Mathematica with a de-identified data file in .csv format. Mathematica validated the data file and removed non-completes before sharing with ASPE. ASPE analyzed the data and generated descriptive statistics using R version 4.4.1. Unless otherwise described, we calculated percentages out of the total number of respondents who answered each question. Sample sizes for each question are provided in the figure and table notes.

RESULTS

Table 1 shows several key demographics of the survey respondents. In total, 112 people completed the survey. Respondents were majority female, and most were 45 years of age or older. The sample was predominantly White. Respondents were distributed around the U.S. and its territories. Additional demographic characteristics of the respondents are available in Appendix Table A1. All respondents reported

having health insurance at the start of their clinical trial. Half of the respondents were employed prior to their clinical trial, and the majority did not have any children at home. About half of respondents reported living in suburban communities with the remainder split between rural and urban communities.

Table 1. Key Demographics of Survey Respondents

		n (%)
Gender identity	Female	79 (70.5%)
	Male	31 (27.7%)
	Non-binary	1 (0.9%)
	Transgender	0 (0%)
	Missing	1 (0.9%)
Age group	18-34	5 (4.5%)
	35-44	13 (11.6%)
	45-54	31 (27.7%)
	55-64	37 (33%)
	65+	26 (23.2%)
Race/ethnicity	American Indian or Alaska Native	4 (3.6%)
	Asian	2 (1.8%)
	Black or African American	14 (12.5%)
	Hispanic or Latino	12 (10.7%)
	Middle Eastern or North African	1 (0.9%)
	Native Hawaiian or Pacific Islander	0 (0%)
	White	86 (76.8%)
Region	Midwest	25 (22.3%)
	Northeast	22 (19.6%)
	South	35 (31.3%)
	West	26 (23.2%)
	U.S. Territories	4 (3.6%)

Note: Age group refers to the respondent's age at the start of their trial participation. Respondents were able to select multiple race or ethnicity categories; therefore, numbers do not add to 100%.

Table 2 shows the cancer stage and type, as well as the treatment received during the respondent's clinical trial. Just under half of the respondents were enrolled in a breast cancer trial; the remaining respondents were distributed among a variety of cancer types. Respondents were distributed among cancer stages 1-4 at the start of their trials. Approximately half of the respondents received chemotherapy as part of their trial; other common trial treatment types included radiation, surgery, and immunotherapy.

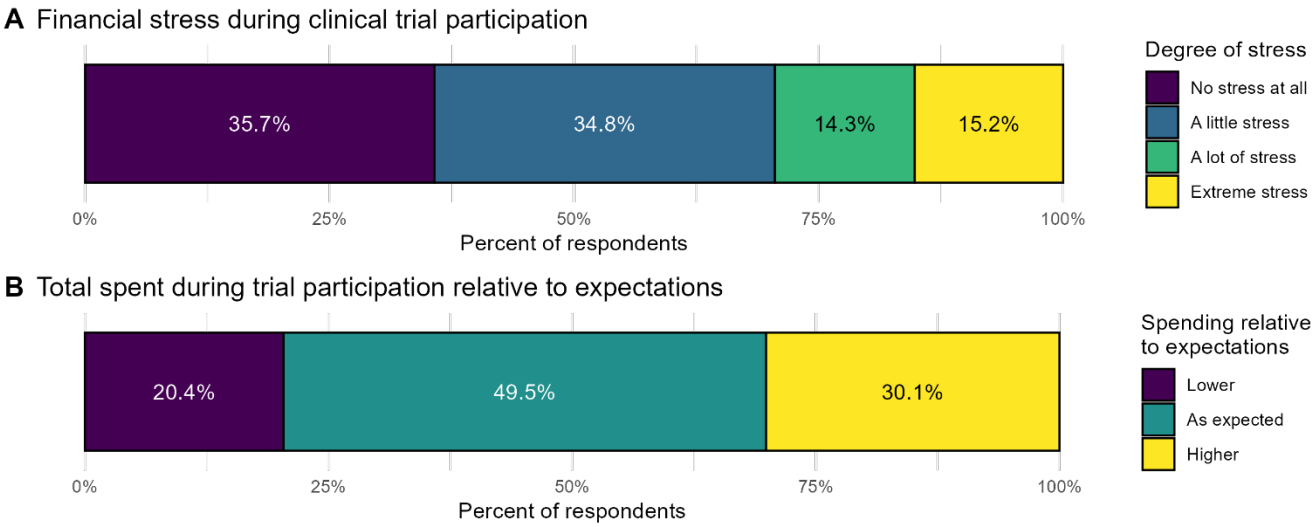
Table 2. Respondents' Cancer and Trial Characteristics

		n (%)
Cancer type	Breast	48 (42.9%)
	Leukemia	9 (8%)
	Lymphoma	8 (7.1%)
	Myeloma	7 (6.3%)
	Prostate	6 (5.4%)
	Head/Neck	5 (4.5%)
	Lung	5 (4.5%)
	Ovarian	4 (3.6%)
	Kidney	2 (1.8%)
	Melanoma	2 (1.8%)
	Brain	1 (0.9%)
	Cervical	1 (0.9%)
	Colon	1 (0.9%)
	Liver	1 (0.9%)
	Other	12 (10.7%)
Cancer stage	Stage 1	18 (16.1%)
	Stage 2	19 (17%)
	Stage 3	21 (18.8%)
	Stage 4	28 (25%)
	Not sure	26 (23.2%)
Trial treatment type	Chemotherapy	61 (54.5%)
	Radiation	35 (31.3%)
	Surgery	33 (29.5%)
	Immunotherapy	24 (21.4%)
	Targeted therapy	18 (16.1%)
	Hormone therapy	10 (8.9%)
	Not sure/don't know	7 (6.3%)
	Stem cell transplant	4 (3.6%)
	Photodynamic therapy	1 (0.9%)
	Hyperthermia	0 (0%)
	Other	12 (10.7%)
Trial end year	2018	10 (8.9%)
	2019	8 (7.1%)
	2020	10 (8.9%)
	2021	16 (14.3%)
	2022	11 (9.8%)
	2023	21 (18.8%)
	2024	2 (1.8%)
	Ongoing	34 (30.4%)

Note: Respondents were able to select multiple trial treatment types; therefore, numbers add up to more than 100%. All variables are self-reported.

The survey asked respondents: "During your clinical trial participation, did your financial situation cause you no stress at all, a little stress, a lot of stress, or extreme stress?" Nearly two-thirds of respondents (64.3%) reported at least some financial stress; over a quarter reported "a lot" or "extreme" stress (Figure 1A). The survey also asked respondents whether their spending during the clinical trial met their expectations. Over a quarter reported spending more than they expected (Figure 1B).

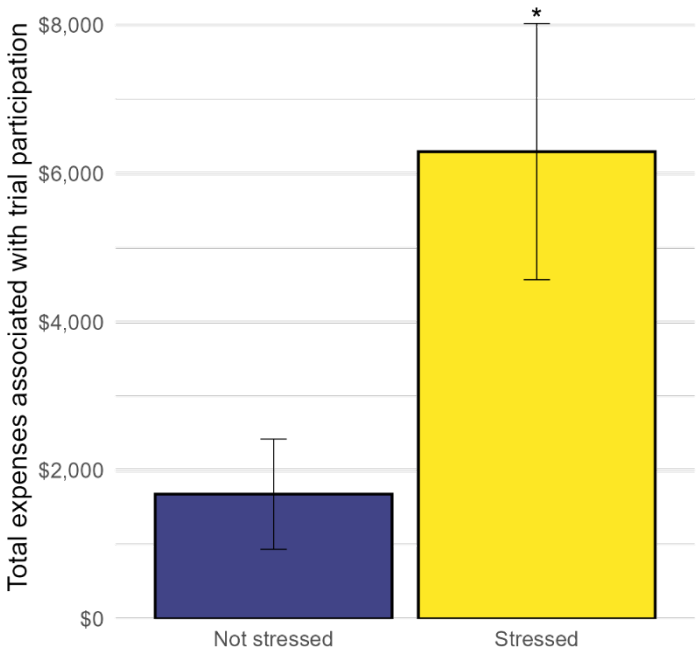
Figure 1. Financial stress and spending expectations during the clinical trial



Note: For Figure 1A, respondents were asked: "During your clinical trial participation, did your financial situation cause you no stress at all, a little stress, a lot of stress, or extreme stress?" For Figure 1B, respondents were asked: "Is the total amount of money you personally spent during your clinical trial participation higher than you thought it would be, lower than you thought it would be, or about what you thought it would be?" Both questions were asked of all respondents; n = 112 for Figure 1A, n = 103 for Figure 1B.

About half of the respondents provided numerical estimates of the total amount of money spent during their clinical trial participation. Although the low response rate to this question limits its reliability, respondents who reported financial stress also reported significantly higher expenditures during the clinical trial (Figure 2). Reported total expenditures during the clinical trial varied dramatically from $0 to $50,000. Mean and median total expenditures were higher among those reporting any financial stress ($6,294 and $3,000, respectively) compared with those reporting no financial stress ($1,680 and $700, respectively).

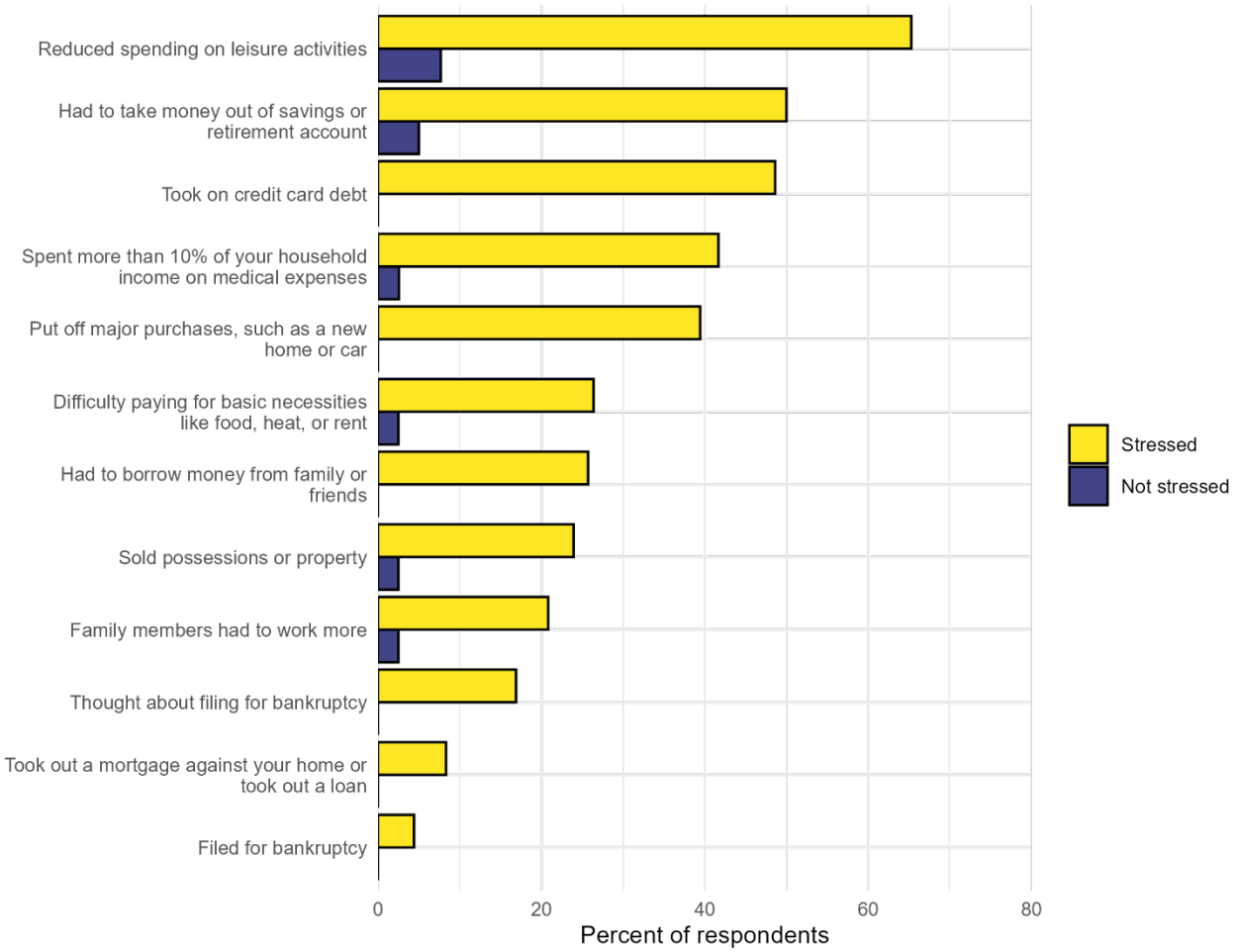
Figure 2. Total amount of money spent on clinical trial care and related services



Note: Respondents were asked: "Thinking about your clinical trial participation overall, how much money did you personally spent for trial-specific cancer care and related services? Cancer care and services include, but are not limited to, laboratory tests, imaging studies like X-rays or MRIs, cancer treatment, prescription and over-the-counter medications, hospitalization, equipment, and in home care." All respondents were asked this question; 49 responded (63 missing). * indicates statistical significance determined by a two-sided t-test, $p < 0.05$.

Respondents were also asked about the impacts of financial stress on their lives. Overall, 64 respondents (57.1%) reported at least one negative impact (as shown in Figure 3) because of expenses related to their clinical trial participation. Responses varied dramatically based on the respondents' reported financial stress. Those who reported no financial stress due to their clinical trial participation had relatively few additional impacts, with the largest being around 8% of respondents reporting reduced spending on leisure activities. In contrast, 65% of stressed respondents reported reduced spending on leisure activities. About half of the financially stressed respondents took money out of savings or took on debt; and of particular concern, a quarter reported difficulty paying for basic necessities like food, heat, or rent.

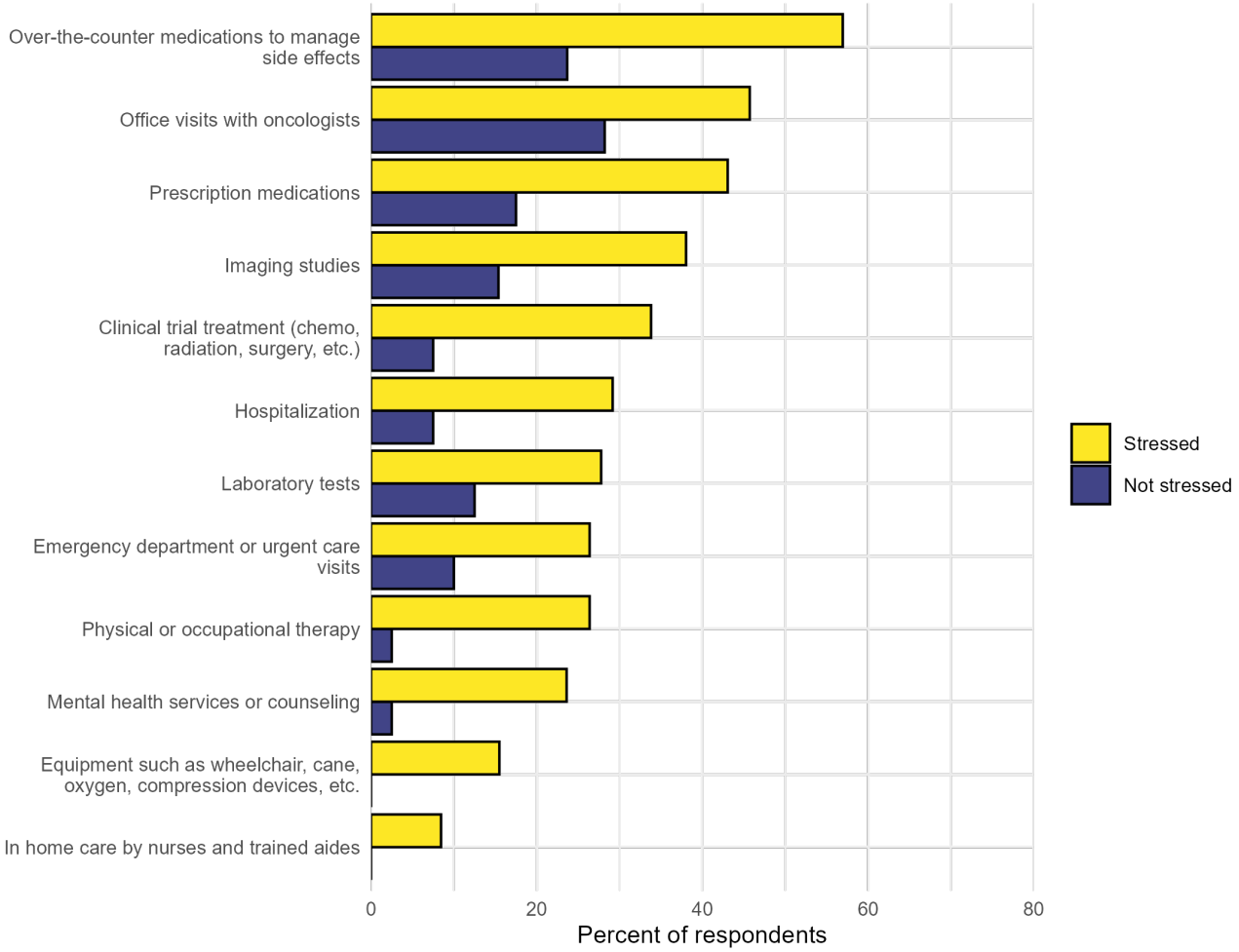
Figure 3. Financial impacts related to clinical trial participation



Note: Respondents were asked: "Have any of the following happened because of expenses related to your clinical trial participation?" Response options were "Yes", "No", and "Not sure/don't know". All respondents were asked this question. Percentages were calculated out of the total number of respondents in each of the two financial stress groups who provided one out of the three available responses for each option. The total sample size ranged from 106-112 respondents for each financial impact.

Respondents were also asked about medical expenses they had to pay for, in whole or in part, during their clinical trial participation. Overall, 73 respondents (65.2%) paid out-of-pocket for at least some of their clinical trial care. Figure 4 breaks down the categories of medical expenses for which respondents may have needed to pay out-of-pocket. In general, a larger proportion of those reporting financial stress paid out-of-pocket for medical services during their trial compared to those who did not report financial stress. Although the majority of respondents in both groups did not pay for their clinical trial treatment, this result indicates that other types of medical expenses related to the clinical trial may also be significant.

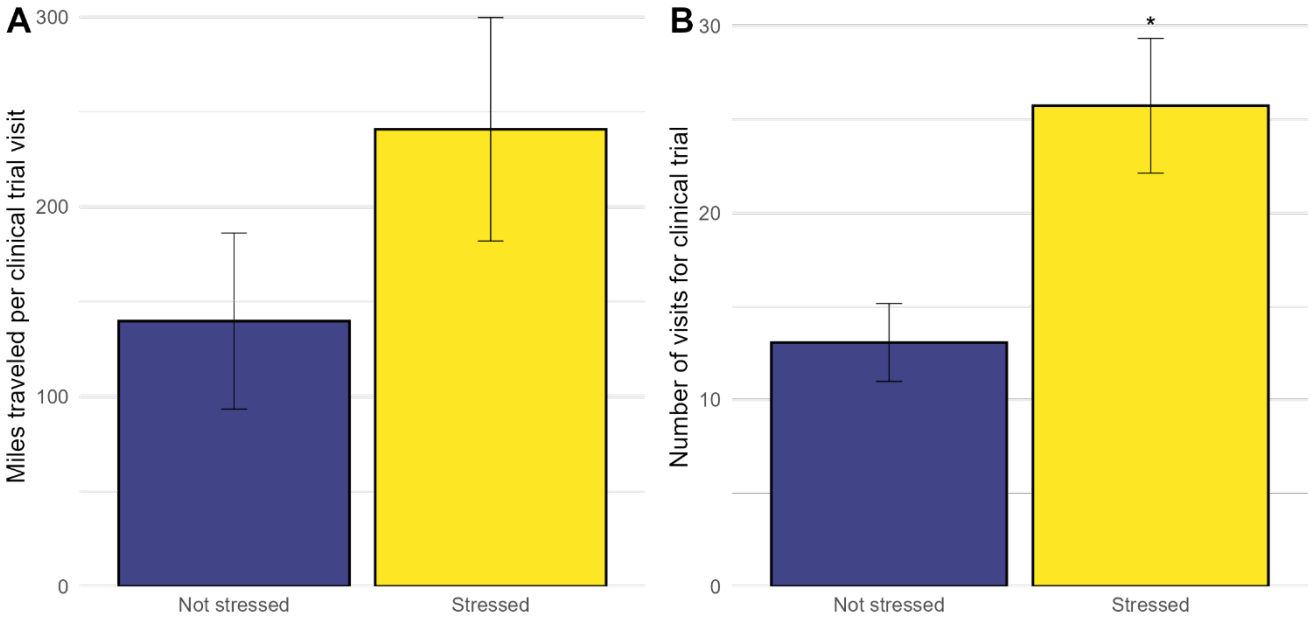
Figure 4. Categories of medical expenses for which respondents paid out-of-pocket



Note: Question asked: "The following are elements of trial-specific cancer care that you may have paid for, in whole or in part. For each, please indicate if you had to pay for some or all of the trial-specific care received during your clinical trial participation." Response options were "Yes", "No", "Not sure/don't know", and "Did not need service". Respondents were able to select multiple items; therefore, numbers do not add to 100%. All respondents were asked this question. Percentages were calculated out of the total number of respondents in each of the two financial stress groups who answered for each option. The total sample size for this question ranged from 109-112 respondents.

Financial stress may also be caused by non-medical costs of clinical trial participation, such as the need to travel long distances to the clinical trial site. Figure 5 shows that those reporting financial stress tended to travel a greater number of miles to their clinical trial site (241 vs 140 miles, on average) and had significantly more visits for their clinical trial (25.7 vs 13.1 trips, on average).

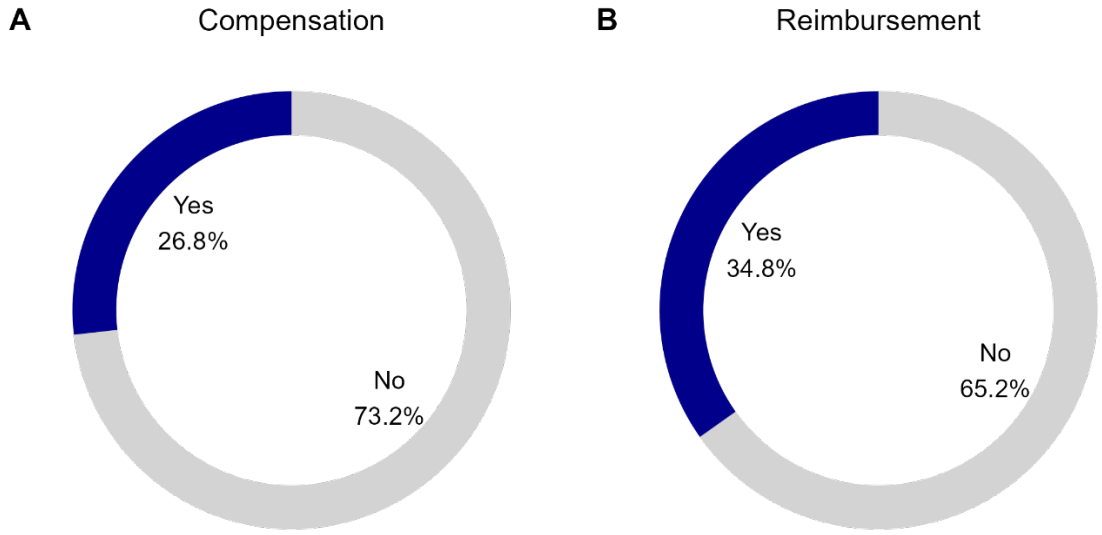
Figure 5. Miles traveled and number of visits to the clinical trial site



Note: For Figure 5A, respondents were asked: "On average, how many miles did you travel to receive your trial-specific cancer care? Please report one-way travel only. If you traveled to multiple facilities, please report the number of miles for the facility that was farthest." For Figure 5B, respondents were asked: "How many trips did you make?" Both questions were asked of all respondents; n = 107 for Figure 5A, n = 100 for Figure 5B. * indicates statistical significance determined by a two-sided t-test, $p < 0.05$.

A minority of respondents received compensation (26.8%) for their clinical trial participation or reimbursement (34.8%) in whole or in part for expenses incurred while participating in the trial (Figure 6). Most respondents who received compensation reported receiving less than $250 over the course of their trial participation (median = $120; range = $8-$2,800). Parking (19.6%) was the most common item for which respondents received reimbursement in full or in part, followed by housing or lodging (8.9%) and food (8.9%). In general, similar trends were observed between the two financial stress groups; however, sample sizes were too small to draw generalizable conclusions. Full results are shown in Appendix Table A2.

Figure 6. Compensation and reimbursement for clinical trial participation



Note: For Figure 6A, respondents were asked: "Patients sometimes receive compensation for their time spent participating in clinical trials. Separate from reimbursements you may have received for other expenses, did you receive compensation for your time participating in your clinical trial from any of the following?" Response options were: "Yes, from my clinical trial sponsor", "Yes, from an outside organization or foundation", "Yes, not sure of the source", and "No, did not receive compensation". Figure 6A shows those who received compensation from any source. For Figure 6B, respondents were asked: "As a result of clinical trial participation, did you receive reimbursement for any of the following or receive any of the following for free or at a reduced cost? Check all that apply." Figure 6B shows those who checked at least one item. Both questions were asked of all respondents and percentages calculated as a function of the full sample (n = 112).

DISCUSSION

Participating in a clinical trial affords the opportunity for patients to access cutting-edge treatments. For patients with some types of cancers, clinical trials may be the only option for treatment.[15] Therefore, ensuring equitable access to clinical trials for all patients – regardless of where they live, their health insurance, their income, or other characteristics – is essential for equitable access to care and well-being. There is relatively little known about the costs of participating in clinical trials, and how trial participation impacts patients' financial well-being. Understanding the size and scope of financial stress for clinical trial participants is particularly important given that research has associated financial stress with poor quality of life, high symptom burden, and even mortality risk.[15-17] The financial burden of participating in a clinical trial may also impact patients' decision-making about participating or staying in a trial – particularly those who are lower-income, underinsured or uninsured, or live far from a trial site. This issue brief provides new evidence for the extent of financial stress among cancer clinical trial participants, how financial stress impacts patients' lives, and characteristics of clinical trials such as proximity to patients and frequency of visits that were associated with financial stress.

Among our survey population of recent cancer clinical trial participants, nearly two-thirds reported at least some degree of financial stress during their clinical trial participation. While many reported that spending was about as much or less than they expected, about a quarter reported that the clinical trial cost was more than they expected. Given the significant impacts of financial stress on well-being, it is important to consider the role of informed consent in setting clear expectations for the costs associated with the trial. Despite requirements for health insurers to cover routine costs associated with clinical trials, respondents also reported paying out-of-pocket for a wide range of services associated with their clinical trial. This may be due

to patient co-pays, deductibles, or over-the-counter products not covered by insurance; our survey did not explore the magnitude nor details of those specific costs. However, given that our entire study population had health insurance at the time of clinical trial participation, this analysis demonstrates that clinical trial participants still incur a wide variety of out-of-pocket medical costs that, cumulatively, may result in participants experiencing considerable financial stress. These impacts would likely be even larger for uninsured individuals.

Among those who reported the total amount of money spent on care and services associated with the clinical trial, the magnitude of the costs varied dramatically. Individuals reporting no financial stress tended to have lower expenditures; individuals reporting at least some financial stress had much higher expenditures on average. The vast range of reported expenditures (from $0-$50,000) underscores the variability of costs associated with clinical trials. This may be due to differing types of trials, length of the trial, distance to trial site, number of visits required, etc. Indeed, we found that participants reporting financial stress tended to travel greater distances for their clinical trial and were required to make more trips to the clinical trial site. This is consistent with a previous study that found respondents traveling more than an hour to their trial site were 2.2 times more likely to experience financial hardship when compared to those traveling less than 30 minutes, even when controlling for race, income, employment, and insurance status.[18] In conjunction with our findings, this underscores the disproportionate impact that financial burden may have on those in rural areas or live far from traditional clinical trial sites. Future work might examine these factors in more detail.

Clinical trial participants are also subject to other types of indirect costs beyond travel expenses – lost wages, child or dependent care, and other factors are frequently cited as potential barriers to clinical trial participation.[2,19] Although our survey did ask respondents about these issues, only half of our sample worked prior to their clinical trial participation, and most did not have children at home. This is likely due to the age distribution of our study population. However, these topics present an opportunity for future work with a larger sample of clinical trial participants.

Our study demonstrates that financial stress is associated with significant negative impacts on the lives of clinical trial participants. Many respondents reported needing to dip into savings or retirement funds, taking on debt, and reduced spending on leisure activities. Of significant concern, however, is the finding that about a quarter of those reporting financial stress (17.8% of all respondents) reported difficulty paying for basic necessities such as food, rent, or heat during their clinical trial participation. These results emphasize the importance in understanding the costs associated with clinical trial participation and potential approaches to mitigate these costs. Monitoring financial impacts during clinical trials – enabling the identification of patients for financial counseling or assistance – has been shown to improve patient outcomes and quality of life.[20]

The results presented in this brief highlight the prevalence of financial stress during cancer clinical trial participation and the significant negative impacts of that burden. Although we did not have a sufficiently large or diverse enough sample to conduct analyses by demographic subgroups, this financial stress likely does not affect all participants equally. It may have a particularly disproportionate impact on those who are lower income, underinsured or uninsured, or living at greater distances from their trial sites. Financial burden may also influence participant retention or the decision to participate in the trial. Previous work has demonstrated that lower income individuals are less likely to participate in cancer clinical trials,[10,21] and that cost is cited as a factor in declining participation.[18] Our results, in conjunction with the published literature, indicate that the cost associated with participating in a clinical trial can be significant and may be a barrier to access.

Although compensation for participating in clinical trials has been increasingly touted as an important approach to improve access to and participation in clinical trials,[22] compensation was relatively uncommon in our study population. Among the approximately one-quarter of respondents who received some compensation, most received less than $250 in total – a nominal amount compared to the thousands of dollars

some respondents reported paying during their clinical trial. This is consistent with previous research that found compensation to be rare in cancer clinical trials.[11] Similarly, only about a third of respondents received full or partial reimbursement for non-medical expenses such as parking, food, or lodging. These results suggest that exploring appropriate compensation and reimbursement strategies may help to ameliorate financial stress for some clinical trial participants.

The current study is subject to a variety of limitations that might be addressed in future work. The survey was conducted using a small, non-representative sample of individuals enrolled in an advocacy survey panel. Members of this survey panel may not be representative of cancer clinical trial participants generally, and the respondents to this survey were also not representative of all cancer types. Therefore, the results of this survey, particularly for items with a low number of respondents, should be interpreted with caution. This survey is also subject to recall bias – although we surveyed individuals who had participated in a cancer clinical trial between 2018 and 2024, it may be difficult for many individuals to recall specifics about their trial, and particularly, to differentiate costs associated with the trial versus costs associated with unrelated aspects of their cancer care (such as an inability to work during cancer treatment). We also surveyed patients regardless of the type of clinical trial treatment they received – trials likely varied in their length and intensity. Future work might examine ways to engage patients prospectively, in advance of or during their clinical trial participation, to improve recall and more accurately document trial elements such as appointment frequency. We also expect that patient experience will vary dramatically based on the disease being studied, the phase of the trial, and the treatment site. In addition to expanding on different types of cancers, understanding the financial costs of participating in non-cancer trials will be an important area for future work.

Finally, the literature is mixed as to whether cancer clinical trial participants have higher out-of-pocket costs than cancer patients undergoing standard treatment. This is an important caveat for our work; cancer care outside of clinical trials is often expensive and may lead to financial stress. Participants in clinical trials may also have already incurred significant costs for their cancer care prior to enrolling in the trial. These issues cannot be disentangled in the current study. However, understanding the difference between costs associated with clinical trial participation versus standard medical care remains an important area for future research.

CONCLUSIONS

This study demonstrates that medical and non-medical expenses associated with participating in a clinical trial can have meaningful impacts on patients' financial well-being. It has previously been shown that these issues may impact patients' overall health and well-being, and may impact patient retention in the trial as well as the decision to participate at all. Equitable access to participate in clinical trials that, in some cases, may be a patient's only treatment option, is an important dimension of equitable access to care. The current study provides a foundation for future work exploring the types and magnitude of costs associated with clinical trial participation.

REFERENCES

1. Kolbe A. HHS Actions to Enhance Diversity in Clinical Research. U.S. Department of Health and Human Services: Office of the Assistant Secretary for Planning and Evaluation; 2024. https://aspe.hhs.gov/reports/diversity-clinical-research
2. Calkins K, Crabtree E, Harrison E, Williams N, Barrett K. Impacts of COVID-19 on Clinical Trials Costs to Patients: Environmental Scan. 2024. https://aspe.hhs.gov/reports/clinical-trial-costs-patients
3. Sidana S, Allmer C, Larson MC, et al. Patient Experience in Clinical Trials: Quality of Life, Financial Burden, and Perception of Care in Patients With Multiple Myeloma or Lymphoma Enrolled on Clinical Trials Compared With Standard Care. *JCO Oncol Pract*. Aug 2022;18(8):e1320-e1333. doi:10.1200/OP.21.00789
4. Kilgore ML, Goldman DP. Drug costs and out-of-pocket spending in cancer clinical trials. *Contemp Clin Trials*. Jan 2008;29(1):1-8. doi:10.1016/j.cct.2007.04.004
5. Borno HT, Zhang S, Lin TK, et al. Evaluating the impact of financial toxicity among cancer clinical trial participants. *International Journal of Cancer Care and Delivery*. 2022;2(1)doi:10.53876/001c.30796
6. American Cancer Society Cancer Action Network. Survivor Views: Majority of Cancer Patients & Survivors Have or Expect to Have Medical Debt. 2024. https://www.fightcancer.org/policy-resources/survivor-views-majority-cancer-patients-survivors-have-or-expect-have-medical-debt
7. Chino F, Zafar SY. Financial Toxicity and Equitable Access to Clinical Trials. *American Society of Clinical Oncology Educational Book*. 2019;39:11-18. doi:10.1200/EDBK_100019
8. Nipp RD, Lee H, Powell E, et al. Financial Burden of Cancer Clinical Trial Participation and the Impact of a Cancer Care Equity Program. *Oncologist*. Apr 2016;21(4):467-74. doi:10.1634/theoncologist.2015-0481
9. Virani S, Burke L, Remick S, Abraham J. Barriers to recruitment of rural patients in cancer clinical trials. *Journal of Oncology Practice*. 2011;7(3):172-177.
10. Unger JM, Hershman DL, Albain KS, et al. Patient income level and cancer clinical trial participation. *J Clin Oncol*. Feb 10 2013;31(5):536-42. doi:10.1200/JCO.2012.45.4553
11. Olivier T, Haslam A, Prasad V. Is financial toxicity captured in quality of life assessments in oncology randomized clinical trials? *J Cancer Policy*. Jun 2023;36:100423. doi:10.1016/j.jcpo.2023.100423
12. Gharzai LA, Jagsi R. Incorporating financial toxicity considerations into clinical trial design to facilitate patient-centered decision-making in oncology. *Cancer*. Apr 15 2023;129(8):1143-1148. doi:10.1002/cncr.34677
13. Food and Drug Administration. Payment and Reimbursement to Research Subjects: Guidance for Institutional Review Boards and Clinical Investigators. 2018. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/payment-and-reimbursement-research-subjects
14. American Cancer Society Cancer Action Network. Survivor Views. https://www.fightcancer.org/survivor-views
15. Nipp RD, Hong K, Paskett ED. Overcoming barriers to clinical trial enrollment. *American Society of Clinical Oncology Educational Book*. 2019;39:105-114. doi:10.1200/EDBK_243729
16. Ramsey SD, Bansal A, Fedorenko CR, et al. Financial Insolvency as a Risk Factor for Early Mortality Among Patients With Cancer. *J Clin Oncol*. Mar 20 2016;34(9):980-6. doi:10.1200/JCO.2015.64.6620
17. Kale HP, Carroll NV. Self-reported financial burden of cancer care and its effect on physical and mental health-related quality of life among US cancer survivors. *Cancer*. Apr 15 2016;122(8):283-9. doi:10.1002/cncr.29808
18. Williams CP, Deng L, Caston NE, et al. Understanding the financial cost of cancer clinical trial participation. *Cancer Med*. Apr 2024;13(8):e7185. doi:10.1002/cam4.7185
19. National Academies of Sciences, Engineering, and Medicine. Improving Representation in Clinical Trials and Research: Building Research Equity for Women and Underrepresented Groups. The National Academies Press; 2022. doi:10.17226/26479
20. Blinder VS, Deal AM, Ginos B, et al. Financial Toxicity Monitoring in a Randomized Controlled Trial of Patient-Reported Outcomes During Cancer Treatment (Alliance AFT-39). *J Clin Oncol*. Oct 10 2023;41(29):4652-4663. doi:10.1200/JCO.22.02834
21. Unger JM, Gralow JR, Albain KS, Ramsey SD, Hershman DL. Patient Income Level and Cancer Clinical Trial Participation: A Prospective Survey Study. *JAMA Oncol*. 2016;2(1):137-139. doi:10.1001/jamaoncol.2015.3924
22. Hurt S. Making the case for fair compensation in clinical trials. *STAT News*. 2024. https://www.statnews.com/2024/05/23/clinical-trials-participation-fair-compensation/

APPENDIX

Table A1. Demographic characteristics of respondents

		n (%)
Household income	35,000 or less	28 (25%)
	35,001-70,000	23 (20.5%)
	70,001-125,000	22 (19.6%)
	More than 125,000	17 (15.2%)
	Not sure/don't know	7 (6.3%)
	Prefer not to answer	15 (13.4%)
Education level	Less than high school degree	0 (0%)
	High school degree or equivalent (GED)	8 (7.1%)
	Post high school training other than college	9 (8%)
	Some college	16 (14.3%)
	Associate's degree	14 (12.5%)
	Bachelor's degree	36 (32.1%)
	Post-graduate/advanced degree	27 (24.1%)
	Prefer not to say	2 (1.8%)
Marital status	Married or partnered	66 (58.9%)
	Single	29 (25.9%)
	Divorced or separated	12 (10.7%)
	Widowed	4 (3.6%)
	Other	1 (0.9%)
Children living in household	0	83 (74.1%)
	1	15 (13.4%)
	2	8 (7.1%)
	3	4 (3.6%)
	4	1 (0.9%)
	5 or more	0 (0%)
	Missing	1 (0.9%)
Employment prior to clinical trial	Yes	56 (50.0%)
	No	56 (50.0%)
Type of insurance	Employer-provided insurance	50 (44.6%)
	Medicare	32 (28.6%)
	Medicaid	10 (8.9%)
	Privately purchased insurance	14 (12.5%)
	Military health care	3 (2.7%)
	Other	3 (2.7%)
	Indian Health Service	0 (0%)
	No health insurance	0 (0%)
Community type	Suburban	52 (46.4%)
	Rural	28 (25%)
	Urban	26 (23.2%)
	Prefer not to say	4 (3.6%)
	Missing	2 (1.8%)

Note: All responses refer to the participant's demographics at the start of the clinical trial.

Table A2. Compensation and reimbursement between financially stressed and non-stressed individuals

	Overall	Stressed (n = 72)	Not stressed (n = 40)
Any compensation	30 (26.8%)	17 (23.6%)	13 (32.5%)
Less than $250	15 (13.4%)	8 (11.1%)	7 (17.5%)
$250-$499	4 (3.6%)	4 (5.6%)	0 (0%)
$500-$999	2 (1.8%)	0 (0%)	2 (5%)
$1000+	2 (1.8%)	2 (2.8%)	0 (0%)
Did not provide	7 (6.2%)	3 (4.2%)	4 (10%)
Any reimbursement	39 (34.8%)	30 (41.7%)	9 (22.5%)
Parking	22 (19.6%)	16 (22.2%)	6 (15%)
Food	10 (8.9%)	6 (8.3%)	4 (10%)
Transportation	8 (7.1%)	6 (8.3%)	2 (5%)
Road tolls	2 (1.8%)	1 (1.4%)	1 (2.5%)
Gasoline	7 (6.2%)	5 (6.9%)	2 (5%)
Housing or lodging	10 (8.9%)	7 (9.7%)	3 (7.5%)
Childcare	1 (0.9%)	1 (1.4%)	0 (0%)
Medications to manage treatment side effects	5 (4.5%)	3 (4.2%)	2 (5%)
Internet service or plan	1 (0.9%)	1 (1.4%)	0 (0%)
Other	2 (1.8%)	0 (0%)	2 (5%)

Note: "Any compensation" is defined as anyone who reported receiving compensation for their time from any source, as described in Figure 6A. Respondents were asked to report compensation either as a lump sum payment or on a per visit basis. If per visit, total compensation was calculated using the reported number of trips to their clinical trial site. This table shows the total compensation received during the course of the clinical trial based on these two sets of questions; out of the 30 respondents who received compensation from any source, 7 did not provide sufficient information to calculate total compensation (shown above as "Did not provide"). "Any reimbursement" is defined as anyone who reported receiving full or partial reimbursement, as described in Figure 6B. Respondents could select multiple items; therefore, numbers do not add to 100%.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Assistant Secretary for Planning and Evaluation

200 Independence Avenue SW, Mailstop 434E
Washington, D.C. 20201

For more ASPE briefs and other publications, visit:
aspe.hhs.gov/reports

ABOUT THE AUTHORS
Allison Kolbe is a Social Science Analyst in the Office of Science and Data Policy in the Office of the Assistant Secretary for Planning and Evaluation.
Trinidad Beleche is an Economist in the Office of Science and Data Policy in the Office of the Assistant Secretary for Planning and Evaluation.

SUGGESTED CITATION
Kolbe, A. and Beleche, T. Financial stress associated with oncology clinical trial participation. Office of the Assistant Secretary for Planning and Evaluation, U.S. Department of Health and Human Services. January 2025.

ACKNOWLEDGMENTS
The Clinical Trial Participation Costs Survey was developed and fielded by Mathematica, under contract HHSP233201500035I with ASPE, in collaboration with the American Cancer Society. The authors thank Kirsten Barrett (Mathematica), Sarah Long (ACS CAN), and Mark Fleury (ACS CAN) for their contributions to this work. We would also like to acknowledge the following individuals:
Hope King, PhD, MSPH, Centers for Disease Control and Prevention
Christine Lee, PharmD, PhD, Food and Drug Administration
Winifred (Ann) Meeker-O'Connell, MS, Food and Drug Administration
Richard P. Moser, PhD, National Cancer Institute, National Institutes of Health
Kelly Blake, SCD, National Cancer Institute, National Institutes of Health
Courtney P. Williams, DrPH, University of Alabama at Birmingham

---

For general questions or general information about ASPE: aspe.hhs.gov/about