original contributions

Implementation of a Multisite Financial Reimbursement Program in Cancer Clinical Trials Integrated With Patient Navigation: A Pilot Randomized Clinical Trial

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QUESTION ASKED: Does additional telephone-based outreach as part of a financial reimbursement program (FRP) offered during therapeutic cancer trial discussions enhance enrollment in clinical trials?

SUMMARY ANSWER: The IMproving Patient Access to Cancer clinical Trials pilot feasibility trial observed that implementation of a FRP at two comprehensive cancer centers is feasible and can serve a diverse patient population. No difference in enrollment in clinical trials between the two study arms was observed; the proportion of enrollment was 70% for both study arms. The most common reason for not enrolling in a clinical trial was due to ineligibility determined through screening procedures (75%).

WHAT WE DID: Study participants were recruited at two National Cancer Institute–designated comprehensive cancer centers. Participants were randomly assigned 1:1 to receive no follow-up (usual care and brochure) or a follow-up telephone call to facilitate FRP utilization stratified by study site. The brochures were available in English, Spanish, and Chinese (traditional and simplified). A language-concordant researcher or telephone translator was provided for non–English-speaking participants.

BIAS, CONFOUNDING FACTORS: Given this study was performed at two comprehensive cancer centers, there is inherent selection bias in offering these services to patients already seeking care at our sites.

REAL-LIFE IMPLICATIONS: We found that offering a FRP as part of therapeutic cancer clinical trial participation is feasible and serves a diverse patient population. It is associated with high therapeutic clinical trial enrollment overall, and a follow-up outreach telephone call does not appear to enhance enrollment.

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CARE DELIVERY

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Implementation of a Multisite Financial Reimbursement Program in Cancer Clinical Trials Integrated With Patient Navigation: A Pilot Randomized Clinical Trial

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abstract

PURPOSE Cancer clinical trial participants face considerable indirect costs associated with participation, such as travel and lodging, which may contribute to poor enrollment. Here, we report the findings in IMproving Patient Access to Cancer clinical Trials, a pilot feasibility study investigating the efficacy of offering a financial reimbursement program (FRP) during a therapeutic clinical trial discussion with or without additional outreach in improving patient enrollment.

METHODS Study participants for this study were recruited at two National Cancer Institute–designated comprehensive cancer centers (CCCs) from April 8, 2019, to September 19, 2019. Eligible participants were adults with a cancer diagnosis being approached to consider enrollment in a clinical trial. Participants were randomly assigned 1:1 to receive no follow-up (usual care) or a follow-up telephone call to facilitate FRP utilization stratified by study site. The target enrollment was 132 patients, with 66 patients in each study arm. The primary outcome was the consent rate to the multisite interventional study on the FRP among participants enrolling in clinical trials.

RESULTS The study had a 78% consent rate and enrolled a total of 132 participants, of whom 51% were non-White compared with 28% of CCC treatment clinical trial participants in 2019. No difference in enrollment in clinical trials between the two study arms was observed as the proportion of enrollment was 70% for both study arms. The most common reason for not enrolling in a clinical trial was due to ineligibility determined through screening procedures (75%).

CONCLUSION The current study observed that implementation of FRP at CCCs is feasible and serves a diverse patient population. Future studies will measure the impact of programs on overall clinical trial accrual and among racial/ethnic minorities.

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BACKGROUND

A lack of racial/ethnic diversity among cancer clinical trial participants remains a critical problem. According to the National Cancer Institute (NCI), the majority of participants in publicly funded phase I-III clinical trials are considered ethnically White.[1] Specifically, middle-class White patients have traditionally had the highest participation rates in cancer treatment clinical trials.[2] While the National Institutes of Health (NIH) promoted greater inclusion of women and racial/ethnic minorities in publicly funded clinical trials through the 1993 Revitalization Act,[3-6] it remains estimated that $< 5\%$ of cancer studies adequately represent minority groups currently.[2,7,8] These observed disparities are influenced by social factors such as insurance status, neighborhood, and household income.[3,9-14]

While under-representation in clinical research is well described in the literature, to date, little research attention has been directed at mitigating factors driving these observed disparities.[15] Efforts to dismantle barriers to enrollment have largely focused on addressing attitudes, knowledge, and beliefs around clinical trials, with implementation of initiatives to improve patient awareness and access to trials.[1,16] Currently, the significance of costs, both direct and indirect, associated with cancer clinical trial participation are increasingly understood. The indirect costs, such as travel, may be considerable for patients in the context of a therapeutic clinical trial

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(TCT).[17,18] Interventions aimed to reduce disparities seldom address these added financial burdens. Most studies avoid engaging with financial models to address clinical trial disparities for fear of being perceived as inducement rather than reimbursement.[19]

Here, we report the findings observed in IMproving Patient Access to Cancer clinical Trials (IMPACT), a pilot study investigating the feasibility of a multisite interventional study offering a financial reimbursement program (FRP) during a TCT discussion with or without additional outreach in improving therapeutic cancer clinical trial (TCT) enrollment (ClinicalTrials.gov identifier: NCT03943082). The objectives of this study were to assess the feasibility of this study design, to test the efficacy of performing follow-up for a sliding scale FRP to improve accrual to cancer TCTs, and to evaluate if a sliding scale FRP improves accrual among racial/ethnic minorities to cancer TCTs by comparing with historical control.

METHODS

Recruitment Methods

Participants for this study were recruited at two NCI-designated comprehensive cancer centers (CCCs)—the University of California San Francisco and the University of Southern California—from April 8, 2019, to September 19, 2019. Eligible participants for the IMPACT study were adults with a cancer diagnosis being approached to consider enrollment in a TCT. Participants were introduced to the IMPACT study at the time of TCT discussion and were identified by their clinicians. All clinicians at the CCC were made aware of the IMPACT study presentations conducted at clinical research meetings. The researcher then obtained informed consent for follow-up and data collection through the IMPACT study. Participants were randomly assigned in a 1:1 fashion to receive a brochure about a FRP at the time of consent for a TCT (usual care) or receive brochure and additional telephone call by the IMPACT study outreach coordinators after a semistructured script regarding the FRP (usual care plus intervention). The brochures were available in English, Spanish, and Chinese (traditional and simplified). A language-concordant researcher or telephone translator was provided for non–English-speaking participants.

Sliding Scale FRP

Before IMPACT, the FRP has been available to patients enrolling in a TCT at the CCC regardless of participation in the IMPACT study. FRP may be offered if patients seek financial support either as a brochure from a provider, clinical trial coordinator, or social worker; however, communication was not standardized before IMPACT. For all patients who receive FRP either through IMPACT or outside of IMPACT, reimbursement receipts are submitted through e-mail, post mail, or fax directly to a centralized reimbursement processor at the Lazarex Cancer Foundation in Danville, California. Representatives from the Lazarex Cancer Foundation contacted the patient to resolve discrepancies and process all claims. The IMPACT study research coordinator served as an onsite integrated navigator for FRP utilization and assisted patients with claim submissions at the patients' request. Expenses eligible for reimbursement included ground transportation, gas mileage, taxi/rideshare, parking, tolls, lodging, air travel, and a companion's travel cost.

Eligibility for FRP

Participants were eligible for FRP if they submitted an application to the Lazarex Cancer Foundation and provided proof of having a household income $\leq$ 700% per the 2018 Health and Human Services Poverty Guidelines. Acceptable proof-of-income documents included a copy of income tax return, a copy of the most recent pay stub, unemployment check, and supplemental security income, social security disability, or public assistance benefit notification. If a patient was not employed or could not provide the aforementioned documents, they could submit a signed letter stating their current financial situation.

Baseline and Follow-Up Measures

Disease characteristics of study participants including stage of disease and tumor type were collected. Clinical trial characteristics such as phase of study and funding type (eg, internal, governmental, or private) were recorded for each participant. IMPACT study participants completed questionnaires at baseline (time of consent) and follow-up (time of TCT completion as defined by the TCT protocol). At baseline, the following items were collected: sociodemographic details including race/ethnicity, household income, wealth/assets, Comprehensive Score for financial Toxicity Patient-Reported Outcome Measure,[20] NIH Patient-Reported Outcomes Measurement Information System (PROMIS) Global Health,[21] National Comprehensive Cancer Network Distress Thermometer (DT), 3-item health literacy assessment,[22] and Brief Resilience Scale.[23] At follow-up, NIH PROMIS Global Health and National Comprehensive Cancer Network DT were collected.

Primary and Secondary Objective

The primary objective was to assess the feasibility of a multisite interventional study on FRP among participants enrolling in TCTs. The primary end point was measured as the percentage of patients who signed consent to the IMPACT study out of all patients who are offered enrollment. The secondary objective was to evaluate how FRP may improve cancer TCT accrual through the mechanism of performing intensive follow-up—defined as a follow-up scripted phone call within 3 days of IMPACT study consent. The secondary end point was the percentage of participants who signed consent for a cancer TCT at day 30 by arm out of the total number of patients in each arm, respectively.

Statistical Analysis

Demographic and clinical characteristics were summarized by descriptive statistics. In general, frequency distribution and percentage were used to summarize categorical variables, and mean with standard deviation (SD) was used to describe continuous variables. If the normality assumption did not hold, median with interquartile range was used to describe continuous variables. Comparison of the continuous variables among groups was assessed using the two-sample *t*-test and analysis of variance for two groups and more than two groups, respectively. If the assumptions did not hold, the corresponding nonparametric tests were applied. The chi-square test was applied to test if there was a statistical association between two categorical variables. The statistical significance was declared at $\alpha < .05$.

Power and Sample Size Calculation

The target enrollment is 132 participants across all sites, 66 participants per site. We estimated an 80% consent rate among patients approached for participation in this study and therefore intended to approach a minimum of 166 patients, which would provide 95% CI (74 to 86) for consent rate. A stratified random assignment was applied, stratified by site (University of California, San Francisco [UCSF] *v* University of Southern California). With a type I error of 0.1, there was at least an 80% power to detect an increase of 0.2 (eg, 0.30-0.50) in the proportion of patients who consent to participate in a TCT and receive an additional follow-up call compared with those who do not by a directional two-sample proportion test with 66 participants in each arm. Hence, this study had adequate power to detect clinically meaningful improvements in TCT consent rate because of this intervention.

All study procedures were reviewed and approved by the Institutional Review Boards at participating sites.

RESULTS

As shown in Figure 1, 170 patients were approached for the IMPACT study (UCSF = 87, University of Southern California = 83) and 132 provided consent to participate with a study consent rate of 78%. Among approached patients, a subset declined to participate (n = 38), of whom 16 (42%) indicated that they were not interested in receiving assistance or knew they would not qualify for the program. Among patients who signed consent for the IMPACT study (n = 132), 67 patients did not proceed on study with the most common reasons being deemed ineligible for TCT (51%) and not qualifying for FRP (11%). We observed no difference in enrollment in TCT between the two study arms as the percentage of enrollment was 70% and 70% for the usual care and usual care plus intervention arms, respectively. Among 170 patients approached for the study, nine (5.2%) patients were ineligible for FRP before providing consent and 10 (5.8%) participants withdrew because of FRP ineligibility.

The characteristics of patients who signed consent for the IMPACT study are reported in Table 1. We observed a mean age of 57 years (SD = 14 years). Among participants, 57% were male. Overall, the majority (49%) of participants were non-Hispanic White. The other major racial groups were Black (5%), Asian (12%), and Hispanic (26%). Among respondents, 24% reported a household income < $25,000 US dollars (USD), 14% reported a household income from $25,001 to $56,000 USD, 4% reported a household income from $56,000 to $99,000 USD, and 8% reported a household income of $100,000 USD or more. In this study, 31% of respondents reported a high school degree or less as highest education attained. Household income and education level were not collected in 50% of the study population. The insurance types included private (32%), Medicaid (33%), Medicare (26%), and Veterans Affairs (< 1%). The most common cancer types were breast (24%), gastrointestinal (36%), and genitourinary (17%). The majority of patients had metastatic disease (73%). At baseline, the PROMIS Global Physicial Health score was 38.9 (SD = 7.9) and the PROMIS Global Mental Health score was 43.1 (SD = 8.0). The mean DT score for participants was 4.7 out of 10. All patient characteristics were balanced between study arms.

As shown in Table 2, 72% of patients reported using private vehicle to travel to clinical trial visits. The time spent to receive care was considerable, with the majority (75%) of study participants reporting > 3 hours to travel and receive care for a cancer care visit; most patients (72%) did not require overnight lodging. The reported out of pocket costs varied across the study population, with 32% reporting <$50 USD per month, 57% reporting between $50 USD and $1,000 USD, and 11% reporting more than $1,000 USD per month. Most patients reported moderate (38%) or significant (30%) financial burden associated with costs of cancer care. Among respondents, 25% reported feeling uncomfortable with discussing finances with their doctor, 35% reported feeling somewhat comfortable, and 40% reported feeling very comfortable.

DISCUSSION

Cancer clinical trials have largely failed to engage and enroll racial/ethnic minorities calling into question the generalizability of these results.[15] In the United States, Black and Hispanic/Latinx patients comprise about 12% and 16% of the US population, respectively; however, these groups each account for < 5% of trial participants.[3,24] In the IMPACT study overall, 5% of FRP recipients were Black and 26% were Hispanic/Latinx which reflect the demographics of the population cared for at the CCCs.[9,25] Overall, this study demonstrated that the IMPACT study oversampled racial/ethnic minorities given that only 28% of TCT participants across the CCC have a non-White race/ethnicity. These data suggest that implementing an FRP for ancillary costs of clinical trial participation is feasible at

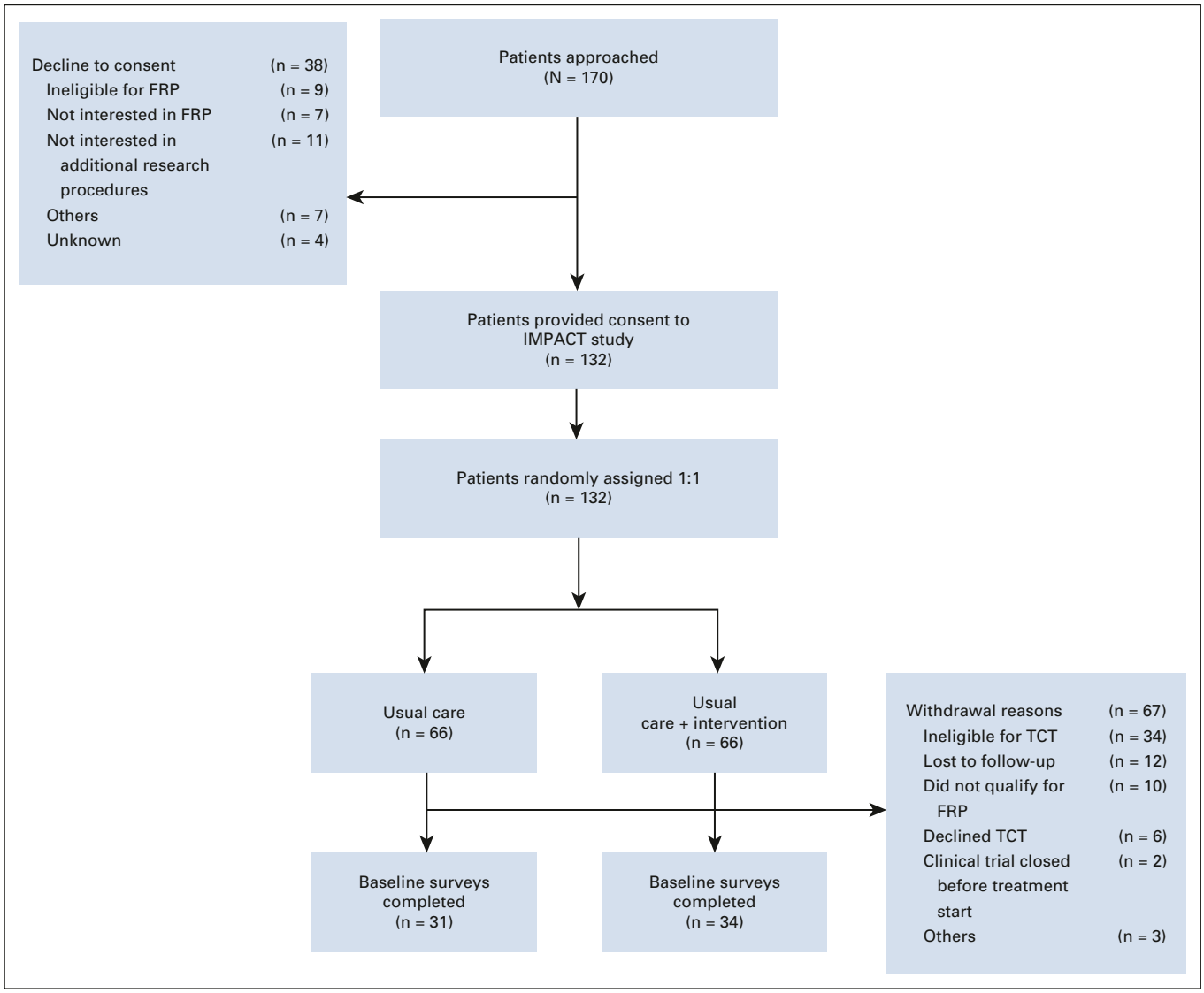

FIG 1. IMPACT study CONSORT diagram. FRP, financial reimbursement program; IMPACT, Improving Patient Access to Cancer clinical Trials; TCT, therapeutic clinical trial.

CCCs. FRP was observed to be used among a diverse patient population. Future research will examine the effect of an FRP on minority clinical trial accrual.

While telephone-based interventions have been shown to promote healthy behaviors in previous research[26,27] and are frequently practiced in clinical settings,[28,29] we did not observe a difference in TCT enrollment between groups on the basis of receipt of an additional telephone call to discuss the FRP. However, we did find a strikingly high proportion of TCT enrollment in both study arms during the RCT, well above the accepted standard consent rate among patients with cancer. Unger et al[30] evaluated 35 studies that offered trial participation to 9,759 patients and observed a consent of 55% overall. Our study observed a TCT enrollment of 70% in both study arms, suggesting that adding a telephone call does not have utility in accelerating recruitment; however, the availability of an FRP in general may accelerate TCT recruitment. We will separately evaluate and report the impact of FRP availability on trial accrual.

As exploratory measures, this study assessed patient burdens, especially as it relates to travel and cost, that may contribute to a lack of diversity in clinical research. Among study participants, the majority of participants (75%) required more than 3 hours to attend cancer treatment appointments, a subset (17%) of who traveled more than 8 hours. This study also observed that one fourth of patients required overnight lodging to receive care in the context of a clinical trial; however, this observation was driven largely by a single study site (UCSF). These data add to the growing body of literature revealing that conventional clinical trials place a high degree of burden on patients. Previous research has shown that the

TABLE 1. Patient Characteristics

Characteristic	Overall (N = 132)		Usual Care (n = 66)		Usual Care Plus Intervention (n = 66)		*P*
	No.	%	No.	%	No.	%	
Age, mean (SD), years	57 (14)		55 (15)		59 (13)		.178
Sex							.725
Male	57	43	27	41	30	46	
Female	75	57	39	59	36	55	
Race							.325
NH White	65	49	30	46	35	53	
Black	6	5	2	3	4	6	
Asian	16	12	8	12	8	12	
Native Hawaiian or Other Pacific Islander	1	1	0	0	1	2	
Hispanic or Latino	34	26	21	32	13	20	
Others	8	6	3	5	5	8	
Unknown	2	3	2	3	0	0	
Household income, USD							.56
$24,999 or less	32	24	15	23	17	26	
$25,000-$55,999	18	14	9	14	9	14	
$56,000-$99,999	5	4	3	5	2	3	
$100,000 or more	11	8	3	5	8	12	
Unknown	66	50	36	55	30	46	
Highest education attained							.11
High school degree or less	41	31	20	30	21	32	
College degree or equivalent	18	14	5	8	13	20	
Graduate degree or equivalent	7	5	5	8	2	3	
Prefer not to answer/unknown	66	50	36	55	30	46	
Insurance type							.52
Private	42	32	19	29	23	35	
Medicaid	43	33	21	32	22	33	
Medicare	35	27	21	32	14	21	
Veterans affairs/military	1	1	0	0.0	1	2	
Not insured	1	1	1	2	0	0.0	
Others	10	7.6	4	6.1	6	9.1	
Cancer type							.51
Breast	32	24	17	26	15	23	
Cutaneous	10	8	7	11	3	5	
GI	47	36	20	30	27	41	
Genitourinary	22	17	11	17	11	17	
Gynecologic	5	4	4	6	1	2	
Head/neck	4	3	2	3	2	3	
Hematologic	4	3	1	2	3	5	
CNS	1	1	1	2	0	0	
Sarcoma	1	1	1	2	0	0	
Thoracic	6	5	2	3	4	6	

(continued on following page)

TABLE 1. Patient Characteristics (continued)

Characteristic	Overall (N = 132)		Usual Care (n = 66)		Usual Care Plus Intervention (n = 66)		*P*
	No.	%	No.	%	No.	%	
Clinical trial phase							.27
I	33	25	11	17	22	33	
I/II	27	21	16	24	11	17	
II	39	30	21	32	18	27	
II/III	1	1	0	0	1	2	
III	27	21	15	23	12	18	
NA	5	4	3	5	2	3	
Clinical trial funding type							.01
Internal funding	15	11	6	9	9	14	
Government	15	1	11	17	4	6	
Private for profit	75	57	42	64	33	50	
Private not for profit	27	21	7	11	20	30	
Stage of disease at enrollment							.59
I	1	1	1	2	0	0	
II	9	7	6	9	3	5	
III	8	6	5	8	3	5	
IV	112	85	53	80	59	89	
NA	2	2	1	2	1	2	
Metastatic	96	73	45	68	51	77	
Mean Health Literacy Score, 3 low—15 high (SD)	11.3 (3.0)		11.4 (3.0)		11.3 (3.0)		.84
Mean Brief Resilience Score, 1 low—5 high (SD)	3.5 (0.6)		3.5 (0.7)		3.6 (0.5)		.65
Mean Financial Toxicity Score, 0 worst—44 best (SD)	14.8 (8.8)		14.1 (8.6)		15.5 (9.0)		.56
Mean PROMIS overall QoL, 1 poor—5 excellent (SD)	2.5 (0.9)		2.6 (1.0)		2.5 (0.9)		.93
Mean PROMIS overall health (SD)	2.2 (1.0)		2.1 (1.1)		2.3 (0.9)		.36
Mean PROMIS global physical health (SD)	11.6 (2.9)		11.2 (3.0)		11.9 (2.9)		.32
Mean PROMIS global mental health (SD)	11.8 (3.2)		12.0 (3.1)		11.6 (3.3)		.61

NOTE. Percentages do not add up to 100% because of rounding.

Abbreviations: NA, not applicable; NH, non-Hispanic; PROMIS, Patient-Reported Outcomes Measurement Information System; QoL, quality of life; SD, standard deviation; USD, US dollars.

burden of travel associated with clinical trial participation is shouldered by patients traveling from low-income neighborhoods.[31] Therefore, mitigating the costs associated with travel is an opportunity to enhance access to trials for patients of low socioeconomic status (SES).

In this study, participants reported out-of-pocket costs associated with cancer care. About half of participants reported a household income < $56,000 USD. Despite being of low SES, 25% of study participants reported feeling uncomfortable bringing up health care cost-related issues with their cancer doctor. Additionally, this study observed that the monthly out-of-pocket costs associated with cancer treatment varied with about one third of participants paying < $50 USD per month; however, 11% had out-of-pocket costs > $1,000 USD. Previous research has described the relationship between financial hardship, patient income, and clinical trial participation. Goldman et al[32] observed that 932 patients with cancer enrolled in NCI-sponsored clinical trials experienced 6.5% higher adjusted costs compared with nonparticipants. A study examining factors that affected patient accrual found that among 276 assessed patients, 13% did not participate in a clinical trial because of travel distance and 8% because of insurance coverage concerns,[33] highlighting the role of indirect costs in informing patient decision making.

TABLE 2. Direct and Indirect Costs of Cancer Care

Survey Question	No.	%
Primary mode(s) of travel to appointments (select all)		
Private vehicle	54	72.0
Public transportation	8	10.7
Taxi	4	5.3
Airplane	3	4.0
Others	6	8.0
How many hours out of your day did your last appointment for cancer care/treatment take (including travel time)?		
< 1	2	3.1
1-3	14	21.5
3-5	24	36.9
5-8	14	21.5
More than 8	11	16.9
About how much out-of-pocket costs did you have related to cancer care/treatment in the last month? This includes hotel/lodging costs, tests, medications, copays, etc, USD		
< $50	21	32.3
$50-$100	11	16.9
$100-$300	12	18.5
$300-$500	7	10.8
$500-$700	5	7.7
$700-$1,000	2	3.1
More than $1,000	7	10.8
Do you usually need to arrange overnight lodging?		
Yes	17	26.2
No	47	72.3
Missing	1	1.5
To what degree has the cost of your cancer care been a financial burden for you/your family?		
Not a financial burden at all	7	10.8
Minor financial burden	12	18.5
Moderate financial burden	24	36.9
Significant financial burden	19	29.2
Catastrophic financial burden	1	1.5
Missing	2	3.1
How comfortable do you feel bringing up health care cost-related issues with your cancer doctor?		
Uncomfortable	16	25.4
Somewhat comfortable	22	34.9
Very comfortable	25	39.7
Missing	2	3.2

Abbreviation: USD, US dollars.

While financial toxicity and out-of-pocket costs assumed by patients are increasingly acknowledged as contributors to cancer disparities,[20] to date, an effective, scalable model for mitigating these risks has not been developed. Previous research from the Cancer Care Equity Program at Massachusetts General Hospital highlighted that addressing indirect costs associated with clinical trials may improve accrual of patients from diverse socioeconomic backgrounds.[16,20,34,35] Despite this evidence to support strategies to mitigate the added costs that may be endured by patients enrolled in therapeutic cancer clinical trials, no model has been developed in cancer clinical research.[17,18] This study provides evidence that FRPs can be implemented at CCCs. Future research is required to further

explore if these programs adequately address financial concerns among under-represented populations.

This study has several limitations worth noting. Cost estimations over the past month among participants were subject to recall bias, therefore introducing error in measurement of financial burdens. Most notably, availability of the FRP was for patients who previously established care and were currently being evaluated at the CCCs. Therefore, there is inherent selection bias in offering these services to patients already seeking care at our sites. Further studies will need to measure the impact of expansion of FRP to patients receiving cancer treatment in other community health centers to understand its universal uptake. In general, we also observed that patients self-screened when completing the application to determine if financial reimbursement was of potential benefit to them. Future research will need to incorporate an FRP on a population level to better assess the impact on clinical trial enrollment. Another serious limitation of this study is that we were unable to collect the number of patients for whom clinical trials discussions occur; therefore, we are unable to report the total number of potentially eligible patients during the study period. Finally, the ability to scale the FRP intervention will require more universal sponsor or payer coverage of indirect costs associated with TCT participation.

Despite these limitations, this study has several strengths. This study operationalized access to an FRP across disease programs at two CCCs. Patients at the CCC had access to the financial assistance program through the Lazarex Cancer Foundation before the launch of the IMPACT study. However, patients were previously only introduced to the resources after referral to social work or if their clinician or research coordinator happened to be aware of the resource. The collaboration between Lazarex and the CCC is a novel initiative that attempted to more systematically address out-of-pocket costs of clinical trial participation. IMPACT formalized informing patients about the Lazarex FRP to evaluate whether operationalizing follow-up improves recruitment to cancer TCTs. Given that cancer clinical research is conventionally siloed by disease indication, a research study that offers FRP to all patients with cancer demonstrates that the availability of an FRP can serve all patients with cancer considering clinical trials, regardless of tumor type.

In conclusion, this study observed that offering an FRP as part of therapeutic cancer clinical trial participation is feasible, associated with high TCT enrollment overall, and a follow-up outreach telephone call does not appear to enhance enrollment. Patients who received financial reimbursement were racially/ethnically diverse and of low SES. Future research will need to expand the FRP to other sites to examine variation in FRP utilization by geography and clinical setting.

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AUTHORS' DISCLOSURES OF POTENTIAL CONFLICTS OF INTEREST

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AUTHORS' DISCLOSURES OF POTENTIAL CONFLICTS OF INTEREST

Implementation of a Multisite Financial Reimbursement Program in Cancer Clinical Trials Integrated With Patient Navigation: A Pilot Randomized Clinical Trial

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