Financial Toxicity Monitoring in a Randomized Controlled Trial of Patient-Reported Outcomes During Cancer Treatment (Alliance AFT-39)

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ABSTRACT

PURPOSE Financial toxicity (FT) affects 20% of cancer survivors and is associated with poor clinical outcomes. No large-scale programs have been implemented to mitigate FT. We evaluated the effect of monthly FT screening as part of a larger patient-reported outcomes (PROs) digital monitoring intervention.

METHODS PRO-TECT (AFT-39) is a cluster-randomized trial of patients undergoing systemic therapy for metastatic cancer. Practices were randomly assigned 1:1 to digital symptom monitoring (PRO practices) or usual care (control practices). Digital monitoring consisted of between-visit online or automated telephone patient surveys about symptoms, functioning, and FT (single-item screening question from Functional Assessment of Chronic Illness Therapy-COmprehensive Score for financial Toxicity) for up to 1 year, with automated alerts sent to practice nurses for concerning survey scores. Clinical team actions in response to alerts were not mandated. The primary outcome of this planned secondary analysis was development or worsening of financial difficulties, assessed via the European Organisation for Research and Treatment of Cancer QLQ-C30 financial difficulties measure, at any time compared with baseline. A randomly selected subset of patients and nurses were interviewed about their experiences with the intervention.

RESULTS One thousand one hundred ninety-one patients were enrolled (593 PRO; 598 control) at 52 US community oncology practices. Overall, 30.2% of patients treated at practices that received the FT screening intervention developed, or experienced worsening of, financial difficulties, compared with 39.0% treated at control practices ($P = .004$). Patients and nurses interviewed stated that FT screening identified patients for financial counseling who otherwise would be reluctant to seek, or unaware of the availability of, assistance.

CONCLUSION In this report of a secondary outcome from a randomized clinical trial, FT screening as part of routine digital patient monitoring with PROs reduced the development, or worsening, of financial difficulties among patients undergoing systemic cancer therapy.

ACCOMPANYING CONTENT

Protocol

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INTRODUCTION

Approximately 20% of cancer survivors report having experienced financial toxicity (FT),[1] which is associated with inferior outcomes, including increased symptoms[2] and decreased quality of life.[3,4] Filing for bankruptcy, a severe form of FT, is associated with increased mortality among cancer survivors (hazard ratio, 1.79),[5] likely because of treatment nonadherence, a well-documented financial coping strategy.[6-9]

To our knowledge, despite widespread calls to incorporate FT screening into clinical care, to date, there has been no large-scale systematic evaluation of this approach.[10] Previous research has shown that patients with cancer favor discussing treatment-related financial concerns with health

CONTEXT

Key Objective

Does screening for financial toxicity (FT) prevent the development of financial difficulties in patients undergoing systemic therapy for advanced cancer?

Knowledge Generated

Only 30% of patients who were screened for FT developed new or worsening financial difficulties, compared with 39% of patients who were not screened, for a number needed to screen of 11.4. Patients and nurses who were interviewed were generally in favor of integrating FT screening into routine clinical care.

Relevance *(S.D. Ramsey)*

This study adds to a growing literature documenting the high prevalence of FT among patients being treated for cancer.*

*Relevance section written by *JCO* Consultant Editor Scott D. Ramsey, MD, PhD.

care providers and prefer that their providers initiate these conversations.[11-13] Yet, clinicians lack guidelines regarding how to ask patients about FT. One potential solution is to integrate routine FT screening into patient-reported digital monitoring programs, which have been evaluated for symptom assessment and distress screening.[14,15]

Patient-Reported Outcomes to Enhance Cancer Treatment (PRO-TECT; AFT-39) is a multicenter randomized trial to evaluate the impact of digital symptom monitoring, including FT screening, into routine clinical cancer care.[16] A key secondary outcome, effect on financial difficulties, is reported here. Additional secondary outcomes, including physical function, symptom control, and health-related quality of life (HRQoL), were reported previously.[16] The primary outcome, overall survival (OS), will be reported after the data for that outcome are mature.

METHODS

PRO-TECT is a cluster-randomized trial, conducted in US community oncology practices through the Alliance for Clinical Trials in Oncology,[17] to evaluate the effect of digital patient monitoring using patient-reported outcome (PRO) surveys compared with usual care (ClinicalTrials.gov identifier: NCT03249090). Randomization was stratified by rural versus urban practice location. The design and methods have been described previously,[16] as has the development of the digital patient monitoring intervention.[18-20]

Practices randomized to the investigational arm received access to a digital patient monitoring intervention[21] (weekly PRO surveys), which included questions about symptoms,[22-24] oral intake, patient-reported performance status,[25] and falls. For each survey, if a participant's answers passed a prespecified threshold on the basis of severity or worsening, an alert was sent to a nurse on their care team. Patients at PRO practices were asked to complete weekly surveys for up to 1 year, or until discontinuation of all cancer treatment. Patients could seek help from caregivers or staff to complete PRO surveys, which were available in English, Spanish, or Mandarin, and via an online or automated telephone interface. Study recruitment began in October 2017.

In March 2019, the intervention and protocol were modified to include FT screening. Once a month, the weekly PRO surveys would include the single-item screener that is part of the Functional Assessment of Chronic Illness Therapy-COmprehensive Score for financial Toxicity (FACIT-COST; "My illness has been a financial hardship to my family and me.").[26-28] Responses are based on a 5-level scale from 0 (not at all) to 4 (very much). As with the other symptom assessments in the intervention, the system triggered a real-time email alert to a care team nurse anytime a patient's FT screening score was >2 (ie, quite a bit or very much).

There were no requirements for what actions the care team should take in response to an alert. However, actions taken were documented in a standardized form that could include information about the response to a FT alert, to another symptom alert for the same patient, or both.

Patients

Adults with metastatic cancer who were undergoing systemic treatment (chemotherapy, targeted oral therapy, or immunotherapy) were eligible if they understood English, Spanish, or Mandarin. Patients with indolent lymphoma, acute leukemia, and those receiving hormonal monotherapy were excluded. Additional details regarding eligibility are available in the study protocol. Each practice was instructed to consecutively approach/enroll up to 50 patients. All patient participants signed informed consent. The Protocol (online only) and consent form were approved by a central institutional review board (IRB) and local IRBs.

Outcomes

The European Organisation for Research and Treatment of Cancer (EORTC) QLQ-C30[29] questionnaire was administered to patients in both arms at enrollment and 1, 3, 6, 9, and 12 months later. The primary outcome of this analysis was change in financial difficulties compared with baseline, measured using a single item from the QLQ-C30. Participants were asked, "Has your physical condition or medical treatment caused you financial difficulties?" and answered using a 4-point scale (not at all to very much). The outcome was operationalized as a change in financial difficulties from baseline to the maximum level of financial difficulties at any time after baseline, dichotomized as financial difficulties developed/worsened versus improved/unchanged. Participants who, at any point, reported development of new or worsening financial difficulties were classified has having worsened, regardless of whether their financial difficulties subsequently improved.

A subset of patients and nurses at PRO practices were randomly selected for interviews about their experiences with the intervention. Interviews were transcribed, systematically coded by study staff, and analyzed for themes related to implementation, barriers, and potential value of systematic FT screening.

Statistical Analysis

Accrual was discontinued on March 23, 2020, due to the COVID-19 pandemic, after recruitment of 1,191 (99.3%) of 1,200 planned participants. Although level of financial difficulties (EORTC QLQ-C30[29]) was measured in both arms throughout the study, FT screening (FACIT-COST[26,27]) was added to the intervention in March 2019, 18 months after study enrollment began (Table 1). By this time, 302 participants had already completed all study participation, including 165 treated at PRO practices who were never screened for FT. The primary analysis presented here includes all participants, regardless of enrollment date (N = 1,191). However, to isolate the impact of FT screening in our analysis, we stratified the analysis of financial difficulties by time of enrollment as follows: (1) participants whose entire participation was outside of the time frame when the intervention included FT screening (n = 302 who were never screened for FT, regardless of their site's assigned treatment arm), and (2) participants who enrolled in the study within the time frame when the intervention included FT screening (n = 889). The proportion of patients with worsening financial difficulties (EORTC QLQ-C30,[29] administered to all patients throughout the study) was compared between arms, controlling for baseline level of financial difficulties, using a generalized linear mixed model with fixed effects for arm and a random practice intercept term to account for clustering by practice. Comparisons for patient characteristics by baseline financial difficulties were performed using chi-square tests for categorical variables and Wilcoxon rank-sum tests. The post hoc intracluster correlation coefficient for the financial hardship item was 0.015 in the parent trial.[16] Statistical testing was two-sided, and $P < .05$ were considered statistically significant. SAS 9.4M6 was used for the analyses. Worsening financial difficulties is considered a secondary outcome in this trial, and the findings described in this article should be considered exploratory.

RESULTS

From October 31, 2017, to March 23, 2020, a total of 52 community oncology practices were randomized 1:1 to

TABLE 1. Financial Toxicity Measures

Trial Component	Item	Responses	Source	Frequency	No. Who Answered at Least Once
Intervention	In the last month, my illness has been a financial hardship to my family and me	Not at all A little bit Somewhat Quite a bit[a] Very much[a] Prefer not to answer	FACIT-COST[26]	Monthly for 12 months to intervention patients[b]	n = 402[c]
Outcome	During the past week, has your physical condition or medical treatment caused you financial difficulties?	Not at all A little Quite a bit Very much	EORTC QLQ-C30[29]	Baseline, 1, 3, 6, 9, and 12 months to entire trial population (intervention and control patients)	n = 1,190[d]

Abbreviations: EORTC, European Organisation for Research and Treatment of Cancer; FACIT-COST, Functional Assessment of Chronic Illness Therapy-COmprehensive Score for financial Toxicity; PRO, patient-reported outcome.

[a]Response triggered an alert to care team for intervention patients.

[b]Added March 2019 after trial began.

[c]n = 889 participants enrolled in the study within the time frame when the intervention included financial toxicity screening (were still on study in March 2019 or enrolled after March 2019). n = 402 were treated at PRO practices and answered the financial toxicity screening question at least once.

[d]n = 1,188 answered this question at baseline and are included in Table 3. However, two additional participants answered this question in a subsequent survey and are included here.

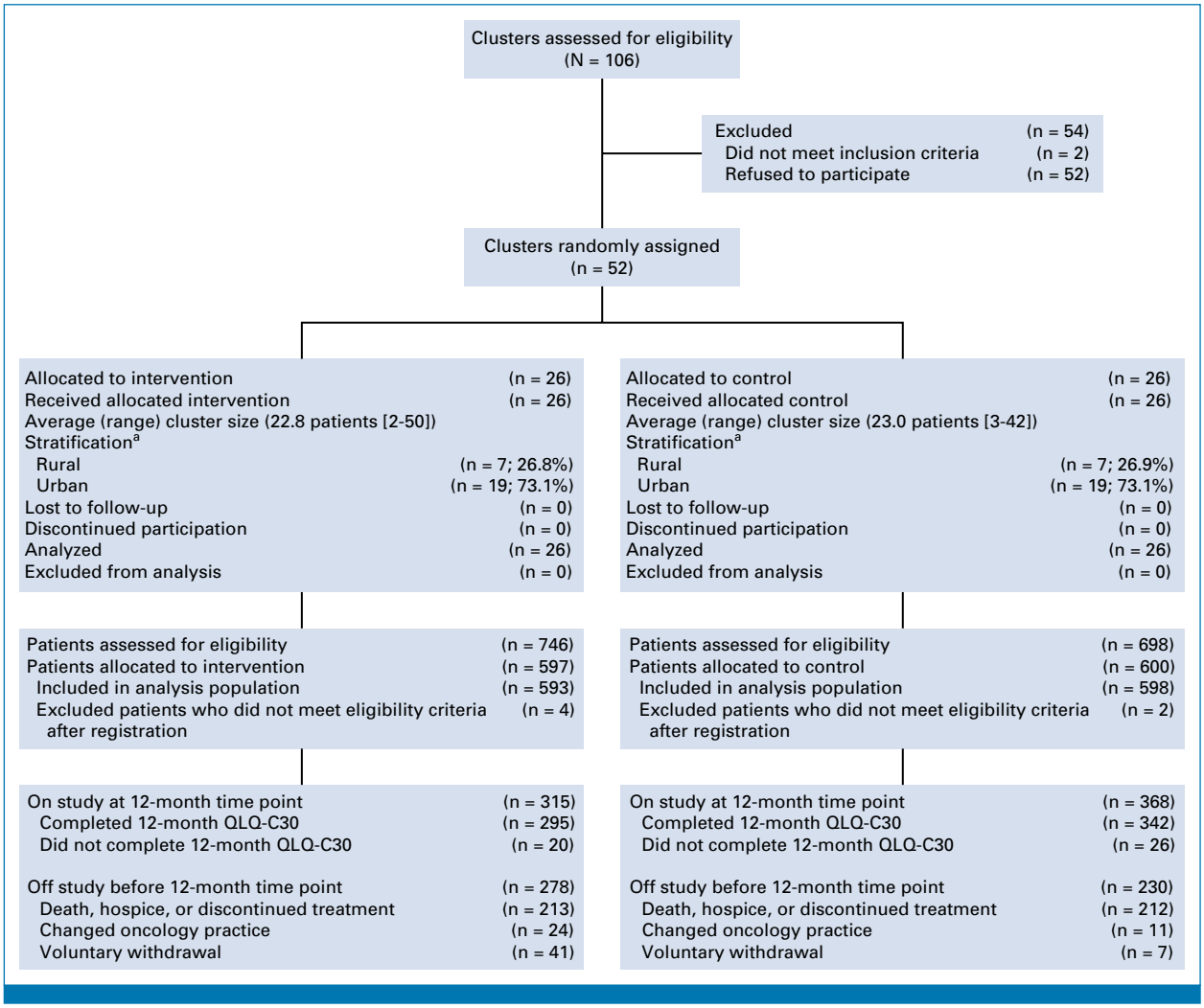

FIG 1. CONSORT diagram of patient recruitment, randomization, and follow-up. [a]Rural/urban practice location on the basis of 2010 US Census data, confirmed with practice self-designation.

receive the digital patient monitoring intervention with PRO surveys or control (Fig 1). No sites discontinued participation. Of 1,444 patients approached, 1,191 enrolled in the study (593 at 26 PRO practices; average 22.8 patients per practice; range, 2-50; 598 at 26 control practices; average 23.0 patients per practice; range, 3-42). Median age was 63 years, 694 (58.3%) were female, 925 (79.5%) were White, and 468 (39.4%) had high school education or less (Table 2). At enrollment, 303 (25.5%) were working; 471 (39.6%) said it was difficult to meet monthly bill payments (somewhat, very, or extremely).

At baseline, 160 (13.4%) said that during the preceding week, they had experienced financial difficulties (EORTC QLQ-C30[29]). Financial difficulties at baseline differed by participant characteristics (Table 3).

Of 1,191 patients enrolled, 1,146 (96%) had both a baseline and at least one postbaseline report of financial difficulties (EORTC QLQ-C30[29]). These patients were included in the models of worsened financial difficulties as a function of study arm, controlling for baseline financial difficulties. Initial reports of worsening financial difficulties occurred across all outcome survey time points, and the timing did not differ by arm.

Overall, 173 (30.2%) of 572 participants at PRO practices developed worsened financial difficulties, compared with 224 (39.0%) of 574 at control practices ($P = .004$). This 8.8% absolute difference corresponds to a number needed to screen of 11.4. Figure 2 compares the percentage of patients who reported worsened financial difficulties by site between arms. To investigate the effect of adding FT screening to the intervention, an interaction test was done to evaluate if the relationship between change in the financial difficulties outcome (EORTC QLQ-C30[29]) by arm differed by time period (pre/post March 2019), although the study was not powered to detect this difference. This interaction test was not significant ($P = .52$), indicating no difference in relationship by time period. However, we were still interested in testing the effect of the intervention within the time period when it

TABLE 2. PRO-TECT Patient Demographics by Randomization Arm

Characteristic	PRO Practices (n = 593)	Control Practices (n = 598)	Total (N = 1,191)
Age, years			
No.	593	597	1,190
Mean (SD)	62.39 (11.5)	62.02 (11.2)	62.20 (11.4)
Median	64.0	62.0	63.0
Q1-Q3	55.0-70.0	55.0-69.0	55.0-70.0
Range	29.0-89.0	28.0-93.0	28.0-93.0
Sex, No. (%)			
Missing	0	1	1
Male	234 (39.5)	262 (43.9)	496 (41.7)
Female	359 (60.5)	335 (56.1)	694 (58.3)
Race, No. (%)			
Missing	5	22	27
Native American or Alaska Native	11 (1.9)	13 (2.3)	24 (2.1)
Asian	2 (0.3)	16 (2.8)	18 (1.5)
Black or African American	99 (16.8)	94 (16.3)	193 (16.6)
Native Hawaiian or Pacific Islander	2 (0.3)	1 (0.2)	3 (0.3)
White	473 (80.4)	452 (78.5)	925 (79.5)
Multiple races selected	1 (0.2)	0 (0.0)	1 (0.1)
Ethnicity, No. (%)			
Missing	2	2	4
Hispanic or Latino	14 (2.4)	39 (6.5)	53 (4.5)
Non-Hispanic	577 (97.6)	557 (93.5)	1,134 (95.5)
Preferred notification method (PRO practices only), No. (%)			
Internet	378 (63.7)	NA	378 (63.7)
Automated telephone	215 (36.3)	NA	215 (36.3)
Highest level of school completed or the highest degree received, No. (%)			
Missing	1	2	3
1st-8th grades	10 (1.7)	14 (2.3)	24 (2.0)
9th-11th grades	35 (5.9)	49 (8.2)	84 (7.1)
High-school graduate/GED	173 (29.2)	187 (31.4)	360 (30.3)
Some college	178 (30.1)	142 (23.8)	320 (26.9)
Associates degree	40 (6.8)	61 (10.2)	101 (8.5)
College degree (BA/BS)	91 (15.4)	93 (15.6)	184 (15.5)
Advanced degree (MA/PhD, etc)	65 (11.0)	50 (8.4)	115 (9.7)
Current employment, No. (%)			
Missing	1	2	3
Full-time (40 hours or more each week)	94 (15.9)	89 (14.9)	183 (15.4)
Part-time	72 (12.2)	48 (8.1)	120 (10.1)
Not currently working	426 (72.0)	459 (77.0)	885 (74.5)
Current marital status, No. (%)			
Missing	0	1	1
Single, never married	58 (9.8)	75 (12.6)	133 (11.2)
Married/partnered	385 (64.9)	349 (58.5)	734 (61.7)
Separated/divorced	82 (13.8)	110 (18.4)	192 (16.1)
Widowed	68 (11.5)	63 (10.6)	131 (11.0)
How often do you use a computer, tablet, or smartphone? No. (%)			
Missing	0	1	1
Never	62 (10.5)	81 (13.6)	143 (12.0)
Once a week or less	44 (7.4)	49 (8.2)	93 (7.8)

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TABLE 2. PRO-TECT Patient Demographics by Randomization Arm (continued)

Characteristic	PRO Practices (n = 593)	Control Practices (n = 598)	Total (N = 1,191)
Several times a week	87 (14.7)	83 (13.9)	170 (14.3)
Daily	400 (67.5)	384 (64.3)	784 (65.9)
How often do you use the internet? No. (%)			
Missing	0	1	1
Never	87 (14.7)	114 (19.1)	201 (16.9)
Once a week or less	57 (9.6)	60 (10.1)	117 (9.8)
Several times a week	92 (15.5)	101 (16.9)	193 (16.2)
Daily	357 (60.2)	322 (53.9)	679 (57.1)
How often do you use email? No. (%)			
Missing	0	1	1
Never	114 (19.2)	158 (26.5)	272 (22.9)
Once a week or less	99 (16.7)	112 (18.8)	211 (17.7)
Several times a week	80 (13.5)	78 (13.1)	158 (13.3)
Daily	300 (50.6)	249 (41.7)	549 (46.1)
How difficult is it for you/your family to meet monthly payments on bills? No. (%)			
Missing	1	2	3
Not at all	260 (43.9)	224 (37.6)	484 (40.7)
Not very	106 (17.9)	127 (21.3)	233 (19.6)
Somewhat	161 (27.2)	184 (30.9)	345 (29.0)
Very	49 (8.3)	42 (7.0)	91 (7.7)
Extremely	16 (2.7)	19 (3.2)	35 (2.9)
Patient followed by a palliative care or pain service, No. (%)			
No	542 (91.4)	504 (84.3)	1,046 (87.8)
Yes	51 (8.6)	94 (15.7)	145 (12.2)
Cancer type, No. (%)			
Thoracic (lung, thymus)	118 (19.9)	110 (18.4)	228 (19.1)
Breast	97 (16.4)	80 (13.4)	177 (14.9)
Colorectal, anal	100 (16.9)	132 (22.1)	232 (19.5)
Prostate	33 (5.6)	18 (3.0)	51 (4.3)
Gynecologic (ovarian, cervix, uterine, vaginal)	64 (10.8)	53 (8.9)	117 (9.8)
Myeloma, lymphoma	31 (5.2)	31 (5.2)	62 (5.2)
Melanoma, skin	11 (1.9)	21 (3.5)	32 (2.7)
Genitourinary nonprostate (bladder, kidney, testicular, penile)	36 (6.1)	26 (4.3)	62 (5.2)
Gastroesophageal, small bowel	25 (4.2)	38 (6.4)	63 (5.3)
Pancreas, hepatobiliary	48 (8.1)	49 (8.2)	97 (8.1)
Other (brain, head/neck, thyroid, sarcoma, other soft tissue, unknown primary)	30 (5.1)	40 (6.7)	70 (5.9)
Rural or urban site, No. (%)			
Rural	154 (26.0)	163 (27.3)	317 (26.6)
Urban	439 (74.0)	435 (72.7)	874 (73.4)

Abbreviations: GED, general educational development; NA, not applicable; PRO, patient-reported outcome; SD, standard deviation; TECT, to enhance cancer treatment.

included FT screening. Among patients who participated in the study after March 2019 (ie, were screened for FT at least once if treated at a PRO practice), worsening of financial difficulties was significantly reduced for patients at PRO practices compared with control practices (31.1% PRO *v* 40.1% control; $P = .014$).

To understand how the effect of the intervention may differ by subgroup, we conducted exploratory analyses stratified by race and sex. Among Black patients, there was no difference in worsening of financial difficulties by arm (38% PRO *v* 39% control). However, among White patients, the effect of the intervention was similar to that found for the overall study

TABLE 3. PRO-TECT Patient Demographics by Baseline Financial Difficulty

Characteristic	Financial Difficulties (n = 435)	No Financial Difficulties (n = 753)	Total (n = 1,188)	*P*
Site randomization arm, No. (%)				.1564[a]
PRO practice	205 (47.1)	387 (51.4)	592 (49.8)	
Control practice	230 (52.9)	366 (48.6)	596 (50.2)	
Age, years				<.0001[b]
No.	435	753	1,188	
Mean (SD)	58.90 (10.8)	64.09 (11.3)	62.19 (11.4)	
Median	60.0	65.0	63.0	
Q1-Q3	52.0-66.0	58.0-72.0	55.0-70.0	
Range	28.0-93.0	30.0-89.0	28.0-93.0	
Sex, No. (%)				.8786[a]
Male	180 (41.4)	315 (41.8)	495 (41.7)	
Female	255 (58.6)	438 (58.2)	693 (58.3)	
Race, No. (%)				<.0001[a]
Missing	14	12	26	
Native American or Alaska Native	13 (3.1)	11 (1.5)	24 (2.1)	
Asian	9 (2.1)	9 (1.2)	18 (1.5)	
Black or African American	97 (23.0)	96 (13.0)	193 (16.6)	
Native Hawaiian or Pacific Islander	3 (0.7)	0 (0.0)	3 (0.3)	
White	298 (70.8)	625 (84.3)	923 (79.4)	
Multiple races selected	1 (0.2)	0 (0.0)	1 (0.1)	
Ethnicity, No. (%)				.0052[a]
Missing	1	2	3	
Hispanic or Latino	29 (6.7)	24 (3.2)	53 (4.5)	
Non-Hispanic	405 (93.3)	727 (96.8)	1,132 (95.5)	
Preferred notification method (PRO practices only), No. (%)				.0752[a]
Internet	121 (59.0)	257 (66.4)	378 (63.9)	
Automated telephone	84 (41.0)	130 (33.6)	214 (36.1)	
Highest level of school completed or the highest degree received, No. (%)				.0011[a]
Missing	2	0	2	
1st-8th grades	13 (3.0)	11 (1.5)	24 (2.0)	
9th-11th grades	32 (7.4)	52 (6.9)	84 (7.1)	
High school graduate/GED	134 (30.9)	226 (30.0)	360 (30.4)	
Some college	127 (29.3)	192 (25.5)	319 (26.9)	
Associates degree	47 (10.9)	53 (7.0)	100 (8.4)	
College degree (BA/BS)	47 (10.9)	137 (18.2)	184 (15.5)	
Advanced degree (MA/PhD, etc)	33 (7.6)	82 (10.9)	115 (9.7)	
Current employment, No. (%)				.0617[a]
Missing	2	0	2	
Full-time (40 hours or more each week)	58 (13.4)	125 (16.6)	183 (15.4)	
Part-time	54 (12.5)	66 (8.8)	120 (10.1)	
Not currently working	321 (74.1)	562 (74.6)	883 (74.5)	
Current marital status, No. (%)				<.0001[a]
Single, never married	54 (12.4)	79 (10.5)	133 (11.2)	
Married/partnered	254 (58.4)	478 (63.5)	732 (61.6)	
Separated/divorced	96 (22.1)	96 (12.7)	192 (16.2)	
Widowed	31 (7.1)	100 (13.3)	131 (11.0)	
How often do you use a computer, tablet, or smartphone? No. (%)				.7690[a]
Never	54 (12.4)	89 (11.8)	143 (12.0)	

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TABLE 3. PRO-TECT Patient Demographics by Baseline Financial Difficulty (continued)

Characteristic	Financial Difficulties (n = 435)	No Financial Difficulties (n = 753)	Total (n = 1,188)	*P*
Once a week or less	38 (8.7)	54 (7.2)	92 (7.7)	
Several times a week	60 (13.8)	109 (14.5)	169 (14.2)	
Daily	283 (65.1)	501 (66.5)	784 (66.0)	
How often do you use the internet? No. (%)				.9027[a]
Never	76 (17.5)	125 (16.6)	201 (16.9)	
Once a week or less	42 (9.7)	73 (9.7)	115 (9.7)	
Several times a week	74 (17.0)	119 (15.8)	193 (16.2)	
Daily	243 (55.9)	436 (57.9)	679 (57.2)	
How often do you use email? No. (%)				.1376[a]
Never	109 (25.1)	163 (21.6)	272 (22.9)	
Once a week or less	84 (19.3)	125 (16.6)	209 (17.6)	
Several times a week	60 (13.8)	98 (13.0)	158 (13.3)	
Daily	182 (41.8)	367 (48.7)	549 (46.2)	
How difficult is it for you/your family to meet monthly payments on bills? No. (%)				<.0001[a]
Missing	2	0	2	
Not at all	44 (10.2)	439 (58.3)	483 (40.7)	
Not very	75 (17.3)	157 (20.8)	232 (19.6)	
Somewhat	216 (49.9)	129 (17.1)	345 (29.1)	
Very	72 (16.6)	19 (2.5)	91 (7.7)	
Extremely	26 (6.0)	9 (1.2)	35 (3.0)	
Patient followed by a palliative care or pain service, No. (%)				.2145[a]
No	389 (89.4)	655 (87.0)	1,044 (87.9)	
Yes	46 (10.6)	98 (13.0)	144 (12.1)	
Cancer type group, No. (%)				.0065[a]
Thoracic (lung, thymus)	87 (20.0)	140 (18.6)	227 (19.1)	
Breast	68 (15.6)	109 (14.5)	177 (14.9)	
Colorectal, anal	104 (23.9)	128 (17.0)	232 (19.5)	
Prostate	20 (4.6)	31 (4.1)	51 (4.3)	
Gynecologic (ovarian, cervix, uterine, vaginal)	35 (8.0)	82 (10.9)	117 (9.8)	
Myeloma, lymphoma	20 (4.6)	42 (5.6)	62 (5.2)	
Melanoma, skin	3 (0.7)	28 (3.7)	31 (2.6)	
Genitourinary nonprostate (bladder, kidney, testicular, penile)	16 (3.7)	46 (6.1)	62 (5.2)	
Gastroesophageal, small bowel	26 (6.0)	37 (4.9)	63 (5.3)	
Pancreas, hepatobiliary	34 (7.8)	62 (8.2)	96 (8.1)	
Other (brain, head/neck, thyroid, sarcoma, other soft tissue, unknown primary)	22 (5.1)	48 (6.4)	70 (5.9)	
Current line of systemic cancer treatment, No. (%)				.0221[a]
First line	174 (40.0)	270 (35.9)	444 (37.4)	
Second line	143 (32.9)	223 (29.6)	366 (30.8)	
Third line	52 (12.0)	139 (18.5)	191 (16.1)	
Greater than or equal to fourth line	66 (15.2)	121 (16.1)	187 (15.7)	
Rural or urban site, No. (%)				.0363[a]
Rural	100 (23.0)	215 (28.6)	315 (26.5)	
Urban	335 (77.0)	538 (71.4)	873 (73.5)	

Abbreviations: GED, general educational development; PRO, patient-reported outcome; SD, standard deviation; TECT, to enhance cancer treatment.
[a]Chi-square.
[b]Wilcoxon.

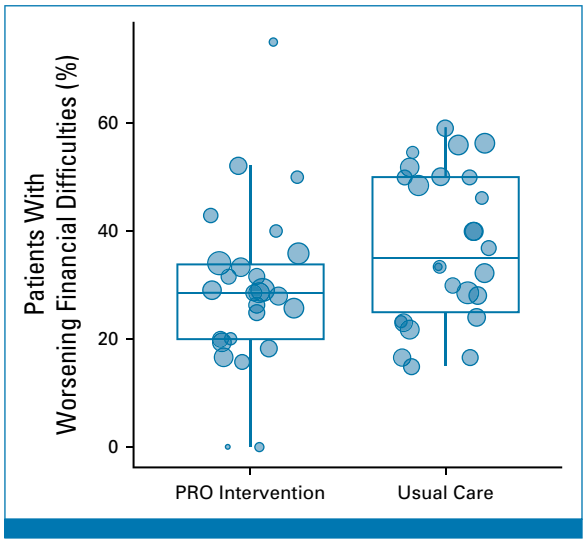

FIG 2. Percentage of patients reporting worsening financial difficulties at each site. The boxplots show the distribution of percent worsening by randomization arm (PRO intervention *v* usual care). For each site, the percentage of patients who experienced worsening financial difficulties was calculated. These values are plotted by study arm. The boxplot shows the spread and median of the data. The overlaid dots are the individual site-level data points, and the size of the dot is relative to the size of the site. Site enrollment ranged from n = 2 to n = 50. PRO, patient-reported outcome.

population (28% PRO *v* 41% control). The intervention effect was similar for women (31% PRO *v* 39% control) and men (28% PRO *v* 39% control).

FT Alerts and Clinician Responses

Of 593 participants at PRO practices, 428 were still on study when FT screening began. Overall, 93.9% (402/428) answered the FT screening question at least once. Most patients (319/402, or 79.4%) never triggered a FT alert; 83/402 (21%) triggered at least one alert. Of 2,969 PRO surveys that included FT screening, only 252 (8.5%) triggered a FT alert; 103 (3.5%) triggered an alert solely for FT (eg, not also including a symptom-related alert).

Documentation about clinic nurse actions in response to alerts was available for 246 (97.6%) of 252 FT alerts and included a telephone call to the patient (131/246; 53.3%), awareness of the issue and no need to call (70/246; 28.5%), and a plan to discuss the issue at the next visit (41/246; 16.7%). Only four alerts (1.6%) were unanswered with no documented plan for response. Documented examples of downstream actions to address FT alerts included referrals to a social worker, a financial navigator, or a patient advocate.

Patient and Clinician Interviews: Perspectives on FT Screening With PROs

A subset of 22 patients at 10 PRO practices were interviewed about their experiences, including their thoughts about the inclusion of FT screening in the PRO surveys. Overall, 19 patients said they were in favor of having the question included. Responses ranged from "I have no problem with that question," to "I think it's a good question to ask because that's something that maybe somebody isn't gonna feel comfortable bringing up to their doctor one-on-one..." One patient noted, "But having it be something that they can just click on and get a phone call might be easier for that person to talk about."

Some patients suggested that additional context should be provided about why the question was being asked and what would be done with the information ("...if people understand why they're being asked that question, that might make 'em answer it more honestly."). Only one patient thought the inclusion of a FT screening question was inappropriate ("That's a question they really don't need to ask, especially when people are more concerned about their health than they are financially."). Two patients did not comment on the appropriateness of asking about FT.

Additionally, 10 nurses at four practices were interviewed. Overall, FT screening was well received and felt to prompt important discussions. "I think that it has been helpful. I think sometimes patients are hesitant to flat out say that they are having financial hardships, and so I think being able to answer that question through a phone or an online thing for some reason doesn't seem quite as invasive or hard for them to answer."

Screening for FT repeatedly was noted to be important in identifying patients who might have been missed if screened only at treatment initiation. "Sometimes...at the beginning of their treatment...everything's fine. Then, all of a sudden—we had a lady a couple weeks ago, a financial hardship. She's never chosen that before, so we can reconnect her to our folks here who can help."

FT screening was also thought to forge a bond between patients and the clinical team. One nurse explained that, although in some cases financial assistance resources may have been exhausted, patients appreciated the ongoing dialogue initiated by screening. "...we have one patient who...clearly feels embarrassed by it, but I think he has appreciated us being able to help find resources. At this point there are no other resources, and he still is reporting it but when I ask him 'bout it he's like I just appreciate you trying to help..."

DISCUSSION

In this multicenter, cluster-randomized trial of approximately 1,200 patients, remote symptom monitoring, including FT screening, protected patients undergoing systemic therapy from experiencing worsening financial difficulties. Overall, 30.2% of patients treated at practices that received the intervention had worsening of financial difficulties compared with 39.0% treated at control practices ($P = .004$), corresponding to a number needed to screen of 11.4 (ie, on average, 11.4 patients would need to be screened for one additional patient to avoid developing new or worsening financial difficulties). On the basis of this relatively low number needed to screen, FT screening appears to be a high-yield intervention.

The finding, in exploratory analyses, that FT screening may not have been effective among Black patients raises concerns that the intervention as implemented may not address FT equitably. This finding is in contrast to what was reported in subgroup analyses of the effect of remote symptom monitoring on HRQoL, as the intervention was associated with improved physical functioning among Black participants treated at PRO sites.[16] Additional research is needed to understand why FT screening may not decrease the development of new or worsening financial difficulties in Black patients. Other race/ethnicity groups should be included in greater numbers to determine if the intervention is effective across groups.

Previous pilot studies of FT interventions have reported that financial navigation programs are feasbile[30] and that patients who receive FT interventions are more likely to apply for and receive financial assistance.[31] To our knowledge, this is the first large-scale randomized controlled trial of a FT screening intervention and the first study to show a significant benefit in mitigating financial difficulties. Despite the lack of a prescribed systematic approach for preventing or alleviating FT in this study, which tested a communication intervention, FT screening as implemented appeared to confer some protection from worsening financial difficulties. Our findings provide support for the future development of robust FT interventions, building upon the use of routine screening to improve patient-clinician communication about FT. The addition of a standardized approach might increase the benefits of a FT screening program.

Previous research suggests that patients welcome the opportunity to discuss financial difficulties with their health care teams but feel reluctant to bring up the topic themselves.[11-13] In our study, most patients who were interviewed felt it was appropriate for the health care team to ask about FT. Furthermore, patients confirmed that being asked about FT explicitly by the health care team enhances patient comfort in talking about a potentially delicate topic and said that providing context for financial hardship screening could improve its effectiveness. Nurses who were interviewed expressed that the inclusion of FT screening helped open lines of communication with patients.

This study has several limitations. First, results for the primary study outcome (OS) were not available at the time of this report. Second, because this study included FT screening as part of a larger intervention, it is possible that routine remote symptom monitoring may have an impact on financial difficulties, even without a specific focus on FT screening. The group considered in these analyses to have received the intervention includes patients who were screened for FT throughout their trial participation and those who were already enrolled and had already completed at least one PRO survey before the addition of FT screening to the intervention. Our ability to distinguish between the different components of the intervention is limited by the small size of the sample who completed all study participation before the addition of FT screening. Third, the use of a single-item measure as the primary outcome may raise concerns about the replicability of our findings. Additional research in this area should use more robust PRO measures to better understand the impact of FT screening on the material, psychological, and behavioral domains of financial hardship.[32] Finally, participating sites did not document the specific procedures implemented to manage FT, and there was likely variability in approaches. Information was not collected on the components of the patient-clinician interactions that led to improvement in financial difficulties versus those that did not. Although beyond the scope of this study, data about different approaches that were taken could inform the development of a more robust intervention that could have an even greater protective effect against financial difficulties. Additional research is needed to understand what kinds of FT interventions are most helpful for patients undergoing systemic therapy for metastatic cancer, and whether these should be tailored to different clinical scenarios and individual patient and family factors. Further research should also aim to identify the optimal timing of intervention delivery to prevent rather than attenuate the severity of FT.

In conclusion, FT screening as part of digital patient monitoring with PROs may reduce the development or worsening of financial difficulties among patients undergoing systemic therapy for metastatic cancer.

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DISCLAIMER

All statements in this publication, including its findings, are solely those of the authors and do not necessarily represent the views of the Patient-Centered Outcomes Research Institute, its Board of Governors, or Methodology Committee.

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Financial Toxicity Monitoring in a Randomized Controlled Trial of Patient-Reported Outcomes During Cancer Treatment (Alliance AFT-39)

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