

# 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

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**QUESTION ASKED:** Do patients with multiple myeloma or lymphoma treated on clinical trials have a different experience on the basis of patient-reported outcomes compared with patients treated outside of clinical trials?

**SUMMARY ANSWER:** There was no difference in the experience of patients treated on clinical trials compared with patients treated outside of clinical trials, on the basis of patient-reported outcome measures (quality of life, quality of care, or financial burden) that were tracked from baseline to 1 year after treatment start.

**WHAT WE DID:** We prospectively evaluated the experience of patients with multiple myeloma or lymphoma who were treated on clinical trials (clinical trial group, n = 35) versus patients treated with standard approaches (nonclinical trial group, n = 88) focusing on quality of life, financial burden of care, and patients' perception of quality of care over a 1-year period.

**WHAT WE FOUND:** There were no significant differences in any of the patient-reported outcomes in patients treated on clinical trials versus those treated outside of clinical trials over the course of 1 year. There was an initial decline in overall quality of life in the first three months across both groups, driven primarily by decline in physical and functional well-being. Quality of life gradually improved in both groups and was above baseline by month 12. Patients reported highest improvement in the functional well-

being subdomain. Patients in both groups reported high satisfaction with the quality of care received, and there were no differences in overall satisfaction, communication with the team, or access to care. At baseline, 16%-19% of patients reported financial burden, which increased to a peak of 33% in the clinical trial group and to 49% in the nontrial group over the course of 1 year. There was no significant difference in financial burden in the two groups overall. Most of the patients reported getting all the care that was deemed medically necessary in both groups. However, a significant proportion of patients reported having to make other kinds of financial sacrifices because of their cancer (clinical trial group: 33% of patients at baseline and 21%-40% over 1 year; nontrial group: 19% at baseline and 25%-36% over 1 year).

**BIAS, CONFOUNDING FACTORS, DRAWBACKS:** Limitations of our study include a smaller cohort size of patients treated on clinical trials and a 50% drop-out rate at one year, which is common in questionnaire-based studies. This study was conducted at an academic center, and our results may not be generalizable to patients treated in community settings.

**REAL-LIFE IMPLICATIONS:** Our findings can serve as a guide to educate patients regarding clinical trial participation and highlight the need to address the significant financial burden experienced by patients with cancer.

## ASSOCIATED CONTENT

### Appendix

### Data Supplement

Author affiliations and disclosures are available with the complete article at [ascopubs.org/journal/op](https://ascopubs.org/journal/op).

Accepted on April 6, 2022 and published at [ascopubs.org/journal/op](https://ascopubs.org/journal/op) on May 17, 2022:

Full-length article available online at DOI <https://doi.org/10.1200/OP.21.00789>

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**PURPOSE** Patients' concerns regarding clinical trial (CT) participation include apprehension about side effects, quality of life (QoL), financial burden, and quality of care.

**METHODS** We prospectively evaluated the experience of patients with multiple myeloma or lymphoma who were treated on CTs (CT group, n = 35) versus patients treated with standard approaches (non-CT group, n = 88) focusing on QoL, financial burden of care, and patients' perception of quality of care over a 1-year period.

**RESULTS** There were no significant differences in any of the patient-reported outcomes in CT versus non-CT groups. We observed an initial decline in overall QoL in the first 3 months across both groups, driven primarily by physical and functional well-being. QoL gradually improved and was above baseline by month 12. Patients reported highest improvement in the functional well-being subdomain. Patients in both groups reported high satisfaction with the quality of care received, and there were no differences in overall satisfaction, communication with team, or access to care. At baseline, 16%-19% of patients reported financial burden, which increased to a peak of 33% in the CT group and to 49% in the non-CT group over the course of 1 year. There was no significant difference in financial burden in the two groups overall. Most of the patients reported getting all the care that was deemed medically necessary in both groups. However, a significant proportion of patients reported having to make other kinds of financial sacrifices because of their cancer (CT group: 33% of patients at baseline and 21%-40% over 1 year; non-CT group: 19% at baseline and 25%-36% over 1 year).

**CONCLUSION** Patients treated on CTs reported comparable QoL and quality of care with the non-CT group. A high proportion of patients reported financial burden over time in both groups. Our findings can serve as a guide to educate patients regarding CT participation and highlight the need to address the significant financial burden experienced by patients with cancer.

JCO Oncol Pract 18:e1320-e1333. © 2022 by American Society of Clinical Oncology

## INTRODUCTION

Clinical trials (CTs) are pivotal for developing novel therapeutics and offer patients access to newer drugs. However, there are many barriers for patient enrollment on CTs, including structural barriers such as trial availability, narrow eligibility criteria, and physician- and patient-related factors.<sup>1</sup> Patient-related factors include psychosocial factors such as concern about impact on quality of life (QoL) because of side effects, lack of trust in the medical establishment, lack of interest, and financial concerns.<sup>2-5</sup>

The impact of experimental treatment on QoL is a significant concern of patients considering participation in a CT,<sup>2,3</sup> with about half the patients listing this as

their chief concern.<sup>2,3</sup> Many CTs now incorporate instruments to assess QoL; however, it is challenging to compare these results with patients not enrolled on that particular trial as such data are not commonly collected in patients treated off study. As a result, there are limited data evaluating QoL among patients enrolled on CTs versus patients treated with standard-of-care approaches. Another concern raised by patients is the financial impact of participating in CTs.<sup>3-5</sup> Beyond the cost of the treatment itself, financial burden may arise because of frequent clinic visits to trial sites, which may be geographically far away. In one study, 28% of patients mentioned concern of the added cost as one of the reasons for not participating in CTs and 12% considered this as the most important factor.<sup>3</sup>

Author affiliations and support information (if applicable) appear at the end of this article.

Accepted on April 6, 2022 and published at [ascopubs.org/journal/op](https://ascopubs.org/journal/op) on May 17, 2022; DOI <https://doi.org/10.1200/OP.21.00789>

Patients' perception of expected care is also an important consideration, with some patients describing a lack of trust in the medical establishment as a reason for not participating in CTs.<sup>2,4</sup>

An evaluation of patients' experience on CTs can provide data for educating patients and other stakeholders on these perceived barriers to enrollment in CTs. In this study, we prospectively evaluated patients with multiple myeloma or lymphoma and their overall experience on trials over the course of 1 year and compared it with patients treated with standard-of-care approaches. Patient experience was evaluated with patient-reported outcomes (PROs) focusing on some of the most important barriers of CT enrollment, specifically QoL, financial burden, and perception of cancer care.

## METHODS

This was a prospective longitudinal study evaluating PROs (QoL, financial burden, and patients' perception of their care) in patients with multiple myeloma or lymphoma enrolled in CTs (CT group) compared with patients treated with standard care (non-CT group). Adult patients with newly diagnosed or relapsed multiple myeloma or lymphoma seen at Mayo Clinic, Rochester, MN, who were about to start a new line of therapy were recruited in two cohorts depending on treatment on a CT or standard of care. This study was approved by the institutional review board. The primary end point was to evaluate longitudinal change in QoL from baseline using the Functional Assessment of Cancer Therapy-General (FACT-G) questionnaire among patients in the two groups. Secondary end points were to evaluate change in subdomains of QoL with FACT-G across the two groups, financial burden over time, and patients' perception of quality of care.

### Study Procedures

After obtaining informed consent, patients were given a self-administered questionnaire at baseline, followed by monthly questionnaires every month for the first 3 months and at 6 and 12 months from the start of therapy. Each patient received a maximum of six questionnaires over a period of 12 months. The FACT-G questions were included in the baseline and month 1, 2, 3, 6, and 12 questionnaire. Financial burden and perception-of-care questions were included in the baseline and month 3, 6, and 12 questionnaire. Criteria for early study exit included disease progression, change in treatment, death, and withdrawal of consent.

### Questionnaire Domains

A copy of the questionnaire is included in the Data Supplement (online only). QoL was assessed with the FACT-G questionnaire,<sup>6</sup> which is a validated tool that has been used extensively in clinical studies of patients with hematologic malignancies.<sup>7</sup> The FACT-G questionnaire consists of 27 questions involving four domains: physical well-being (WB) (seven items, score range 0-28), social WB (seven items, score range 0-28), emotional WB (six items, score range 0-24), and functional WB (seven items, score range 0-28).

Each subscale can also be scored individually, provided that more than 50% of the items are answered. For this study, we scored the overall instrument and subscales if 80% of the items were answered. An overall score can be generated for each patient by summing the subscales (score range 0-104), provided that more than 80% of all items are answered. Financial burden was assessed using a set of 10 questions adapted from the Medical Expenditure Panel Survey.<sup>8</sup> These questions specifically address the impact of cancer treatment on employment status of the patient, the need for patient or family members to borrow money or undertake extra work to pay for cancer treatment, and an inability to pay for medical care or not receiving required treatment because of lack of resources. A composite financial burden score was calculated and assessed on the basis of responding yes to at least one of four of the questions as shown in Appendix Table A2 (online only) that addressed patients having to borrow money to pay for treatment, need to file for bankruptcy to pay for treatment, worry regarding paying large medical bills, or inability to pay their share of cancer care. These four questions were selected by the study team to develop this novel composite score for financial toxicity as they assessed the most critical aspects of financial toxicity. To assess perception of cancer care, we adapted six questions from Consumer Assessment of Healthcare Providers and Systems cancer care survey.<sup>9</sup> These include questions related to communication with the health care team, access to cancer, specialty care, as needed, and overall perception of care. Social desirability bias was minimized by the fact that the questionnaires were self-administered and mailed back (or completed on a web-based interface) by the patient. Patients were also asked about self-reported performance status adapted from Eastern Cooperative Oncology Group (ECOG) performance status<sup>10</sup> and their attitude toward CT participation.

### Statistical Analysis

Individual scores at each time point were generated as described for each questionnaire domain. Longitudinal change in QoL was estimated using mixed models incorporating scores from all available time points. Each time point was evaluated for the difference in scores for that time point versus baseline for both positive and negative changes. Differences were evaluated for both statistical significance and clinically significant changes. Minimal clinically important differences (MCID) for moderate effect size have been well-established as follows: FACT-G total: 9 points, FACT-G physical and functional WB: 3 points, and FACT-G emotional and social WB: 2 points.<sup>11,12</sup> Financial burden questions were scored individually and a composite score was calculated, as described above, which were compared using Fisher's exact tests. Perception-of-care questions were calculated as the proportion of patients with the top choice (top-box scores) for questions 1-5 and as mean score for question 6. Differences across groups or longitudinal differences within the same group were

evaluated using Fisher's exact test for top-box scores and Kruskal-Wallis tests for question 6. A *P* value of  $< .05$  was used to determine statistical significance. All statistical analyses were performed using SAS (v 9.4).

## RESULTS

The study and follow-up were conducted from August 2017 to October 2019. Overall, 123 patients were enrolled, of whom 35 were in the CT group and 88 were in the non-CT group. [Table 1](#) shows the baseline characteristics of patients in the two cohorts. There was no significant difference in patient age (median 63-64 years), sex distribution (43% females in both), or self-reported performance status (ECOG 0-1 54% in the CT group and 44% in the non-CT group) across the two cohorts. The majority of patients in both groups (77%) were newly diagnosed and starting first line of therapy. There was a higher proportion of patients with multiple myeloma in the CT group (77% v 28%). Baseline QoL, including subdomains of QoL, was similar across the two groups, with the exception of higher social well-being in the non-CT group at baseline. Annual household income was similar across the two groups. There was no difference in financial burden at baseline as assessed by a composite end point, with 16% of patients in the CT group reporting baseline financial burden compared with 19% of patients in the non-CT group. Patients' overall perception of cancer care was also identical across the two groups, with a mean overall satisfaction of care of 10 on a scale of 1-10. As shown in [Figure 1](#), there was about a 50% drop-out rate by 1 year across both groups.

Patients were asked about their attitudes about CT participation. Thirty of 88 (34%) patients in the non-CT group reported being offered participation in a CT. Of those, three did not participate and five did not report their participation status. Patients who declined trial participation were asked about reasons for not participating in a CT and could select more than one reason. The reasons reported were as follows: (1) did not meet eligibility criteria one (33%), (2) concern about side effects of treatment 0 (0%), (3) concern about added costs 0 (0%), (4) concern about added tests 0 (0%), (5) concern about experimental treatment 0 (0%), and (6) other concerns two (67%).

### QoL

[Figure 1](#) and [Appendix Table A1](#) (online only) show the change in QoL and subdomains of QoL over 1 year among patients in the two groups. There was an initial drop in QoL in both groups in the first few months compared with their baseline, which was statistically significant in the non-CT group but did not meet the MCID of 9 points. QoL improved after the first 3 months. At 12 months, overall QoL in both groups was higher than baseline (CT: 5.2 points and non-CT 4.5 points higher) although the difference did not meet the MCID for moderate effect size. Importantly, there was no significant difference in QoL between the two groups at any time point. Similar trends were observed for subdomains of

physical and functional well-being. There was an initial drop in physical well-being in both groups in the first 3 months, which gradually improved back to baseline by 1 year. Although the drop was statistically significant versus baseline in the first few months, it did not cross the MCID of 3 points except at month 1 in the CT cohort. There was no difference in physical well-being across the two groups at any time point. Functional well-being followed a similar trajectory with an initial drop in the first 3 months and then gradual improvement. At 12 months, functional well-being was higher than baseline in both groups (CT cohort: 2.3 points, non-CT cohort: 3.1 point, and MCID: 3 points). We did not observe any significant change in emotional well-being, which remained stable across 1 year in both groups. Similarly, there was minimal change in patients' social well-being with a slight decrease from baseline in the non-CT cohort in the first 2 months, but this change was not clinically meaningful. There was no difference in social and emotional well-being between the two groups at any time point.

We also evaluated QoL in the subgroup of patients with multiple myeloma as a similar number of patients with myeloma were treated on a CT ( $n = 27$ ) versus not ( $n = 25$ ; [Appendix Fig A1](#), online only). Results of this subgroup analysis were similar to those of the main analysis, and there was no meaningful difference in QoL or subdomains of QoL in the CT versus non-CT group, with the exception of social well-being at month 3 being significantly better in the CT group.

### Financial Burden

Data regarding financial burden at baseline and at 3, 6, and 12 months are described in [Figure 2](#) and [Table A2](#). At baseline, 16% of patients in the CT group and 19% of patients in the non-CT group reported experiencing financial burden on the basis of answering yes to at least one of four questions regarding having to borrow money for cancer treatment, filing for bankruptcy, inability to pay treatment-related bills, or worry about paying large bills. Financial burden increased over time. In the CT group, financial burden at months 3, 6, and 12 was reported by 30%, 21%, and 33% of patients, respectively. In the non-CT group, financial burden at months 3, 6, and 12 was reported by 49%, 44%, and 41% of patients, respectively. Although the absolute increase in financial burden was higher in the non-CT cohort, this difference was not statistically significant. Although none of the patients reported having to file bankruptcy at any point, the proportion of patients needing to borrow money because of cancer treatment increased over time. At baseline, 6%-9% of patients reported having to borrow money for cancer care, which peaked to 15% in both groups over the course of 1 year. The proportion of patients not being able to cover their share of medical costs was about 13% at baseline in both groups. At 12 months, 25% of patients in the CT cohort and 15% of patients in the non-CT cohort reported not being able to cover their portion of the costs although this

**TABLE 1.** Baseline Characteristics of Patients in the CT Group Versus Non-CT (standard care) Group

Variable	CT Group	Non-CT Group (standard care)	P
	n = 35, No. (%) or Median (range)	n = 88; No. (%) or Median (range)	
Age at consent, years	64 (29-84)	63 (19-84)	.90
Sex, female	15 (43)	38 (43)	.97
ECOG performance status			
0-1	19 (54)	39 (44)	.23
2-4	16 (46)	48 (55)	
Missing	0	1	
Diagnosis			
Lymphoma	8 (23)	63 (72)	<b>&lt; .001</b>
Multiple myeloma	27 (77)	25 (28)	
Disease status			
Newly diagnosed	27 (77)	68 (77)	.99
Relapsed	8 (23)	20 (23)	
Quality of life at baseline			
Overall (score range: 0-108)	78 (44-104)	82 (51-106)	.1
Physical well-being (score range: 0-28)	22 (9-26)	23 (7-28)	.29
Functional well-being (score range: 0-28)	17 (7-27)	18 (4-28)	.22
Social well-being (score range: 0-28)	23 (11-28)	26 (15-28)	<b>.02</b>
Emotional well-being (score range: 0-24)	18 (8-24)	19 (3-24)	.64
Annual household income, USD			
< \$21,000	0 (0)	4 (5)	.77
\$21,000-\$39,999	3 (9)	6 (7)	
\$40,000-\$65,999	11 (31)	20 (23)	
\$66,000-\$105,999	9 (26)	20 (23)	
≥ \$106,000	8 (23)	24 (27)	
Choose not to answer/do not know	4 (11)	14 (16)	
Financial burden at baseline <sup>a</sup>	5 (16)	15 (19)	.73
Overall perception of quality of care at baseline on score of 1-10, mean (range)	10 (5-10)	10 (7-10)	.3

NOTE. P values of 0.05 or less are shown in bold.

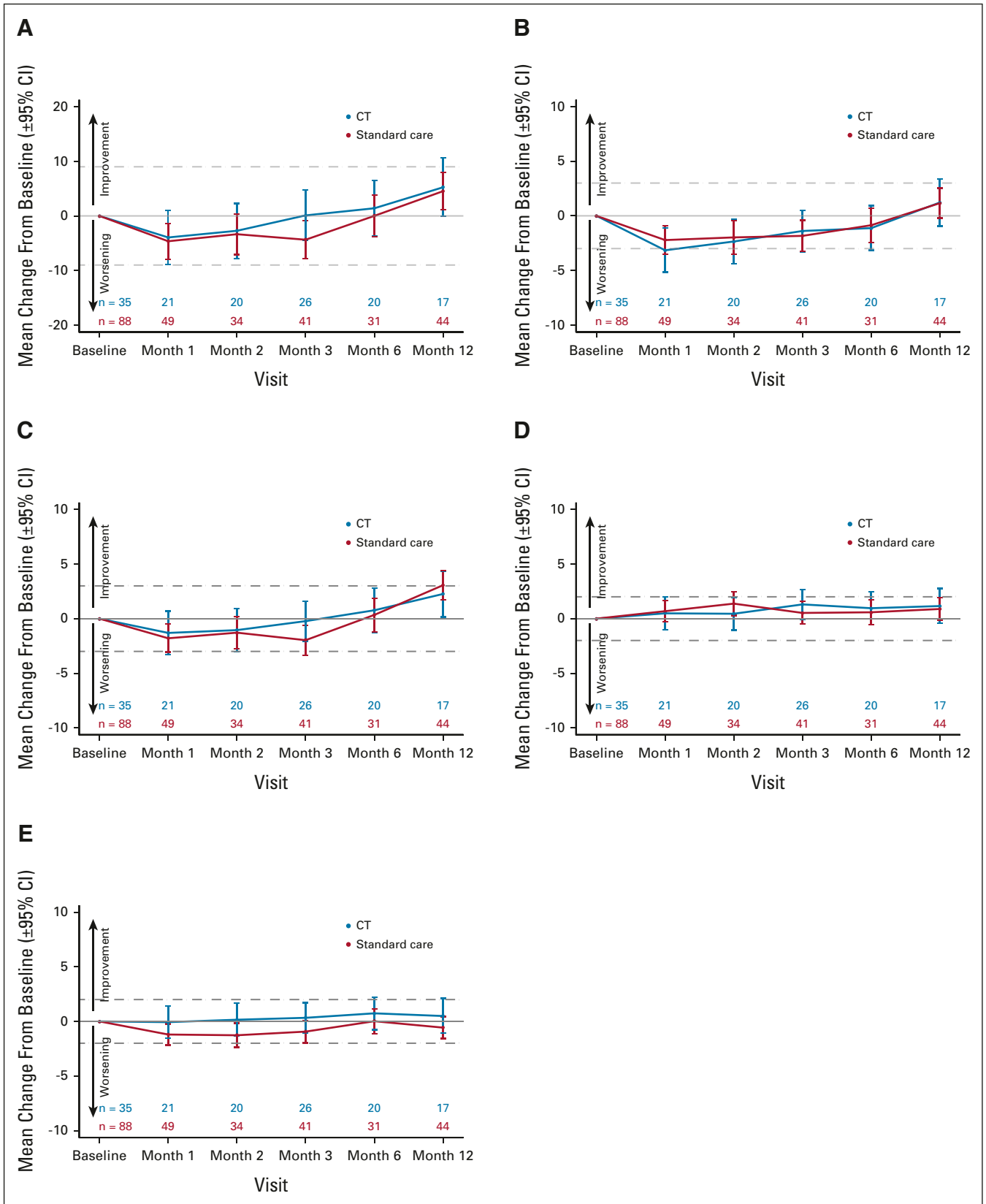
Abbreviations: CT, clinical trial; ECOG, Eastern Cooperative Oncology Group; MEPS, Medical Expenditure Panel Survey; USD, US dollars.

<sup>a</sup>Financial burden estimated as a composite end point on the basis of four questions from the MEPS questionnaire.

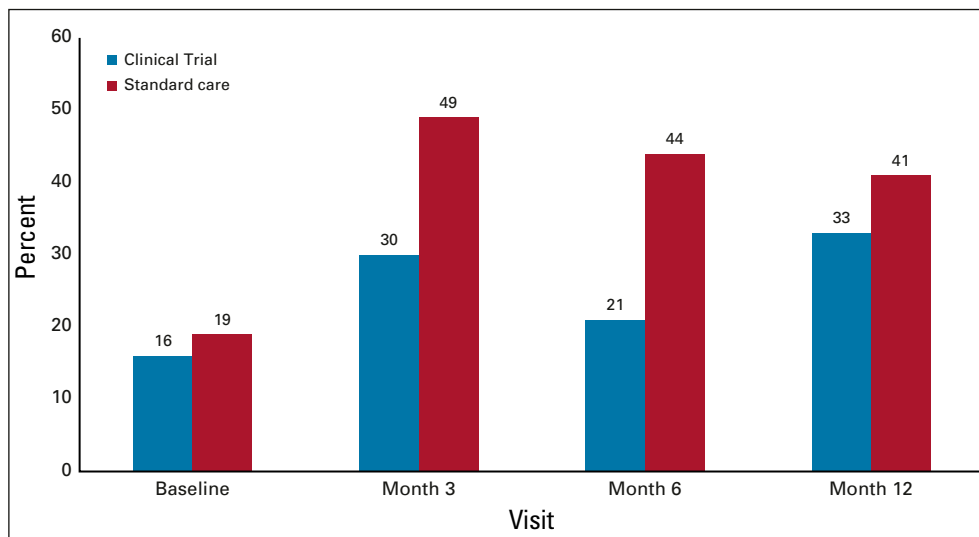
difference was not statistically significant. At baseline, none of the patients reported being worried about paying large medical bills, but this proportion significantly increased over time. In the CT group, 40% of patients expressed this concern at 3 months, 0% at 6 months, and 13% at 12 months. In the non-CT group, the increase was sustained over time, with 49% of patients expressing this concern at 3 months, 52% at 6 months, and 42% at 12 months. The only significant difference among the two cohorts was at 3 months, with the CT group faring better.

It was reassuring to see that most of the patients reported getting all the care that was deemed medically necessary in

both groups. However, a significant proportion of patients reported having to make other kinds of financial sacrifices because of their cancer, with 33% of patients in the CT group reporting this at baseline and 21%-40% over the next 1 year. In the non-CT group, 19% of patients reported having to make other financial sacrifices at baseline and 25%-36% of patients reported this over the course of 1 year. A high proportion of patients reported that they themselves or their caregivers had to take extended time off or make a change in their work hours or work status, with two thirds reporting this at baseline and in the early treatment phase and about half by the end of 1 year.



**FIG 1.** Change in QoL and subdomains of QoL over time compared with baseline in patients with lymphoma/multiple myeloma on the basis of treatment on CTs versus standard care: (A) FACT-G total score, (B) FACT-G physical well-being, (C) FACT-G functional well-being, (D) FACT-G functional well-being, and (E) FACT-G social/family well-being. CT, clinical trial; FACT-G, Functional Assessment of Cancer Therapy-General; QoL, quality of life.



**FIG 2.** Financial burden over time in patients with lymphoma/multiple myeloma on the basis of treatment on CT versus standard care. CT, clinical trial.

### Perception of Care

Perception of care was assessed by the percentage of patients with top-box answers to questions on communication with the medical team, access to care, and overall satisfaction with care as described in Appendix Table A3 (online only). There was no difference across the two groups in communication from the medical team including the medical team listening to patients, explanation of cancer treatment and side effects, and patients getting necessary follow-up care and help when calling the doctor's office across all time points. When asked about overall quality of care received on the basis of interactions with the medical team on a scale of 1-10, the mean scores were above 9 at all time points and were similar across both groups, indicating high overall satisfaction with care. There was no significant change in overall scores over time.

### DISCUSSION

We prospectively evaluated the experience of patients with multiple myeloma or lymphoma treated on a CT versus standard-of-care approaches focusing on QoL, financial burden, and patients' perception of the quality of care. Over a 1-year period, there were no significant differences in these PROs among patients in the CT versus non-CT cohorts.

Around 5% of adult patients with cancer participate in CTs.<sup>1,13</sup> There are several barriers to CT participation, including structural barriers such as availability of trials, narrow eligibility criteria, physician-related barriers such as conscious and unconscious bias in offering a trial to a patient, and the additional time needed to enroll patients on CTs.<sup>1</sup> There are several ongoing efforts to overcome these barriers, which occur before a trial is presented to a patient. Patient-related barriers represent the other side of the

equation although a significant number of patients are willing to participate in CTs. One meta-analysis noted that 50% of patients offered participation in CTs were willing to accept and there was no difference by race or ethnicity.<sup>14</sup> This is similar to what was reported in our study, where about a third of patients in the non-CT group reported having been offered a CT in the past. Of these patients, the majority (73%) stated that they agreed to participate. We do not have data on whether those studies were interventional trials or noninterventional clinical studies. Our population may be skewed as it includes patients who agreed to participate in a research study (the study being reported). Studies have shown that patients decline CT participation for several reasons including concern for side effects and QoL, costs associated with CT participation, concern about trials not personally benefitting them, lack of trust about receiving optimal care, preference for a given treatment, or lack of interest.<sup>2,15,16</sup> Efforts are ongoing to increase patient and community engagement in CTs, especially in historically under-represented communities.<sup>17</sup> Our study provides valuable data, which can address patient concerns regarding CT participation and can be used to educate patients considering CT participation. Although treatment-related side effects that can affect QoL will vary with treatment in each CT, in general, patients treated on CTs experienced comparable QoL as a contemporaneous cohort of patients treated with standard-of-care approaches. Patients' experience of their quality of care, including communication received from the medical team regarding treatment and ability to get all follow-up care, was also similar across patients treated on CTs versus not.

In our study, the overall trajectory of QoL in the CT cohort was similar to the non-CT cohort. We observed an initial decline in overall QoL in the first 3 months across both groups, primarily

driven by a decrease in physical and functional well-being. QoL gradually improved and was better than that at baseline by month 12. Patients reported highest improvement in the functional well-being subdomain. Although there are several published studies evaluating QoL in individual trials or disease cohorts, there are limited data comparing QoL in patients treated on CTs with patients treated with standard-of-care approaches. In a study of older women with breast cancer receiving adjuvant therapy, patients treated on two CTs reported better QoL over time compared with patients receiving standard adjuvant therapy.<sup>18</sup> Our results did not indicate any difference across the two groups, and this could be due to the difference in underlying diagnoses in the two studies and smaller sample size in our study. Overall, the trajectory of QoL noted in our study is similar to that observed in epidemiologic studies of patients with multiple myeloma or lymphoma and CTs in this population. Most studies report a small initial decline in QoL in the first few months followed by gradual improvement, with QoL often improving to better than patients' baseline.<sup>19-22</sup>

Direct and indirect costs associated with CTs are a major barrier to CT participation.<sup>3,23-25</sup> Patients with lower household income are less likely to participate in CTs.<sup>26</sup> We observed that self-reported financial burden at baseline and over a 1-year period was not significantly different among patients treated on CTs versus not. Annual household income was similar across the two groups. However, we cannot account for other socioeconomic factors that may affect a patient's decision to participate in a CT. It is very concerning to note that a significant proportion of patients in our study reported financial burden. At baseline, 16%-19% of patients reported financial burden across the two groups, which increased over time to a peak of 49% in the non-CT group. In comparison, financial burden was reported by a lower proportion of patients in the CT group (peak over 1 year: 33%), but the differences were not significant. These results highlight that patients undergoing cancer therapy experience significant financial burden. Although most patients were able

to get the cancer care they needed, a significant proportion reported having to make other financial sacrifices because of their cancer care. Our findings are similar to previous studies, which show that financial toxicity is experienced by a high proportion of patients undergoing treatment for cancer, including patients treated on CTs.<sup>27,28</sup> Resources such as financial counselors or social workers to help address this burden should be made available to all patients with cancer at diagnosis and subsequent care where possible.

Strengths of our study include prospective evaluation of PROs in patients treated on CTs over the course of 1 year and a contemporaneous comparative cohort of patients treated outside of CTs. We included patients with multiple myeloma or lymphoma, which are hematologic malignancies that are primarily treated in the outpatient setting. Patients in the CT and non-CT cohort had similar baseline characteristics, including demographics, performance status, household income, baseline QoL, and baseline financial burden. Limitations of our study include a smaller cohort size of patients treated on CTs and a 50% drop-out rate at 1 year, which is common in questionnaire-based studies. This study was conducted at an academic center, and our results may not be generalizable to patients treated in community settings. Despite these limitations, our data provide valuable insights into patients' experience on CTs and can serve as a guide to educate patients and caregivers regarding their concerns about QoL and quality of care with CT participation.

In conclusion, we observed that patients treated on CTs reported comparable QoL and quality of care with patients treated outside of CTs. Our study also highlights financial burden experienced by patients with cancer, with a high proportion of patients in both groups reporting financial burden with cancer care.

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## SUPPORT

Supported by the ASCO Conquer Cancer Foundation Young Investigator Award 2017. S.S. was supported by KL2TR003143, KL2 Mentored Career Development Program, Stanford Clinical Translational Science Award Program for part of the study duration. This study was also supported by National Institutes of Health funding, grant U01 CA195568.

## AUTHORS' DISCLOSURES OF POTENTIAL CONFLICTS OF INTEREST

Disclosures provided by the authors are available with this article at DOI <https://doi.org/10.1200/OP.21.00789>.

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**ACKNOWLEDGMENT**

We would like to acknowledge patients and their families who participated in the study, the medical teams treating these patients, and

the research team from Mayo Clinic, including the Lymphoma Epidemiology and Outcomes (LEO) study.

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**AUTHORS' DISCLOSURES OF POTENTIAL CONFLICTS OF INTEREST****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**

The following represents disclosure information provided by authors of this manuscript. All relationships are considered compensated unless otherwise noted. Relationships are self-held unless noted. I = Immediate Family Member, Inst = My Institution. Relationships may not relate to the subject matter of this manuscript. For more information about ASCO's conflict of interest policy, please refer to [www.asco.org/rwc](http://www.asco.org/rwc) or [ascopubs.org/op/authors/author-center](http://ascopubs.org/op/authors/author-center).

Open Payments is a public database containing information reported by companies about payments made to US-licensed physicians ([Open Payments](#)).

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**Patents, Royalties, Other Intellectual Property:** I am a coinventor on a patent application filed by Mayo Clinic and pending on the combination of CRM1 inhibitors with salicylates. Note—simply filed—not even close to being granted (Inst)

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No other potential conflicts of interest were reported.

## APPENDIX

**TABLE A1.** Change in Quality of Life Over Time Compared With Baseline in Patients With Lymphoma/Multiple Myeloma on the Basis of Treatment on CTs Versus Standard Care

Scale	Total Score Range	Clinically Meaningful Change	CT Group Mean (SE)	Non-CT Group Mean (SE)	CT v Non-CT <i>P</i>
FACT-G total score	0-108	9 points <sup>a</sup>			
Month 1			-3.9 (2.5)	-4.6 (1.7) <sup>b</sup>	.82
Month 2			-2.7 (2.6)	-3.4 (1.9)	.85
Month 3			0.1 (2.4)	-4.4 (1.8) <sup>b</sup>	.13
Month 6			1.4 (2.6)	0.0 (2.0)	.67
Month 12			5.2 (2.7)	4.5 (1.7) <sup>b</sup>	.83
FACT-G physical well-being	0-28	3 points <sup>a</sup>			
Month 1			-3.2 (1.0) <sup>b</sup>	-2.2 (0.7) <sup>b</sup>	.45
Month 2			-2.4 (1.0) <sup>b</sup>	-2.0 (0.8) <sup>b</sup>	.77
Month 3			-1.4 (1.0)	-1.8 (0.7) <sup>b</sup>	.71
Month 6			-1.1 (1.0)	-0.9 (0.8)	.84
Month 12			1.2 (1.1)	1.2 (0.7)	.96
FACT-G functional well-being	0-28	3 points <sup>a</sup>			
Month 1			-1.3 (1.0)	-1.8 (0.7) <sup>b</sup>	.68
Month 2			-1.1 (1.0)	-1.3 (0.8)	.85
Month 3			-0.2 (0.9)	-2.0 (0.7) <sup>b</sup>	.13
Month 6			0.8 (1.0)	0.3 (0.8)	.74
Month 12			2.3 (1.1) <sup>b</sup>	3.1 (0.7) <sup>b</sup>	.53
FACT-G emotional well-being	0-24	2 points <sup>a</sup>			
Month 1			0.5 (0.8)	0.7 (0.5)	.83
Month 2			0.4 (0.8)	1.4 (0.6) <sup>b</sup>	.33
Month 3			1.3 (0.7)	0.5 (0.5)	.37
Month 6			1.0 (0.8)	0.6 (0.6)	.7
Month 12			1.2 (0.8)	0.9 (0.5)	.78
FACT-G social/family well-being	0-28	2 points <sup>a</sup>			
Month 1			-0.1 (0.7)	-1.2 (0.5) <sup>b</sup>	.21
Month 2			0.2 (0.8)	-1.3 (0.6) <sup>b</sup>	.13
Month 3			0.3 (0.7)	-0.9 (0.5)	.15
Month 6			0.7 (0.8)	0.0 (0.6)	.45
Month 12			0.5 (0.8)	-0.6 (0.5)	.27

NOTE. All estimates and comparisons are based on mixed modeling. Positive change scores represent improvement; negative change scores represent worsening.

Abbreviations: CT, clinical trial; FACT-G, Functional Assessment of Cancer Therapy-General.

<sup>a</sup>King et al.<sup>11</sup>

<sup>b</sup>Within-group change statistically significantly different from zero ( $P < .05$ ).

**TABLE A2.** Financial Burden Over Time in Patients With Lymphoma/Multiple Myeloma on the Basis of Treatment on CTs Versus Standard Care

Results for Answer of 'Yes' to the Following Questions <sup>a</sup>	Baseline			3 Months		
	CT Group (n = 35), No. (%)	Non-CT Group (n = 88), No. (%)	P	CT Group (n = 28), No. (%)	Non-CT Group (n = 43), No. (%)	P
Have you had to borrow money or go into debt because of your cancer?	2 (6.3)	7 (8.5)	.68	2 (7.7)	6 (15.4)	.36
Did you ever file for bankruptcy because of your cancer?	0 (0)	0 (0)	—	0 (0)	0 (0)	—
Have you ever been unable to cover your share on the cancer visits?	4 (12.9)	10 (12.5)	.95	3 (10.7)	5 (12.8)	.79
Have you worried about having to pay large medical bills?	0 (0.0)	0 (0.0)	—	4 (40.0)	16 (50.0)	.58
<b>Financial burden total score (based on four questions above, at least one answer is yes)</b>	<b>5 (16.1)</b>	<b>15 (19.0)</b>	<b>.73</b>	<b>8 (29.6)</b>	<b>19 (48.7)</b>	<b>.12</b>
If you were working for pay at the time of diagnosis, did you take extended paid time off or made change in hours, duties, or status?	11 (61.1)	35 (71.4)	.27	10 (58.8)	15 (62.5)	.90
Did you or your caregivers take extended paid time off or made changes in hours, duties, or status?	7 (21.9)	38 (45.8)	.02	9 (34.6)	14 (36.8)	.86
Did you or your caregivers take an extra job or work additional hours?	1 (3.1)	6 (7.5)	.39	2 (7.7)	3 (7.7)	1.00
Did you get all of the medical care that your doctor believed was necessary?	33 (97.1)	81 (95.3)	.66	23 (100.0)	12 (100.0)	—
Have you made any other kinds of financial sacrifices because of your cancer?	11 (33.3)	15 (19.2)	.11	6 (21.4)	14 (35.9)	.20
	6 Months			12 Months		
	CT Group (n = 21), No. (%)	Non-CT Group (n = 34), No. (%)	P	CT Group (n = 18), No. (%)	Non-CT Group (n = 48), No. (%)	P
Have you had to borrow money or go into debt because of your cancer?	3 (15.0)	4 (12.5)	.80	2 (12.5)	4 (11.8)	.94
Did you ever file for bankruptcy because of your cancer?	0 (0)	0 (0)	—	0 (0)	0 (0)	—
Have you ever been unable to cover your share on the cancer visits?	2 (10.0)	2 (6.5)	.65	4 (25.0)	5 (14.7)	.38
Have you worried about having to pay large medical bills?	0 (0.0)	12 (52.2)	.01	1 (12.5)	10 (41.7)	.13
<b>Financial burden total score (based on four questions above, at least one answer is yes)</b>	<b>4 (21.1)</b>	<b>14 (43.8)</b>	<b>.10</b>	<b>5 (33.3)</b>	<b>14 (41.2)</b>	<b>.60</b>
If you were working for pay at the time of diagnosis, did you take extended paid time off or made change in hours, duties, or status?	5 (45.5)	11 (52.4)	.01	5 (55.6)	13 (54.2)	.42
Did you or your caregivers take extended paid time off or made changes in hours, duties, or status?	5 (25.0)	7 (21.9)	.79	5 (31.3)	12 (35.3)	.78

(continued on following page)

**TABLE A2.** Financial Burden Over Time in Patients With Lymphoma/Multiple Myeloma on the Basis of Treatment on CTs Versus Standard Care (continued)

	6 Months			12 Months		
	CT Group (n = 21), No. (%)	Non-CT Group (n = 34), No. (%)	<i>P</i>	CT Group (n = 18), No. (%)	Non-CT Group (n = 48), No. (%)	<i>P</i>
Did you or your caregivers take an extra job or work additional hours?	2 (10.0)	2 (6.3)	.62	1 (6.3)	1 (2.9)	.58
Did you get all of the medical care that your doctor believed was necessary?	16 (94.1)	11 (91.7)	.80	14 (100.0)	8 (80.0)	.08
Have you made any other kinds of financial sacrifices because of your cancer?	8 (40.0)	8 (25.0)	.25	5 (31.3)	9 (28.1)	.82

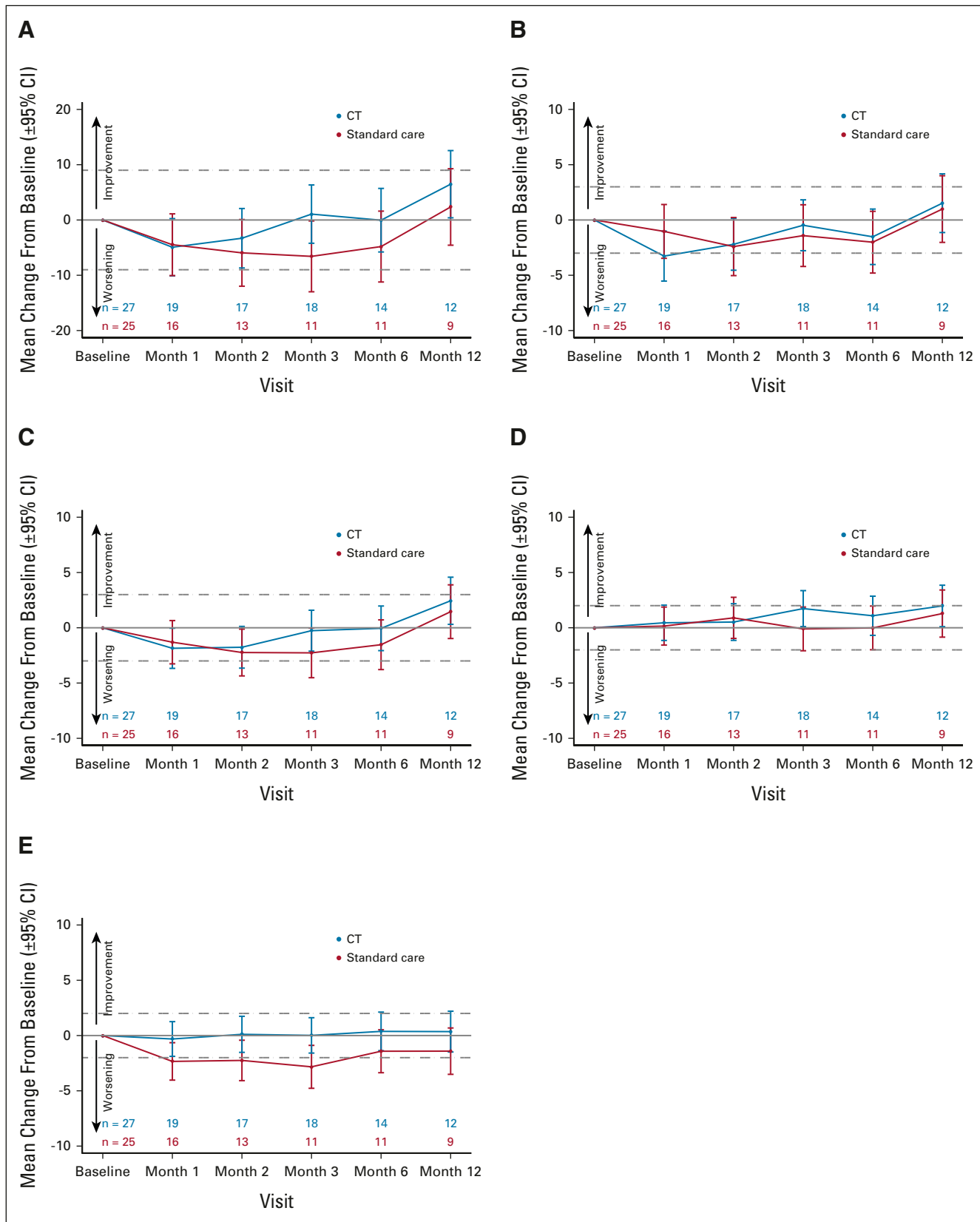
Abbreviation: CT, clinical trial.

<sup>a</sup>The questionnaire had 10 questions. Only nine are shown here as one question was a two-part question. Patients were asked if they were working for pay at the time of diagnosis, and if so, they were asked if they needed to take extended time off or make changes in their work hours/duties/status.

**TABLE A3.** Perception of Clinical Care Over Time in Patients With Lymphoma/Multiple Myeloma in the CT Group (CT) and Non-CT (non-CT) Group

	Baseline			3 Months			6 Months			12 Months		
	CT (n = 35), No. (%)	Non-CT (n = 88), No. (%)	P	CT (n = 28), No. (%)	Non-CT (n = 43), No. (%)	P	CT (n = 21), No. (%)	Non-CT (n = 34), No. (%)	P	CT (n = 18), No. (%)	Non-CT (n = 48), No. (%)	P
Q1: How often did your cancer doctor listen carefully to you and explain things in a way you could understand? (communication)												
Always	24 (83)	51 (86)	.65	22 (85)	34 (87)	.77	13 (77)	20 (71)	.71	11 (69)	26 (79)	.44
Missing	6	29		2	4		4	6		2	15	
Q2: Did your cancer doctor discuss your cancer treatment with you? (communication)												
Always	23 (79)	54 (93)	.06	21 (81)	35 (90)	.30	13 (77)	24 (86)	.43	12 (75)	28 (88)	.27
Missing	6	30		2	4		4	6		2	16	
Q3: Did your cancer doctor discuss side effects of drugs you are receiving for your cancer treatment with you? (communication)												
Always	21 (78)	44 (82)	.69	18 (69)	30 (79)	.38	11 (61)	18 (67)	.70	9 (56)	19 (59)	.84
Missing	8	34		2	5		3	7		2	16	
Q4: How much of a problem, if any, was it to get the follow-up care that you and medical team believe was necessary? (access to care)												
Never	17 (81)	29 (69)	.32	20 (87)	27 (75)	.27	13 (81)	20 (74)	.59	11 (79)	23 (70)	.53
Missing	14	46		5	7		5	7		4	15	
Q5: When you called your doctor office, how often did you get the help needed? (access to care)												
Always	19 (86)	26 (84)	.80	17 (85)	25 (74)	.33	12 (75)	17 (74)	.94	9 (69)	19 (70)	.94
Missing	13	57		8	9		5	11		5	21	
Q6: Based on interactions with your medical team, how would you rate the quality of care you received (on a scale of 1-10)?												
Mean	9.3	9.6	.32	9.5	9.3	.49	9.4	9.3	.45	9.4	9.3	.91

NOTE. Percentage of patients with top-box answers are shown (always for questions 1-3 and 5 and never for question 4).  
Abbreviation: CT, clinical trial.



**FIG A1.** (A) FACT-G total score, (B) FACT-G physical well-being, (C) FACT-G functional well-being, (D) FACT-G functional well-being, and (E) FACT-G social/family well-being. CT, clinical trial; FACT-G, Functional Assessment of Cancer Therapy-General; QoL, quality of life.