Coaching Intervention As a Strategy for Minority Recruitment to Cancer Clinical Trials

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Abstract

Purpose: Lack of trust and rapport with health care providers has been identified in the under-representation of racial/ethnic minorities within clinical trials. Our study used a coach to promote trust among minority patients with advanced cancer.

Patients and Methods: Minority patients with advanced breast, colorectal, lung, or prostate carcinoma were randomly assigned to receive a coach Intervention (CI) or usual care (UC). All patients completed baseline and 6-month telephone interviews to assess demographics, trust in health care providers, attitudes toward clinical trials, and quality of life. Patients randomly assigned to CI were assigned a coach, who made bi-weekly contacts for 6 months to address general issues, progress or development in cancer care, and available resources. Patients randomly assigned to UC received the standard of care, without this intervention. Clinical trial enrollment was assessed.

Results: Over 21 months, we screened 268 patients and enrolled 73 African Americans and two Asian Americans. Patients were randomly assigned to CI (n = 38) or to UC (n = 37). Longitudinal analyses were conducted on 69 patients who completed the 6-month follow-up assessment. Trial enrollment was 16 and 13 patients for the CI and UC groups, respectively. This difference was not significant (P = .351). Higher quality of life (1-point odds ratio on Functional Assessment of Cancer Treatment-General = 1.033, P = .036) and positive attitudes toward trials predicted enrollment. There was no significant difference between these groups in quality of life, attitudes toward clinical trials, perceptions of racism, trust in doctors, or depression.

Conclusions: Quality of life and positive attitude toward trials predicted trial enrollment, regardless of assignment to CI or UC.

Introduction

Clinical trials evaluating new cancer treatments in comparison with existing treatments are essential to increase the cure rate in cancer. Yet, it is estimated that less than 5% of adults with cancer participate in clinical trials, and many populations are under-represented.1,2 In an evaluation of National Cancer Institute (NCI) Clinical Trial Cooperative Group breast, colorectal, lung, and prostate cancer trials from 1996 through 2002, racial/ethnic minorities were assessed. In this evaluation, 85.6%, 9.2%, 1.9%, 0.3%, and 3.1% of the participants were White non-Hispanic, Black, Asian, American Indian/Alaskan Native, or Hispanic, respectively.2

Given that the burden of cancer morbidity and mortality in members of racial/ethnic minorities, is disproportionate to that of Whites, The National Institutes of Health Revitalization Act of 1993 authorized that minorities be appropriately represented in clinical trials. Yet minorities remain under-represented in NCI publically funded treatment trials.2,3 There are several possible barriers for the under-representation of minorities, including (1) patient-related barriers, including mistrust of research and suspicion of experimentation; lack of confidentiality; safety concerns; lack of knowledge; language and cultural differences; and low socioeconomic status with concerns over additional costs related to transportation, child care, and so on; (2) physician-related barriers such as time constraints and competing demands, concerns of patient safety related to age and comorbidities, logistical challenges, lack of knowledge of available trials, and failure to ask patients to participate; and (3) protocol-related barriers including inadequate infrastructure, insufficient and/or untrained personnel, no formal screening processes to identify prospective patients, and restrictive eligibility criteria.4-7

To address patient-related barriers to cancer clinical trial accrual such as mistrust of research, lack of knowledge, and cultural differences, we proposed to evaluate the impact of a coaching intervention on minority recruitment. This coaching intervention was described in a previous study that engaged minority and underserved populations in the St Louis community.8,9 In this study, a trained lay person, the asthma coach, provided nondirective, flexible interpersonal support and encouragement about basic asthma education and management among mothers of low-income, African American, Medicaid-enrolled children who had been hospitalized for asthma in order to reduce rehospitalizations among them.8,9 This randomized study of a coaching intervention (CI) versus usual care (UC) demonstrated a decrease in rehospitalizations for parents randomly assigned to CI. Other studies have shown that coaches have a positive effect on the patient’s knowledge, decision making, and satisfaction regarding treatment decisions.10,11 Accordingly, we proposed evaluating the impact on minority recruitment to cancer clinical trials of a lay coach who would interact with patients in a flexible, nondirective manner. The
coaching activities on patients’ completion of treatment, ratings of quality of life (QOL) and depression, ratings of trust and rapport with health care providers, and attitudes toward clinical trials. We envisioned that this strategy would take steps toward fostering understanding and trust, and ultimately translate into increased accruals to cancer clinical trials.

Patients and Methods

Patient Characteristics

Patients with cancer were recruited through the Siteman Cancer Center (SCC) from February 2004 through November 2005. Patients were identified by their medical, radiation, or surgical oncologist at the time of evaluation for treatment. Patients were ≥18 years of age; English speaking; self-reported as a member of a racial or ethnic minority; diagnosed with advanced breast, colorectal, lung, or prostate carcinoma with an Eastern Cooperative Oncology Group (ECOG) performance status of 0 to 2. The Washington University Human Research Protection Office approved this protocol, and all patients provided written informed consent before study entry.

Data Collection

A staff position, referred to as the “screener,” screened and enrolled patients. Because African Americans are the largest minority population in the St Louis metropolitan area and we felt it important for patients to identify with the individual presenting the study, the screener was African American. After enrollment, the screener conducted telephone interviews with patients to obtain baseline measures. These measures were repeated during a phone call 6 months later. Eight data surveys—Demographics, Trust in Doctors, Characteristics of Medical Care, Attitudes Towards Trials, Social Support Inventory, Center for Epidemiologic Studies Depression Scale, and Quality of Life Surveys (Functional Assessment of Cancer Treatment—General [FACT-G], FACT—Breast [FACT-B], FACT—Colorectal [FACT-C], FACT—Lung [FACT-L], and FACT—Prostate [FACT-P])—were used (Appendix Table A1, online only).

The screener performed all data surveys with computer-assisted telephone interviewing software. Answers were directly entered into the computer and stored in an ASCII file. Data were exported for statistical analysis to address the aims of the study as described above.

Intervention

After completion of the baseline data surveys, patients were randomly assigned to CI or UC. CI was performed by an African American coach, trained and regularly supervised by a medical oncologist (P.M.F.) and psychologist (M.S.W.) to have the understanding of a highly knowledgeable patient with cancer. The purpose of the CI was to provide flexible, individualized, nondirective basic education and support for patients in order to create a context of trust that promoted clinical trial enrollment. Patients assigned to CI were contacted by the coach within 1 week of enrollment and had biweekly contacts for 6 months. Depending on the patient’s preference, contacts with the coach consisted of phone calls or face-to-face visits at the SCC or at the patient’s home to accommodate the patient’s schedule.

The coach provided flexible social support and education addressing (1) general issues in the patient’s life (to establish rapport and show interest in the patient), (2) progress or developments in the patient’s cancer care and treatment, (3) programs and activities at SCC and in the community that might address the patient’s questions and concerns, and (4) promotion of participation in clinical trials (Appendix, online only, for a detailed description of the coach; Data Supplement, for data collection forms used by the coach). The coach integrated education regarding clinical trials, and the need for minority participants in trials, into their general interactions with patients. Strategies of proactive, stage-based counseling describing the pros and cons of trial enrollment were used to inform the patients. Those expressing reluctance to enter a trial were offered help in pursuing enrollment if they were to become interested, whereas those who expressed interest were provided assurance that the coach would help them with entry to and continuation in the trial. Patients were assured that their coach’s contact with them, including the commitment to provide care throughout their cancer treatment, was not in any way contingent on their willingness to enter a trial or continue in a trial they entered. If patients indicated disinterest in interaction with the coach, either initially or during the intervention, the coach attempted to engage them in general conversation, expressed interest in their lives, and reminded them of the coach’s availability during the balance of the 6-month intervention. All patients initially assigned to the coach were counted as part of the CI, regardless of the extent of their contact with the coach. Patients assigned to UC received standard treatment without this intervention.

Statistical Analyses

The end point of clinical trial enrollment was planned to include only enrollments in early-phase interventional clinical trials. However, given the small study sample, enrollment in both interventional (any phase) and noninterventional trials was included. The trial enrollment period included any point from the start of the intervention in February 2004 through February 2007, 10 months after the last participant completed the 6-month follow-up.

Fisher’s exact test was used to assess for simple differences in proportions among categorical variables, including rates of participation in clinical trials across the CI and UC conditions. Binary logistic regression was used to examine continuous predictors of trial enrollment, as well as trial enrollment across CI and UC groups controlling for other clinical factors that may affect trial participation such as age, presence of comorbidities, etc. Fisher’s exact test was used to assess for simple differences in proportions among categorical variables, including rates of participation in clinical trials across the CI and UC conditions. Binary logistic regression was used to examine continuous predictors of trial enrollment, as well as trial enrollment across CI and UC groups controlling for other clinical factors that may affect trial participation such as age, presence of comorbidities, etc.
and cancer type. Data regarding the frequency and nature of coach contacts were evaluated using mixed model analyses of variance. Fisher’s exact test, analysis of covariance, and logistic and linear regressions were used to evaluate the effect of the CI on patients’ adherence with recommended treatments and their ratings of QOL and depression, trust and rapport with health care providers, and attitudes toward clinical trials. Demographic and clinical characteristics were evaluated as potential covariates in analysis of covariance and regression models.

Results
A total of 268 racial/ethnic minority patients with advanced breast, colorectal, lung, and prostate carcinoma were screened from February 2004 through November 2005. A total of 231 patients were eligible; 156 refused, and 75 (73 African Americans and two Asian Americans) were enrolled, with patient follow-up concluding in April 2006 (Tables 1 and 2). Patient characteristics are summarized in Table 3. Several distinctions were noted between the sexes. First, women were younger than men (51.2 years vs 60.0 years, \( P < .003 \)). Second, women with breast cancer were younger than men with prostate cancer (49.1 years vs 65.1 years, \( P < .003 \)). Third, women were more educated than men, as reflected in the number with a high school education or less versus the number with some college education (ie, 19 vs 37 for women, and 14 vs five for men, respectively, \( P < .003 \)).

There were no baseline differences observed between CI (n = 38) and UC (n = 37) groups. Prior trial enrollment was slightly higher in the CI group, but the difference was non-significant (\( P = .150 \)). The number of patients by disease site and assignment to CI versus UC groups was as follows: breast cancer, 19 and 19; colorectal cancer, eight and 10; lung cancer, nine and four; and prostate cancer, two and four, respectively.

Longitudinal data analysis was conducted on 69 patients who completed the 6-month follow-up assessment. Six patients died or were lost to follow-up during the study period and provided no follow-up data. Analysis of trial enrollment during or after the intervention did not differ by group (16 CI vs 13 UC, one-sided \( P = .351 \)). There was no evidence of a selective benefit of the CI among patients with breast, colorectal, lung or prostate cancer, nor was there a difference in adherence to care among patients with the CI versus those with UC. In addition, within the CI group, adherence to care was unrelated to the number of contacts with the coach. However, missed physician appointments among all patients was associated with baseline depression (\( P = .039 \)). Further, there was no apparent effect of the CI on trust in doctors, attitudes toward trials, perceptions of racism, medical mistrust, depression, and generalized distress. There was no effect of the CI on overall QOL as measured by the FACT-G (mean = 79.3, SD = 18.1; and mean = 82.4, SD = 17.69, for CI and UC, respectively, \( P = .473 \)). Finally,

Table 1. Patients Screened and Enrolled

<table>
<thead>
<tr>
<th>Disease Site</th>
<th>Screened</th>
<th>Eligible*</th>
<th>No. Enrolled</th>
<th>Refused†</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No.</td>
<td>% (of total)</td>
<td>No.</td>
<td>% (of total)</td>
</tr>
<tr>
<td>Breast</td>
<td>113</td>
<td>42</td>
<td>94</td>
<td>41</td>
</tr>
<tr>
<td>Colorectal</td>
<td>56</td>
<td>21</td>
<td>51</td>
<td>22</td>
</tr>
<tr>
<td>Lung</td>
<td>62</td>
<td>23</td>
<td>51</td>
<td>22</td>
</tr>
<tr>
<td>Prostate</td>
<td>37</td>
<td>14</td>
<td>35</td>
<td>15</td>
</tr>
<tr>
<td>Total</td>
<td>268</td>
<td>100</td>
<td>231</td>
<td>100</td>
</tr>
</tbody>
</table>

* Thirty-seven patients ineligible because of performance status, wrong stage, multiple malignancies, and non-English speaking.
† Refusal related to cancer site \( P = .051 \). Refusal related to breast versus prostate cancer \( P = .013 \).

Table 2. Reasons for Refusal

| Reason                 | Breast | | | Lung | | | Prostate | |
|------------------------|--------|--------|--------|--------|--------|--------|--------|
|                        | No. | % | No. | % | No. | % | No. | % |
| Not interested         | 14 | 25 | 15 | 45 | 15 | 39 | 8 | 28 |
| None given             | 13 | 23 | 7 | 21 | 8 | 21 | 1 | 3 |
| Overwhelmed/too busy  | 11 | 20 | 3 | 9 | 3 | 8 | 7 | 24 |
| Family decision        | 4 | 7 | 3 | 9 | 4 | 11 | 6 | 21 |
| Insurance concerns     | 5 | 9 | 2 | 6 | 1 | 3 | 2 | 7 |
| Adequate family support| 4 | 7 | 1 | 3 | 2 | 5 | 1 | 3 |
| “Private” person       | 1 | 2 | 2 | 6 | 2 | 5 | 3 | 10 |
| Patient feels too ill  | 2 | 4 | - | - | 2 | 5 | 1 | 3 |
| Other                  | 2 | 4 | - | - | 1 | 3 | - | |
| Total                  | 56 | 33 | 38 | 4 | 29 | |

* One patient elected surgery; two patients moved to another state.
among those in the CI group, there was no evidence of dose-response relationship with the CI on these measures.

The study did find several predictors of enrollment not specific to either group. The FACT-G QOL score was a significant predictor of enrollment to any clinical trial (1-point odds ratio [OR] on FACT-G = 1.033; 95% CI, 1.002 to 1.065; \( P = .036 \)) and specifically, enrollment to a therapeutic clinical trial (1-point OR = 1.088; 95% CI, 1.014 to 1.167; \( P = .019 \)) either during or after the intervention, with higher QOL associated with greater likelihood of trial enrollment. The broad FACT-G effect was also seen in the emotional, social, and functional well-being subscales, but not in the physical well-being subscale.

From the Attitudes Towards Trials survey, two items were significant predictors of decreased likelihood of enrollment in any clinical trial. Patients who reported greater agreement with the statement, “Minorities bear most of the risk of medical research,” were less likely to enroll into any clinical trial (OR = 0.503 for a 1-point change on 5-point agree/disagree scale; 95% CI, 0.272 to 0.933; \( P = .029 \)). Similarly, patients who reported greater agreement with the statement, “The poor bear most of the risk of medical research,” were also less likely to subsequently enroll into any clinical trial (OR = 0.458; 95% CI, 0.253 to 0.829; \( P = .010 \)).

**Discussion**

Lack of trust regarding research among minority patients is a serious barrier to accrual to clinical trials.\(^5,7,12-21\) Media attention to research misconduct, such as the Tuskegee studies, has compounded the difficulty of recruiting minority subjects to clinical trials. Moreover, in the St Louis metropolitan area, mistrust by minority patients has been exacerbated by political issues, such as the closing of primarily minority-serving hospitals over the last 50 years. Nevertheless, in focus groups, African Americans report that despite some reservations or mistrust, they would participate in research if they received adequate information regarding the purpose and logistics of the trial.\(^22\) Further research has suggested that although African Americans may have a greater fear of participation in clinical trials as a result of these barriers, their willingness to participate is no less than Whites.\(^23,24\)

To address the issue of lack of trust, participants in the focus groups described above also identified factors that would increase their interest in participating in clinical research. These included receiving information from multiple sources, having time to process decisions with friends and family, and knowing that the doctor or researcher would be available for later questions.\(^25\) Other studies demonstrated that rapport with staff is associated with retention of research participants. Patients who consider their health care provider competent and compassionate are more likely to participate in research if they received adequate information regarding the purpose and logistics of the trial.\(^26\) Additional studies reported that innovative strategies to foster trust and communication can be effective in spreading awareness, enhancing trust, and reducing barriers to research in minority communities.\(^5,15,19,20,27-31\)

This study sought to determine the effect of a CI on minority enrollment in cancer clinical trials. We analyzed its effect on screening, accrual, and completion of clinical trials, as well as on trust of health care providers and attitudes toward clinical trials. In addition, adherence to and premature dropout from standard cancer treatments were also assessed. On the basis of the outcomes examined, the impact of the CI was shown to be nonsignificant. In addition, there was no evidence of a dose-response effect of the intervention on any of the end points among those who received it. After receipt of a 6-month CI, there was no apparent effect on the attitudes of patients regarding trust in doctors, perceptions of racism, attitudes toward trials, medical mistrust, depression, overall QOL, or generalized distress. There was no evidence of a selective benefit of the coaching intervention among patients with breast,
colorectal, lung, or prostate cancer, nor was there a difference in adherence to care among patients assigned to CI versus those with usual care.

Seventy-five (33%) of 231 eligible patients were accrued and participated in this interventional trial. This produced a modest sample overall. The intervention was short and of low intensity (coach contacts every other week). Furthermore, although the coach was well trained and supervised, the size of the study permitted only a single coach. The general coaching intervention effects were not distinguishable from coach-specific factors (ie, knowledge of cancer treatment, skill level with interviews, and experience with data collection). In addition, the willingness to participate in this trial could have constituted a selection bias for those more likely to participate in another clinical trial. Finally, the known role of physicians on patient enrollment was not assessed.32 Given these limitations, it is not surprising that the study did not demonstrate an effect of the CI on trial accrual. Future studies would benefit from a larger sample size, several different coaches, longer intervention and follow-up, and the use of a more structured approach to informing patients about trials.

This study produced two outcomes among all patients, regardless of group assignment, that are of interest for the clinical care of patients with cancer and for the design of future trials on this topic. First, this study showed that a higher overall QOL was a positive predictor of enrollment onto clinical trials. The reason that higher QOL predicted trial enrollment is not clear, but it may simply reflect greater engagement in care in general. Because patient engagement in care is likely to enhance other outcomes besides trial enrollment, patient QOL should be assessed as a routine part of clinical care. Second, poor adherence to care was associated with baseline depression. This finding may reflect the same effect as described above regarding QOL and engagement, but in negative terms, namely, that poor psychosocial functioning, specifically depression, is related to disengagement—here presenting as poor adherence. Either way, this finding stresses the importance of assessing and treating depression among patients with cancer in order to increase adherence to care as well as trial enrollment.

A similar interventional model, patient navigation, has been used to address barriers to all aspects of the cancer care continuum from prevention, screening, diagnosis, treatment including clinical trials, and survivorship care.33,34 Several trials have used patient navigation to increase enrollment onto clinical trials, with two of the three studies indicating increased enrollment, though there was no control group in either study.35-37 Given the significant shortage of medically trained personnel in oncology,38-40 adequate preparation and training of lay individuals regarding cancer and clinical trials may increase patient accrual to cancer clinical trials, especially with patients identified as reporting low health-related QOL, negative attitudes toward trials, and/or depression. Although the role of the physician as the driver of clinical trial enrollment remains central to the process, training of other individuals may facilitate this process by extending the reach of the physician, and further research should be performed in this area.32-34 Further, a promising randomized study reported on a Web-based tool for clinical trial education before the initial oncology consultation.41 This, too, may extend the reach of the research team.

Although the principal findings of this study were negative, the challenges involved in minority recruitment to clinical trials have been further highlighted. The findings that a higher overall QOL was a positive predictor of enrollment in clinical trials and that adherence to care was inversely associated with baseline depression stress the importance of assessment and intervention regarding the complex needs of patients with cancer.

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Although all authors completed the disclosure declaration, the following author(s) and/or an author’s immediate family member(s) indicated a financial or other interest that is relevant to the subject matter under consideration in this article. Certain relationships marked with a “U” are those for which no compensation was received; those relationships marked with a “C” were compensated. For a detailed description of the disclosure categories, or for more information about ASCO’s conflict of interest policy, please refer to the Author Disclosure Declaration and the Disclosures of Potential Conflicts of Interest section in Information for Contributors.

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Data analysis and interpretation: Paula M. Fracasso, Sherry A. Goodner, Allison N. Creekmore, Seth J. Engel, Brian C. Springer, Katherine J. Mathews, Mark S. Walker
Manuscript writing: All authors

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References


Appendix

The Coach Intervention: Components of the Coach’s Role

After informed consent and administration of baseline measures, patients were randomly assigned to a coach or to usual care. The coach intervention was designed to provide flexible, individualized, nondirective basic education and support for minority cancer patients in order to create a context of trust that promotes early phase trial enrollment. Adapting procedures we developed in our asthma coach project,8,9 the coach initially contacted all individuals randomized to this intervention as soon as it was feasible following randomization, and generally within one week of enrollment. Treating clinicians described the coach and encouraged (but not prescribed) interaction with the coach. Once initiated, the coach contacted the patient on a biweekly basis throughout their cancer treatment. Depending on the patient’s preference, contacts consisted of phone calls, or face-to-face visits at the Siteman Cancer Center (SCC) or the patient’s home. As with all characteristics of the coach intervention, the schedule and mode of contact was fully flexible and accommodated periods when the patient may have needed more frequent contact with or visits from the coach. During these contacts, the coach addressed the following topics: (1) general issues in the patient’s life, family, and so on, which was important to establish rapport, to communicate the coach’s interest in the person, and to frame discussion of other topics with emerging issues that were important to the patient (eg, recent mishap, illness or death of friend or relative); (2) progress or developments in the patients cancer care and treatment; (3) programs and activities that may address patient’s concerns or questions.

The coach was trained to the level of a highly knowledgeable patient with cancer by P.M.F. and M.S.W., who also provided ongoing supervision. The coach received didactic training in oncology from oncology-focused meetings such as the Multidisciplinary Cancer Conference, Breast Conference, Colorectal Conference, Genitourinary Conference, Thoracic Oncology Conference, and Clinical Research Associate Forum. In addition, the nursing and medical staff at the SCC were available for questions on an as-needed basis. The combination of training resources allowed the coach to become familiar with all common aspects of patients’ treatments, side effects, and sequelae, as well as with common approaches to addressing them. This enabled the coach to provide knowledgeable support based on close understanding of the issues patients face and to assist patients in troubleshooting their reactions to care, their disease management tasks, coping with emotional issues, and so on. In particular, the coach addressed the following key areas:

1. Collaborative relationship with health care providers: Adapting common patient empowerment and patient activation tactics, the coach encouraged patients to take an active, collaborative role in their care and, particularly, to ask questions of their providers and initiate contact with the care team in the event of unexpected symptoms and other concerns. The coach served not as a substitute for the judgment or knowledge of the care team, but as a prompt to get patients in touch with the care team when situations dictated. Along these lines, the coach was instructed and supervised to err on the side of recommending contacting the team rather than trying to troubleshoot problems with patients alone.

2. Self-management issues and adherence to cancer treatment: The coach received thorough training in self-management approaches to such issues as adherence, resisting temptations, and planning pleasurable activities and worked with patients in developing concrete plans for building their regimen into their daily lives to maximize the benefits from their cancer care.

3. Referrals to other SCC resources (ie, information center, financial counseling): The coach was part of Patient & Family Education & Support, the overall group of services and professionals of the SCC that included psycho-oncology, the Cancer Information Center, various support and educational groups for patients and their families, arts as healing, pastoral care, liaison psychiatry, and specific programs such as Reach to Recovery. The coach helped patients identify services and programs that matched their preferences and met their needs.

4. Promotion of participation in clinical trials: The coach integrated education regarding clinical trials and the need for minority participants into the more general interactions the coach had with patients. This identified the advantages and disadvantages to the patient of being in a clinical trial, as well as the need for minority participants in trials in order to develop treatments that will be maximally beneficial to other patients from minority groups. In the event patients expressed initial reluctance to enter a trial, the coach, following strategies of proactive stage-based counseling, simply described the pros and cons of being in a trial, offered help in pursuing a clinical trial should the patient decide they would like to enroll, and then left the subject for discussion in a subsequent contact. As patients expressed some interest in entering a trial, the coach would discuss the pros and cons of entry, ask patients what reservations they had, discuss what services or safeguards exist that address those reservations (but, very importantly, not minimize patient’s reservations), and reassure the patient of the coach’s readiness to help the patient through entry into and continuation in the trial. When patients were ready to enter a trial, the coach facilitated patient interaction with clinical trials staff to ensure that entry was smooth and to minimize any stress on the patient. It is important to note that, in none of these interactions, did the coach imply that contact with the patient, including the commitment to provide care throughout the patient’s cancer treatment, was in any way contingent on the patient’s willingness to enter a trial or continuation in a trial they entered.

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Periodic contacts initiated by the coach were planned for discontinuation at 6 months after enrollment. All patients were reminded of the planned discontinuation of coach contacts 2 months in advance, with appropriate attention to feelings of abandonment that some patients might experience. All patients were informed of alternative resources for psychological and emotional support, including psychosocial services offered through SCC and support groups available through the SCC and in the community. Although many patients were in follow-up and doing well medically at this time, some patients were dealing with a recurrence of their disease and were in active treatment. Others were receiving palliative care. In the interest of humanitarian care, and although no follow-up data were collected beyond 6 months after enrollment, patients who were in active treatment or in palliative care at the 6-month point, and who requested continued access to the coach, were allowed ongoing coach contact and support until the conclusion of the study. Before the conclusion of the study, these patients were informed of alternative sources of support as described above, and appropriate referrals were made as needed.

Throughout the intervention, individuals were invited to call their coach as much as they wished. In cases where individuals used this for assistance in dealing with psychological problems that the coach was not equipped to handle, M.S.W. (a clinical psychologist) was available to work with the coach to facilitate a referral to an appropriate professional or to other resources in the community, including Psychosocial Services at SCC and American Cancer Society programs. In keeping with ethical considerations, those who explicitly asked not to be contacted were coded as drop-outs and received no further intervention or evaluation contacts, depending on their stated requests.

### Table A1. Data Surveys

<table>
<thead>
<tr>
<th>Name of Survey</th>
<th>No. of Items</th>
<th>Focus of Assessment</th>
</tr>
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<tbody>
<tr>
<td>Demographics</td>
<td>10</td>
<td>Gender; race; ethnicity; education; marital status; employment; family income, size, and composition</td>
</tr>
<tr>
<td>Trust in Doctors</td>
<td>10</td>
<td>Minority attitudes toward health care providers</td>
</tr>
<tr>
<td>Characteristics of Medical Care</td>
<td></td>
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<tr>
<td>Racism in Medical Care</td>
<td>4</td>
<td>Administered only to African-American participants to assess beliefs regarding the prevalence of racism among health care professionals that influence trust</td>
</tr>
<tr>
<td>Medical Mistrust Index</td>
<td>5</td>
<td>Attitudes of trust toward hospitals and institutions (ie, health care providers)</td>
</tr>
<tr>
<td>Attitudes Towards Trials</td>
<td>6</td>
<td>Attitudes toward clinical trials and willingness to participate in clinical trials</td>
</tr>
<tr>
<td>Social Support Inventory</td>
<td>37</td>
<td>Extent to which patients saw the overall clinical care team as providing nondirective versus directive support*</td>
</tr>
<tr>
<td>Center for Epidemiologic Studies Depression Scale†</td>
<td>20</td>
<td>Depressive symptomatology and decision making</td>
</tr>
<tr>
<td>Quality of life survey: FACT-General‡</td>
<td>27</td>
<td>Multidimensional quality of life with subscales for physical, social/familial, emotional, and functional well-being</td>
</tr>
</tbody>
</table>

Abbreviation: FACT, Functional Assessment of Cancer Therapy.

* Nondirective support focuses on accepting recipients’ choices and feelings without “taking over”; directive support prescribes or takes control of recipient’s tasks, issuing “correct” choices and feelings.

† Included because of the prevalence of depression as comorbidity for patients with cancer and a potential influence in decisions about enrolling in clinical trials.

‡ FACT includes four separate surveys targeted specifically for individual cancer types: FACT-B (breast), FACT-C (colorectal), FACT-L (lung), FACT-P (prostate).