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

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Supplementary Material

Supplement Table A

Data Surveys	# of items	Focus of Assessment
Demographics	10	Gender, race, ethnicity, education, marital status, employment, family income, size and composition
Trust in Doctors (TID)	10	Minority attitudes towards health care providers
Characteristics of Medical Care: Racism in Medical Care	4	Administered only to African-American participants to assess beliefs regarding the prevalence of racism among health care professionals that influence trust
Medical Mistrust Index	5	Attitudes of trust towards hospitals and institutions (i.e. versus health care providers)
Attitudes Towards Trials (ATT)	6	Attitudes towards clinical trials and willingness to participate in clinical trials
Social Support Inventory (SSI)	37	Extent to which patients saw the overall clinical care team as providing Nondirective versus Directive support*.
Center for Epidemiologic Studies Depression Scale (CES-D)**	20	Depressive symptomalogy and decision making
Quality of Life survey: FACT-G (Functional Assessment of Cancer Therapy – General) Includes: four separate surveys targeted specifically for individual cancer types: FACT-B (breast), FACT-C (colorectal), FACT-L (lung), FACT-P (prostate)	27	Multidimensional quality of life with subscales for physical, social/familial, emotional, and functional well-being.

*Nondirective support focuses on accepting recipients' choices and feelings without "taking over" versus Directive support, which prescribes or takes control of recipient's tasks, issuing "correct" choices and feelings.

** Included because of the prevalence of depression as co-morbidity for cancer patients and a potential influence in decisions about enrolling in clinical trials.

Supplement B The Coach Intervention – Components of the Coach's Role

Following informed consent and administration of baseline measures, patients were randomized to be assigned a Coach or to Usual Care. The Coach intervention was designed to provide flexible, individualized, non-directive 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, etc., 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 (e.g., 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. The Coach was trained and supervised by Drs. Fracasso and Walker. 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 and 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 trouble shooting their reactions to their care, their disease management tasks, coping with emotional issues, etc. 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, etc. 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 adherence, resisting temptations, planning pleasurable activities, etc. 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 Siteman Cancer Center resources (i.e. information center, financial counseling): The Coach was part of the overall group of services and professionals of the Siteman Cancer Center named Patient & Family Education & Support 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 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 reassured 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.

Periodic contacts initiated by the Coach were planned for discontinuation at 6 months following enrollment. All patients were reminded of the planned discontinuation of coach contacts two 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 this point, and who requested continued access to the coach, were allowed ongoing Coach contact and support until the conclusion of the study. Prior to 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 utilized this for assistance in dealing with psychological problems that the Coach was not equipped to handle, Dr. Walker (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.

Supplement C: Coaching Intervention – Case Report Forms for Coach Contacts

Coaching Intervention

Initials: (F M L) _____ **Patient ID #:** _____

Locale preference of patient for interviews:

Telephone _____

Siteman Cancer Center _____

Home _____

_____

_____

Contacts (coach initiated contacts should be on a bi-weekly schedule)

Scheduled Contact Date	Actual Contact Date	Problems Identified (Key words - See attached forms for details)	Home	MD office	Phone	Other	Duration	Continue Contacts
								Yes / No
								Yes / No
								Yes / No
								Yes / No
								Yes / No
								Yes / No
								Yes / No
								Yes / No
								Yes / No
								Yes / No
								Yes / No
								Yes / No
								Yes / No
								Yes / No
								Yes / No

Coaching Intervention Telephone Sheet: A

(page1)

Initials: (F M L) _____ **Patient ID #:** _____

Date of Contact: _____

Coding discussion of topics (Do not use previous coding 1 – 7)

Discussed (even if very briefly) = 8	Applicable but not discussed = 9	Not applicable to this patient at this time = 10

Diagnostic and Treatment Planning Phase: *Partnering with Oncologists – Discussion and Dialogue*	**Coding**
1. Dialogue Indicates belief of partnership between physician and patient	
2. Indicates understanding of treatment plan	
3. Indicates agreement of treatment plan	
4. Discusses concerns of physical symptoms with doctor or nurse	
5. Writes down questions/answers to ask of doctor or nurse	

Treatment Phase: *Adherence to recommended adjuvant or neoadjuvant treatment* Is able to state/identify . . . (use for #s 1-5)	
1. Treatment plan (adjuvant/neoadjuvant)	
2. Rationale for recommended treatment	
3. Potential consequences of non-adherence	
4. Potential barriers to adherence (e.g., transportation, child care etc)	
5. Ways of coping with barriers to adherence	
6. Develops plan to implement means of coping with barriers to adherence	
7. Attends agreed upon chemotherapy	
8. Attends agreed upon radiation therapy	

Follow-up and Survivorship Phase: *Development of concrete health behavior adherence plan* Accepts coach's help in making plan to adhere to . . .	
1. Recommended dietary patterns	
2. Recommended physical activity	
3. Recommended strategies for stress management	
4. Stop smoking	

All Phases, including Disease Progression and End of Life	
Soliciting support from family or friends	
1. Asks friends/family to accompany to appointment	
2. Asks friends/family for assistance with tasks	
3. Talks with friends/family about his/her feelings about the illness	
4. Talks with friends/family about their feelings about the patient's illness	
Identifying and Utilizing agreed upon resources	
1. Agrees to be shown Siteman Cancer Information Center	
2. If appropriate, agrees to referral to Psycho-oncology services	
3. If appropriate, agrees to referral to support group	
Having substantive contact with Coach	
1. If needed, initiates contact with coach	
2. Talks with coach about having cancer	
3. Talks with coach about non-cancer issues	
Willingness to learn about available clinical trials	
1. Agrees for coach to introduce possibility of participation in clinical trials	
2. Asks questions of coach regarding clinical trials (studies)	
3. Accepts coach's assistance in investigating appropriate clinical trials	

Coaching Intervention Telephone Sheet: A

(page 2)

Initials: (F M L) _____ **Patient ID #:** _____

Date of Contact: _____

Intruding Events

_____ **Phone disconnected**

_____ **Request resources**

_____ **Need housing referral**

_____ **Parent illness**

_____ **Lost Medicaid**

_____ **Hot lined**

_____ **Gave up custody**

_____ **New job**

_____ **Need emergency housing**

_____ **Death in family**

_____ **Moved**

_____ **Unemployed**

_____ **No insurance**

_____ **Need Christmas assistance**

_____ **Pregnant**

_____ **No phone**

_____ **Homeless**

_____ **Address unknown**

_____ **Off welfare**

_____ **Other**

_____

_____

PERSONAL PROBLEMS:

_____ **Seems depressed**

_____ **Seems lonely**

_____ **Other**

_____

_____

Coaching Intervention Telephone Sheet: B

Initials: (F M L) _____ **Patient ID #:** _____
Date of Contact: _____

Problem: