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A Qualitative Descriptive Analysis Of The Experiences Of Blacks In Cancer Clinical Trials

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Abstract

Participation in cancer clinical trials (CCTs) is an effective means of reducing cancer disparities among Black cancer patients because they provide an opportunity to receive high quality health care from leading healthcare providers and researchers. Yet, Black cancer patients remain underrepresented in CCTs. The purpose of this study was to understand the patient, family member, physician, and protocol factors that influence Black cancer patients to participate and to remain in CCTs and the day-to-day experiences of Black cancer patients as they navigate their way through the clinical trial process. Albrecht's model of treatment decision making was used as a theoretical guide. A multimethod approach was used and included a qualitative descriptive design with semi-structured face-to-face interviews with 21 Black cancer patients involved in CCTs and a descriptive statistical analysis of the sample's sociodemographics and a quantitative measure of symptom burden (the Memorial Symptom Assessment Scale-Short Form). Participants reported mild levels of symptom burden based on the mean values of the assessment scale. Elements of real-time data capture were also used to facilitate collection of four semi-structured cell phone participant interviews over a two month period, in order to understand patient-participants' everyday experiences in CCTs. The majority of participants self-identified as Black-African American (80%) and attended college or had a college degree (55%). A majority had comorbid conditions (70%) and 40% were diagnosed with Stage 4 cancer. The findings suggest that patient, family member, physician, and protocol factors in Albrecht's model are important in decision making related to cancer clinical trial participation and retention, but in varying degrees. Patient-participants identified getting a second opinion, helping themselves, and helping others as important factors to their decisions to seek treatment at the Cancer Center and to enroll in CCTs. The support of family members was identified primarily in CCT retention, and the qualities of the cancer physician motivated participant enrollment and retention. These qualities included trust, attentiveness, timely referrals, and willingness to provide detailed explanations of treatment options. Protocol features, such as provision of targeted therapy, randomization, and additional diagnostic surveillance, attracted participants to enroll in such trials. Finally, elements of real-time data capture highlighted patient-participants' everyday qualitative experiences, that included interactions with their clinical care team, events surrounding their outpatient cancer clinical trial appointments, and information shared at their appointments; and, the symptom burden issues that arose as patient-participants progressed in their trials. Patient-participants provided vivid descriptions of their CCT treatment, expectations and events surrounding CCT participation, their symptom experience, personal thoughts and feelings of the effect of CCT participation on their daily lives, and their relationships with family members, the CCT Team, and others during CCT participation.

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IN CANCER CLINICAL TRIALS

Terease S. Waite

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A QUALITATIVE DESCRIPTIVE ANALYSIS OF THE EXPERIENCES OF BLACKS
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DEDICATION

I dedicate this work to Anthony, Brandon, Connor, and Duncan, who have endured this long journey at the University of Pennsylvania School of Nursing with me for the last 12 years—through Bridges to the Doctorate, Bioethics classes in the evening, and the last seven years of doctoral studies (I love you all so very much);

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ABSTRACT

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Terease S. Waite

Connie M. Ulrich

Participation in cancer clinical trials (CCTs) is an effective means of reducing cancer disparities among Black cancer patients because they provide an opportunity to receive high quality health care from leading healthcare providers and researchers. Yet, Black cancer patients remain underrepresented in CCTs. The purpose of this study was to understand the patient, family member, physician, and protocol factors that influence Black cancer patients to participate and to remain in CCTs and the day-to-day experiences of Black cancer patients as they navigate their way through the clinical trial process. Albrecht's model of treatment decision making was used as a theoretical guide. A multimethod approach was used and included a qualitative descriptive design with semi-structured face-to-face interviews with 21 Black cancer patients involved in CCTs and a descriptive statistical analysis of the sample's sociodemographics and a quantitative measure of symptom burden (the Memorial Symptom Assessment Scale-Short Form). Participants reported mild levels of symptom burden based on the mean values of the assessment scale. Elements of real-time data capture were also used to facilitate collection of four semi-structured cell phone participant interviews over a two month period, in order to understand patient-participants' everyday experiences in CCTs. The majority of participants self-identified as Black-African American (80%) and attended

college or had a college degree (55%). A majority had comorbid conditions (70%) and 40% were diagnosed with Stage 4 cancer. The findings suggest that patient, family member, physician, and protocol factors in Albrecht's model are important in decision making related to cancer clinical trial participation and retention, but in varying degrees. Patient-participants identified getting a second opinion, helping themselves, and helping others as important factors to their decisions to seek treatment at the Cancer Center and to enroll in CCTs. The support of family members was identified primarily in CCT retention, and the qualities of the cancer physician motivated participant enrollment and retention. These qualities included trust, attentiveness, timely referrals, and willingness to provide detailed explanations of treatment options. Protocol features, such as provision of targeted therapy, randomization, and additional diagnostic surveillance, attracted participants to enroll in such trials. Finally, elements of real-time data capture highlighted patient-participants' everyday qualitative experiences, that included interactions with their clinical care team, events surrounding their outpatient cancer clinical trial appointments, and information shared at their appointments; and, the symptom burden issues that arose as patient-participants progressed in their trials. Patient-participants provided vivid descriptions of their CCT treatment, expectations and events surrounding CCT participation, their symptom experience, personal thoughts and feelings of the effect of CCT participation on their daily lives, and their relationships with family members, the CCT Team, and others during CCT participation.

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CHAPTER 1: INTRODUCTION

The Problem

Introduction

In 2016, approximately 70,000 Blacks are expected to die from cancer (American Cancer Society, 2016). While Blacks comprise 12% of the U.S. population, they have the highest incidence and mortality rates for more types of cancer than any other population in the U.S. (American Cancer Society, 2016). This group also has the shortest cancer survival from most cancer types (American Cancer Society, 2016). Unfortunately, stark differences continue to exist between Whites and Blacks in cancer incidence, prevalence, mortality, burden, and survivorship (DeSantis et al., 2016). Researchers acknowledge that Blacks suffer cancer health disparities; however, they differ on how these cancer health disparities can be eliminated (Flowers et al., 2007; Halpern & Holden, 2012; Howerton et al., 2007; Kauh, Brawley, & Berger, 2007; Nurgalieva et al., 2013).

Although cancer mortality rates for Blacks and Whites actually declined between 2008 and 2012, Black men continue to have higher incidence rates and mortality rates than White men for all cancers sites (American Cancer Society, 2016; DeSantis et al., 2016). In fact, Black men have higher mortality rates for gastrointestinal cancers (i.e., colorectal, pancreas, gastric, and liver), oral cancers (i.e., oral cavity, larynx, and pharynx), prostate cancer, multiple myeloma, and lung cancer (American Cancer Society, 2016; DeSantis et al. 2016). During this same time frame, Black women had higher mortality rates than White women for gastrointestinal cancers (i.e., colorectal, gastric,

liver, and pancreas), gynecologic cancers (i.e., uterine corpus, and uterine cervix), multiple myeloma, breast, esophagus, and urinary/bladder (American Cancer Society, 2016; DeSantis et al. 2016). For the same years, Black women also had higher incidence rates for selected types of cancer: Kaposi's sarcoma, multiple myeloma, gastrointestinal (e.g., stomach, pancreas, liver, and colorectal), uterine cervix, esophagus, kidney, and breast (American Cancer Society, 2016; DeSantis et al., 2016). This dismal picture of cancer in the Black population statistics calls for further research that addresses the continuing cancer burden borne by this population group and ways to mitigate this burden.

Cancer Health Disparities in the Black Population

The bases for the existence of cancer health disparities among Blacks are multifactorial and include commonly reported factors such as reduced access to healthcare, lower socioeconomic status (SES), lack of access to quality healthcare, differences in treatment modalities, distrust of the healthcare system, stigma associated with cancer and death, differences in individual treatment decision-making, and refusal of standard therapeutic treatment (Brawley, 2007; Fedewa et al. 2010; Flowers et al., 2007; Howerton et al., 2007; Rizzo et al., 2009; Ward et al. 2008). However, recent research has articulated other factors which impact cancer disparities among Black cancer patients, such as delay in treatment and advanced cancer stage at presentation for treatment—both of which may make standard cancer treatment inadequate and favor the use of novel treatment available in CCTs to promote positive treatment outcomes (Halpern & Holden, 2012; Nurgalieva et al., 2013).

The benefits of cancer clinical trial (CCT) participation are well-known. Many CCTs significantly extend the overall survival of cancer patients and offer considerable clinical benefit (Attal et al. 2012; Brufsky, et al., 2012; O’Shaughnessy et al., 2011). CCT participation offers cutting edge advances in cancer prevention and therapy, improves therapeutic outcomes, promotes progress in the treatment of cancer, and predicts over-all and cancer-specific survival (Baquet, Commiskey, Mullins, & Mishra 2006; Chow et al., 2013; Held, Wedel, & Wilhelmssen, 2003). Further, certain cancers (e.g., triple negative breast cancer which has a poor response rate to standard treatment) affect Blacks in disproportionately higher rates, such that therapeutic CCTs are the only option to promote positive therapeutic outcomes and improve survival (Carey et al., 2006; Santana-Davila & Perez, 2010). More significantly, research indicates that participation in a CCT, in fact, does improve survival and positive outcomes for lung, breast, and colo-rectal cancer—three of the four cancers with the highest incidence and mortality rates among Black cancer patients (Chow et al., 2013; Howlader et al., 2012). Blacks’ participation in CCTs is exceptionally poor when compared to their cancer incidence, mortality, and burden. In this way, lack of CCT participation can translate into survival disparities for Black cancer patients.

Rates of Research Participation in Cancer Research

Of the approximately 3-5% of adults with cancer who participate in CCTs, Whites represent the majority of participants at 85.6% and Blacks account for less than 9.2% (Murthy, Krumholz, Ellison, & Gross, 2004). Under-representation of Blacks in CCTs continues, despite efforts by the federal government in 1993 and amended in 2001

to establish guidelines mandating greater numbers of under-represented minority populations in NIH supported clinical trial research (Brawley, 2004; Hayat et al., 2007; Howlader et al., 2012). The 1993 Guidelines required inclusion of minorities (as well as women) in research supported by the National Institutes of Health (NIH) and mandated that the NIH must ensure (a) inclusion of minorities in all human research projects, (b) inclusion of minorities/subpopulations of minorities in all phase III clinical trials in order to accomplish valid analyses of intervention effect differences, (c) preclusion of cost as a reason to exclude minorities/subpopulations of minorities, and (d) establishment of outreach efforts to encourage recruitment of minorities/subpopulations of minorities in clinical research studies. (59 Federal Register Sections 11146-11151, 1994; 42 U.S. Code section 289a-2; National Institutes of Health, 2001).

Researchers continue to struggle to meet the NIH's mandate. In a recent review of 304 peer-reviewed articles concerning 227 phase three cancer treatment and 27 prevention trials with more than 100 participants, Kwiatkowski et al. (2013) reported that diversity of participants in therapeutic CCTs has improved only slightly, since publication of the 1993 Guidelines. However, increases in Asian and Hispanic participants were countered by decreases in Black participants. For the years 2001-2010 and 1990-2000, Black participation in treatment CCTs decreased to 6.1% from 10.5%, respectively (Kwiatkowski et al., 2013). In contrast, White participants continued to represent more than 80% of participants in cancer trials.

Recruitment Methods

Researchers have not agreed on a method to achieve the goal of improving participation of Black cancer patients in CCTs. Frequently utilized methods include instituting patient navigation, addressing organizational and provider-mediated barriers, and initiating community-based participatory research (Adams et al., 2014; Anwuri et al., 2013; Blakeney et al., 2014; Ghebre et al., 2014, Holmes et al., 2012; Wujcik & Wolff, 2010). All of these CCT recruitment methods seek to engage Black cancer patients by forging linkages between the Black cancer patient and the healthcare institution.

Changing the research infrastructure and organizational culture at the provider and institutional levels has been implemented by some cancer centers as a means of increasing Black CCT enrollment (Anwuri et al., 2013; Joseph, & Dohan, 2009b). This approach addresses perceived or potential institutional barriers to CCT recruitment and participation, such as provider coordination of patients involved in research studies, institutional standards and accrual targets for minority recruitment, and efficient monitoring and assessment of minority CCT participation and retention (Anwuri et al., 2013, Joseph, & Dohan, 2009b). Inherent in this approach is the necessity of administrative leadership and oncology physicians to commit to increasing Black accrual to CCTs, to set enrollment benchmarks, and to accept changes to established clinical practices (Anwuri et al., 2013). However well-intended, a limitation of these approaches is their focus on increasing the quota of enrolled Blacks in CCTs, instead of providing Black cancer patients with the necessary resources and time to process the requisite

information to make informed decisions for themselves and for their families (Denicoff et al., 2013).

Utilization of community-based participatory research (CBPR) as a methodological approach to address the informational needs of Black cancer patients involves the members of a Black community in the planning, development, implementation, and evaluation of CCT recruitment strategies and CCTs (Adams et al., 2014; Blakeney et al., 2014; Seifer, Michaels, & Collins, 2010). CBPR involves the formation of genuine partnerships between researchers and community members, as represented by shared decision-making on the type and dimensions of the research undertaken in the community, sharing of data produced from the research, and involvement of community members in the research process (Greiner et al, 2014). However, CBPR is most useful if Black cancer patients are represented among the key community leaders/informants and are integral members of the stakeholder community groups, the research planning committees, and the research team.

Finally, patient navigation has been employed increasingly and successfully as a means of providing access and identifying barriers to cancer care and cancer screening for Blacks (Freund et al., 2014; Halbert et al., 2014; Jandorf et al., 2013; Sly et al., 2013). Recently, patient navigation has been employed to ascertain and to surmount the barriers to CCT accrual and continued enrollment among Black cancer patients (Holmes et al., 2012; Wujcik & Wolff, 2010). Patient navigators are utilized as vital connections between the healthcare institution, the community, and the Black cancer patient. They interact more directly with prospective and actual CCT participants by providing

information and access to CCTs, enrolling community members onto appropriate CCTs, and monitoring research participants as they proceed along the CCT trajectory (Fouad, et al., 2014; Holmes et al. 2012; Schapira & Schutt, 2011).

Addressing organizational and provider-mediated barriers, CPBR, and patient navigation seek to ameliorate ineffectual CCT accrual processes by influencing the cancer health behaviors, health beliefs, and health decision-making of the Black cancer patient at institutional, community, and interpersonal levels. However, central to all of these recruitment interventions are Black cancer patients. Only they can discuss their reasons for accruing to, continuing to participate in, and withdrawing from CCTs, as well as address the factors which figure most prominently in their on-going treatment decision-making process. In addition, only they can describe the dynamic processes of symptom burden prior to and incident to CCT participation and establishing and maintaining relationships with members of the CCT team. Very few studies have utilized Black cancer patients as the sole members of a study sample or requested their individual perspectives on CCT participation. This study is one of the first studies specifically to enroll Black cancer patients actively involved in a cancer clinical trial, in order to determine the factors influencing their enrollment and continued participation. This study also explores and captures the daily experiences of Black CCT participants.

CCT participation encompasses much more than enrollment; it is the totality of each participant's day-to-day experience. During the course of CCT treatment, participants in CCTs contend with a plethora of daily challenges which may not be adequately captured by even the most well-crafted, valid, and reliable research tools.

Daily challenges such as differential access to CCT trial treatment based upon insurance, caregiving responsibilities for parents and children, the deleterious and life-changing effects of symptom burden, dwindling financial resources, and receipt of CCT treatment while homeless cannot be encompassed in one study by surveys and questionnaires without obscuring the ardent, rarely heard voice of each Black cancer patient. The relevant literature lacks a focused consideration of the experiences of Black cancer patients during the CCT process and the personal decisional factors which motivate Black cancer patients to accrue and to remain in CCTs. There is emerging literature regarding CCT decision-making from the perspective of the Black cancer patient, which will be discussed in Chapter 2. However, there is no literature regarding the experiences of Black cancer patients during CCTs. This literature would be useful in informing decision-making interventions and more effective recruitment practices.

Purpose of the Study

The purpose of this study is two-fold: (1) to identify and describe the patient, protocol, physician, and family member factors that Black cancer patients consider important in their decision to participate and remain in CCTs; and (2) to use real-time data capture methods to understand the daily experiences of patient-participants who are participating in CCTs. The following research objectives will be addressed:

1. To understand how patient, family member, physician, and protocol factors are expressed by patient-participants in their decisions to participate and remain in CCTs;

2. To understand the daily experiences of Black patient-participants as they navigate through their CCTs.

Significance of the Study

This study is an important first step in giving voice to Black adults living with cancer who are participating in clinical research, by examining how their life events and real-time daily experiences positively or negatively influenced their participation and retention in cancer clinical research. This study is unique in its use of real-time data capture (RTDC) using qualitative methods to capture the experiences of Black cancer patients as they occurred in real-time. Typically, RTDC is used to acquire quantitative data for producing analytic models to examine within-person and between-person variations in experience, behavior, or physiological state (Shiffman, Stone, & Hufford, 2008). However, surveys and questionnaires are prone to retrospective bias and, therefore, may fail to capture the dynamic processes of the real world and how an individual negotiates his way through it. Real-time insights from Black participants on their experiences of CCT participation will inform possible strategies at the individual, family, and community levels to enhance future CCT recruitment and retention by providing Black cancer patients with the information and resources necessary to make informed CCT treatment decisions. Further, the findings will serve as the basis for the long-term goals of developing and testing culturally relevant, theoretically based behavioral change interventions designed to increase recruitment and retention of eligible Blacks in CCTs.

Significance of the Study to Nursing

This study is significant to nursing for three reasons. First, it will enhance nursing research knowledge by explicating factors influencing CCT enrollment and retention for Black cancer patients. In so doing, it may be a first step in reducing disparities in cancer outcomes and developing interventions for the Black population. Understanding the patient, family member, physician, and protocol, factors that are important to cancer trial participation and retention is integral to further conceptual development and refinement of models. This understanding can lead to dialogue about CCTs with the Black community and to culturally competent care that advances our knowledge of fears or other misperceptions of CCTs. Second, it will advance nursing's knowledge of methodological techniques, such as using real-time data capture.

Last, this study will approach the issue of Black CCT participation with a nursing lens (i.e., with a perspective reflecting the inherent strengths of nursing practice and research). Foremost among a nurse's commitments is a focus on providing care to the patient in the larger context of his psychosocial environment—ever mindful of the individuals who support and provide resources for the patient (Disch, 2012). In a similar way, the nurse researcher must respect and uphold the ethical principles of conducting research with human participants by understanding the preferences and goals of patient-participants. Therefore, examining the relationships forged by the Black cancer patient with his family (however, the family is defined) and the cancer clinical trial team is integral to understanding his CCT participation (including recruitment and retention) (Disch, 2012). This focus is a fulfillment of the “nursing lens” which seeks to know each

Black cancer patient within the confines of his daily experience in order to understand why he has chosen to be, and why he remains, a CCT participant (Gardner, 1995). For this reason, this study was significant to nursing in its emphasis on the individual experience of each Black participant as he was impacted by his family, the CCT in which he was enrolled, and the oncology physician and CCT team who supervised his research treatment.

The Definitions of Terms

Following is a list of terms used in this study:

Accrual is a term that is often used interchangeably with enrollment or recruitment to CCTs.

Cancer clinical trial (CCT) is synonymous with therapeutic CCT, or a CCT with curative intent that uses drugs, radiation, surgery, other biological agents, or behavioral or other interventions (V. Sallee, personal communication, July 8, 2011).

“Black,” is a term used instead of African American and signifies an individual who is identified as a domestic or foreign-born descendant of Africans, as well as an individual through acculturation who identifies as Black (Nelson et al., 2011).

Symptom burden is the totality of the severity and impact of observations of an individual which evidence disease or physical disturbance and can only be learned by patient self-report (Cleeland, 2007).

Real time data capture (RTDC) is defined as the acquisition of self-reported health information as it occurs in an individual’s immediate environment in real-time (Stone et al., 2007).

Research participation is a broad term; and, for the purposes of this study may include recruitment, enrollment, and retention in CCTs.

Summary

The primary purpose of this study is to examine the factors influencing CCT participation among Black cancer patients by adding the individual voices of Black cancer patients currently accrued to CCTs. In addition, this study seeks to understand the influence of patient, family member, physician, and protocol factors on Black cancer patients' CCT accrual and continued enrollment. By describing factors influencing CCT enrollment from the patient-participants' perspective in real-time, this study achieves some measure of ecological validity—that is, reflects the behaviors of other Black CCT participants in the real world as they progress through CCTs. Further, this study ascertains the daily challenges and experiences of Black patients during their CCT participation as devoid as possible of retrospective bias. The statement of the problem, purpose, and significance to nursing, as well as specific aims were presented

CHAPTER II

REVIEW OF THE LITERATURE

Introduction

The purposes of this study were to identify and to describe the influence of patient, family member, physician, and protocol factors on Black cancer patient CCT accrual and continued participation, as well as to understand the daily experiences of Black cancer patients enrolled in CCTs. The literature reviewed for this chapter includes four main areas. First, the chapter begins with an overview of the research on Black cancer patient CCT participation. Second, there will be a discussion of Albrecht's theoretical framework and its application to this study. Third, research that focuses on the four main factors of Albrecht's model will be discussed. This includes patient, family member, physician, and protocol factors. Fourth, in order to describe the phenomenon of CCT participation by Black cancer patients in the everyday language of the patient-participants (Sandelowski, 2000), the relevant literature underpinning the use of elements of real-time data collection (RTDC) method used in this study will be discussed. Finally, a summary of the gaps in the literature will be provided.

Black Cancer Patients and Barriers to Cancer Care and Clinical Trials

Three systematic reviews encompassing the period 1960 through 2011 enumerated barriers to cancer care and CCTs and reflected the influential role of patient, family member, physician, and protocol factors. Shavers and Brown (2002) published one of the earliest reviews of the literature—from 1960 through 1997—addressing cancer health disparities among racial and ethnic minorities. Their review identified racial and

ethnic gaps¹ in cancer treatment for several types of cancer (i.e., breast, lung, colo-rectal, prostate, and cervical cancer) that decreased disease-free survival and that increased mortality and disease recurrence rates. They also identified three broad factors that potentially affected receipt of cancer treatment: structural, physician/clinical, and patient barriers (Shavers & Brown, 2002). Structural barrier factors included insurance status, insurance type, geographic region where care was received, and the type of institution where treatment was received. Physician/clinical factors centered on factors that influence physician recommendations for cancer treatment, such as the presence of comorbidities, physician preference or bias, and physician perception of patient willingness to adhere to treatment. Patient factors addressed patient preferences and biases, ability to access medical treatment, and attitudes and beliefs surrounding recommended treatment. These three broad factors, along with family members (as broadly or narrowly defined by the participant), have come to be viewed as barriers and facilitators to CCT participation among Black cancer patients (Ford et al., 2008; Heller et al., 2015; Langford et al., 2013; Rivers et al. 2013; Sheppard et al., 2011; Royak-Schaler et al., 2008).

In their review of barriers to recruitment of under-represented populations from quantitative and qualitative studies for the period 1996 to 2005, Ford et al. (2007) found that reduced recruitment was influenced by barriers to awareness, opportunity, and acceptance of CCTs. Barriers to CCT recruitment included physician awareness of

¹ The researchers evaluated racial/ethnic gaps in cancer treatment among Black, Hispanic, Native American, and Asia/Pacific Islander populations (Shavers & Brown, 2002). The study focused predominantly on treatment care disparities among Blacks.

CCTs, lack of education about cancer, and the presence of culturally-relevant information. The opportunity to participate in CCTs was affected by such factors as provider attitudes and characteristics, CCT design barriers (comorbid conditions and age-based exclusions), sociodemographic factors (e.g., age, member of a racial/ethnic group, and socioeconomic status), provider communication, and CCT-associated costs. Barriers to acceptance of CCTs included family influences, fear, direct and indirect costs, time commitment, transportation, and distrust of physicians and the healthcare system.

Rivers et al. (2013) synthesized the existing studies over a ten year period (from 2002 to 2011) to better understand the key factors that influence the participation of Blacks to CCTs. In this review, five elements were found to influence the participation of CCTs: negative attitudes towards CCTs, the importance of faith, knowledge deficits related to CCTs, the role of healthcare providers, and the recommendations of friends and family members. Blacks were more likely to enroll in CCTs, if family and friends had enrolled or had knowledge of CCTs, promoted CCT enrollment, and provided support. Knowledge of CCTs, and certain sociodemographic factors such as higher income and education which increase the likelihood of CCT awareness, influenced the prospect of CCT accrual. The presence of negative beliefs and attitudes, such as fear of experimentation, decreased the likelihood of Blacks enrolling in CCTs. Religious faith was likely to discourage CCT participation among Blacks, secondary to beliefs that God controlled the outcome of their disease progression or cure and on reliance on religious intervention. Finally, the role of healthcare providers was found to both encourage and discourage CCT participation among Blacks.

Although the three systematic reviews lacked a focused consideration of the experiences of Black cancer patients during the CCT process and the personal decisional factors which motivate Black cancer patients to accrue and continue to participate in CCTs, they still enabled an examination of the four major factors which influence CCT participation among Black cancer patients: patient, family member, physician, and protocol. Further, the three systematic reviews showed a temporal movement (from 1960 to 2011) from a consideration of the factors required for CCT enrollment (insurance, the healthcare institution, physicians/clinical settings, and cancer patients), to the recruitment process and its effect on CCT recruitment, and, finally, to a focus on factors influencing Blacks to enroll in CCTs (Ford et al., 2008; Rivers et al. 2013; Shavers & Brown, 2002).

Albrecht's Theoretical Model of CCT Decision-making

Albrecht's Model (see Figure 2-1) served as the analytic starting point for this dissertation study (Albrecht et al., 2003). Albrecht et al (2003) reported that cancer clinical trial decision-making is influenced by four factors: patient, family member, physician, and protocol. Albrecht et al. (2003) posited that patient decisions surrounding cancer treatment, including patient decision-making regarding CCT enrollment, generally were physician-dominated and the "patient and family member are primarily in response-based roles where they react to the behavior of the physician (Albrecht, p. 41, 2003)." Albrecht et al. (2003) did not explicate specifically, or define the four factors, nor did the researchers delineate the particular patient, family member, physician, and protocol factors that influence treatment decision-making. However, the researchers acknowledged that the four factors have socio-demographic and attitudinal features that

influenced patients' decision-making when choosing CCT participation (Albrecht et al., 2003). Moreover, the researchers stated that aspects of the protocol which impacted patient treatment decisions included trial phase and composition of the CCT study arms (Albrecht et al., 2003).

Albrecht's Model provided information regarding the role of the physician in the cancer treatment enrollment process. Successful patient enrollment to CCTs was ascribed to the relevant physician's support and responsiveness to a patient's concerns, barriers to accepting treatment, and uncertainty (Albrecht et al., 2003). Further, communication, which included a mediating role in CCT decision-making in Albrecht's Model, was specifically defined as physician communication. It provided the nexus for the patient, family, physician, and protocol factors to influence decision-making.

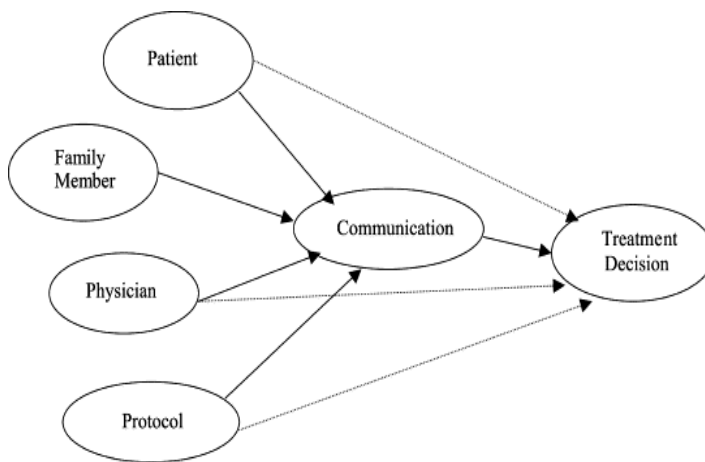


Figure 2-1: Albrecht's Theoretical Model of Cancer Clinical Trial Decision-making

Physicians were considered integral in referring cancer patients to CCTs, influencing decision-making by cancer patients, and discussing informed consent (Albrecht et al. 1999; Albrecht et al., 2003; Albrecht et al. 2008).

Although the four factors and their attributes were not clearly defined in Albrecht's Model, research literature has pointed to some of these attributes. Several researchers, for example, identified factors influencing CCT treatment decisions. These

included patient factors such as altruism, an expectation of personal benefit, improvement of cancer-related symptoms, the absence of other treatment, and maintenance of hope (Agrawal et al., 2006; Kvale et al., 2010; Todd et al., 2009; Truong, Weeks, Cook, & Joffe, 2011; Ulrich et al., 2012; Wright et al., 2004). Protocol-related factors also influenced CCT enrollment. Wujcik and Wolff (2010) identified eligibility requirements related to the protocol as problematic. Indeed, from 2001-2007, of the 1,125 individuals screened for a clinical trial during this time period, only 30% had an available trial and 21% enrolled. Initial barriers included issues such as lack of transportation, missed appointments, insurance constraints, miscommunication, and concerns surrounding informed understanding of patients. Other protocol-related factors that have been discussed in the literature included loss of relationship with a primary oncology physician, compensation for participation, lack of insurance coverage for CCTs, complex study protocols and informed consent documents, and increasing CCT requirements (Basche et al., 2008; Joseph & Dohan, 2009a; Klamerus et al., 2010).

Albrecht et al. (2003) freely acknowledged the influence of the behaviors of family members and significant others on CCT decision-making. However, again, Albrecht's Model did not delineate the elements or the nature of the family member factors, yet research suggested that family member-related factors directly influence CCT enrollment, since cancer patients rely heavily on the tangible support and caregiving of family members and friends (Sheppard et al. 2011; Ulrich et al. 2012; Wootten et al., 2011). Family issues positively and negatively influenced CCT enrollment as some cancer patients felt compelled to enroll to appease family members, while others did not

participate because of concern for burdening family members with additional responsibilities or depriving them of care (Quinn et al., 2011; Ulrich et al 2012; Wootten et al. 2011).

Additionally, other factors beyond Albrecht's Model were important in CCT treatment decision-making for CCT enrollment. Concerns about treatment side effects and resultant symptom burden figured prominently among participants in CCTs in several research studies (Ulrich et al. 2012; Wootten et al. 2011). Albrecht's Model did not consider the impact of symptom burden on continued participation in cancer research, nor did it consider the effect of symptom burden on treatment decision-making on Black cancer patients with a history of prior cancer treatment. Albrecht's Model was physician-centered, and, therefore, discussed the integral role that physicians play in the care and treatment of cancer patients. Therefore, significantly, Albrecht's Model overlooked the influence of nurses in their various roles during the CCT process (Grady & Edgerly, 2009; Ulrich et al., 2012; Wootten et al., 2011). Ulrich et al. (2012) clearly illustrated the pivotal presence of nurses in the CCT process. Further, nurses function as clinical research coordinators and nurse navigators who interact directly with potential participants prior to enrollment in CCTs and have a significant impact on CCT decision-making and participation.

Albrecht's Model provided a starting point for exploring decisional components that impact the clinical research decisions of Black adults living with cancer, since it acknowledged the complex factors that might influence Black cancer patients' decision-making related to CCT treatment options, i.e., the influences of patient, family member,

physician, and protocol-related factors, as well as the mediating role of physician communication (Basche et al., 2008; Lara et al., 2005; Ulrich et al. 2012; Wootten et al., 2011). Although it outlined these important variables in treatment decisions, Albrecht's Model was silent on the role of nurses and other members of the CCT team, as well as the potentially negative effects of symptom burden on CCT treatment decision-making and on continued CCT participation. More significantly, it listed the patient as a factor, rather than focusing on the perspective of the patient and his or her preferences and goals related to research participation.

Patient Factors

The willingness of Blacks to participate in medical research frequently has been referenced to a general distrust of physicians and medical research, with some of the distrust stemming from the ethical and human rights abuses perpetrated on rural Southern Blacks in the Tuskegee syphilis experiments (Tuskegee Study) (Linden et al., 2007; Shavers, Lynch & Burmeister, 2002). Researchers have posited that knowledge of Tuskegee and its abuses have deterred Black participation in medical research, such as CCTs. In a national telephone survey from a sample of the 527 Black and 328 White respondents, Corbie-Smith, Thomas, and St George (2002) found significant levels of distrust among Blacks regarding physicians and differences in trust among Blacks and Whites. Overall, Blacks had significantly higher distrust scores than Whites, as well as more distrust of physicians than Whites. In this study, Blacks as compared to Whites were more likely not to trust physicians to explain research to participants (41.7% vs. 23.4%, $p < .01$), to state that their physician sometimes exposed them to unnecessary

risks (45.5% vs. 34.8%, $p < .01$), to believe that someone like them would be treated as “guinea pigs” without their consent (79.2% vs. 51.9%, $p < .01$), and to believe that physicians often prescribed medication as a means of experimentation without consent (62.8% vs. 38.4%, $p < .01$). After controlling for sociodemographic factors such as education, employment, and income, race continued to be significantly associated with distrust—which in turn, could affect willingness of Blacks to participate in CCTs.

Shavers, Lynch, and Burmeister (2002) affirmed this stance in their mail and telephone survey data collected in Detroit, Michigan, from predominantly White and Black Detroit residents (Blacks ($N = 91$), Whites ($N = 88$), and individuals of other racial and ethnic groups ($N = 19$)). They found that knowledge of the Tuskegee Study was a factor deterring willingness of more Black respondents, than White respondents, to participate in medical research. Eighty-one percent of Blacks and 28% of Whites stated awareness of the Tuskegee Study. Fifty-one percent of the Black respondents reported that the Tuskegee Study resulted in less trust of medical researchers, 41% reported that their trust in medical researchers had not changed, and one percent reported feeling more trust. Of the Whites who had knowledge of the Tuskegee Study, 17% percent stated that this knowledge resulted in less trust in medical researchers, and 83% reported no change in their trust of medical researchers. Further, 49% of Blacks and 17% of Whites stated that their knowledge of the Tuskegee Study was a barrier to future participation in medical research studies. Knowledge of the Tuskegee Study and its negative effect on CCT participation was found in participant samples in later studies concerning Blacks

and CCT participation (Evans, Lewis, & Hudson, 2012; Robinson, Newman, Wallington, & Swain, 2016).

Other studies found conflicting information regarding the willingness of Blacks to participate in CCTs. Meng, McLaughlin, Pariera, and Murphy (2016) compared the effect of distrust on the willingness of Blacks and Whites to participate in CCTs via the use of an online survey. They found that distrust increased unwillingness to enroll participate in CCTs in both Whites ($p < .01$) and Blacks ($p < .05$). Moreover, willingness to participate in CCTs was significantly influenced by Blacks seeking CCT information from hospitals ($p < .05$) and by religious belief ($p < .05$). Via the use of focus groups, Linden et al. (2007) explored the willingness or unwillingness of 58 African American women (ages 30 to 65) to participate in a hypothetical randomized clinical trial for breast cancer. None of the participants had ever been diagnosed with breast cancer. In all the focus groups, there emerged a general distrust of the healthcare system, with frequent reference made to the Tuskegee Study. However, the focus groups felt that this distrust could be ameliorated by culturally sensitive recruitment to CCTs. Interestingly, four other common themes emerged from the focus groups that reflected a willingness to participate in a CCT: (1) if participation was personally meaningful to the individual or to the community, (2) the necessity of being able to make an informed choice, (3) a preference among some members of the focus groups for spiritual or alternative/natural treatments, rather than medical care, and (4) use of a cost-benefit analysis, whereby the subjects weighed the benefits and costs of participation in a research clinical trial versus the costs and benefits of travel, medication and medical care, and time expended.

Recent research indicates that Blacks have moved beyond the specter of Tuskegee as a deterrent to medical research participation. In fact, as found by Linden et al. (2007) and Meng et al. (2016), Black cancer patients were willing to participate in CCTs as much as White cancer patients (Byrne et al. 2014; Ford et al., 2013). However, other factors such as concerns about insurance, lower socioeconomic status, and ineffective physician-patient communication have emerged in the literature as barriers to CCT participation (Brown et al., 2013; Byrne et al., 2014; Ford et al., 2013; Du et al., 2005; Lara et al., 2005). Ford et al. (2013) conducted six racial and ethnically homogeneous focus groups of Latinos and Blacks from the general population of six counties in South Carolina. They sought recommendations for removing barriers to clinical trials from members of the two groups who are under-represented in clinical trials. Both groups identified barriers and offered solutions for their amelioration. Using content analysis, the researchers formulated themes common to Blacks and Latinos, exclusive to the Black participants, and exclusive to the Latino participants. The Black participants stated willingness to participate in clinical trials (1) in health systems that performed patient satisfaction surveys and admitted and formally apologized for mistakes, (2) if clinicians were trained in improved patient communication, and (3) with more racially diverse clinical trial teams. Themes common to both groups included (1) lessening costs associated to clinical trials, (2) moving recruitment to the community (especially to churches), (3) the necessity for clinicians to use ample time to discuss clinical trial associated risks, learn communication skills targeted to diverse groups, and permitted the

participants' physicians to remain involved in their treatment, and (4) physicians accepting more responsibility for the adverse effects of clinical trials.

In their survey of 1100 Black, Hispanic, and White patients from a Florida cancer registry with lung, breast, colorectal, and prostate cancer, Byrne et al. (2014) did not find a difference in willingness to participate among the three groups. Only eight percent of the sample reported having participated in a CCT. The top five reasons the sample cited for CCT enrollment were (1) the desire to improve cancer treatment, (2) the oncologist advised undertaking enrolment in a CCT, (3) the CCT offered optimum treatment for their cancer, (4) the CCT offered more information, and (5) the CCT was the sole treatment option (Byrne et al., 2014). The most cited barrier by over 90% of the sample was concern whether insurance would cover the costs of CCT enrollment. Other top barriers reported included (1) fear of side effects from CCT medications, (2) the belief that their physician did not want the individuals to participate, (3) the cancer patient did not want to transfer his care from his present physician, and (4) the cancer patient not wanting to be a "guinea pig" (Byrne et al., 2014).

Du et al. (2005) conducted a retrospective chart review of 427 lung cancer patients eligible to participate in CCTs for the years 1994 through 1998 at a comprehensive cancer center in Detroit, Michigan, to determine predictors of CCT enrollment. Only 91 of the 427 cancer patients participated in a CCT. Using univariate and multivariate analyses to compare CCT enrollees and non-enrollees, as well as non-Black and Black cancer patients, the researchers determined that Blacks were more likely to live in low rank census tracts (83% vs. 23%, $p < .001$), less likely to have an Eastern

Cooperative Group (ECOG) performance status equivalent to zero (27% vs. 35%, $p = .054$,² and less likely to have commercial insurance (27%-49%, $p < .001$) (Du et al., 2005). Conversely, non-enrollees were more likely to be Black (45% vs. 25%, $p = .001$), to live in a low rank census tract (52% vs. 37%, $p = .028$), and less likely to have commercial insurance (37% vs. 55%, $p = .002$) (Du et al., 2005). Black cancer patients significantly were less likely to have commercial insurance (conventional, HMO, and private party provider) and significantly more likely to live in lower socioeconomic areas.

Disparate communication patterns between Black cancer patients and their oncologists have been cited as contributing to less information-sharing regarding cancer care and CCT information. Studies have shown that oncology physicians engage in more relationship building language, have longer appointments, have more utterances at appointments, and have higher frequencies of information-sharing statements (Eggly et al., 2015; Gordon et al., 2006; Siminoff et al., 2006). Also, when CCTs were discussed, the discussion involved less statements containing information concerning diagnoses/prognoses, explanations, risk/benefit, and treatment options (Eggly et al., 2015; Gordon et al., 2006; Siminoff et al., 2006). In Eggly, Barton, Winckles, Penner, and Albrecht (2015), the researchers analyzed the word count and word content of conversations that occurred in videotaped clinic interactions between Black cancer patients and their oncologists. Eggly et al. (2015) determined that appointments with

² The ECOG performance status is a measure of a patient's functional status, i.e., a measure of a patient's ability to carry on his activities of daily living, self-care activities (dressing, feeding oneself, etc.), and strenuous physical activity (Oken et al., 1982). It is meant to be an objective measure of a patient's functional status prior to clinical trial participation, as well as a means of evaluating a patient's changes in functional status during the course of a clinical trial. It is a six-point scale which ranges from zero to five, with zero representing optimum functional status and five signifying death.

Black cancer patients were shorter in length than White cancer patients and had fewer discussions of CCTs. Mean word counts of oncologists' visits with Black cancer patients were shorter, than for visits with White cancer patients (4877.73 vs. 7247.18). The topic of CCTs was raised less frequently during visits with Blacks, than with Whites. Even in discussions involving offers of CCTs, oncology physicians were found to have discussions with Black cancer patients that had lower mean word count (1089.64 vs. 1867.09) and contained fewer elements of informed consent, than the same discussions with White cancer patients (Eggly et al., 2015).

Researchers have surmised a probable reason for this disparate information-sharing by oncology physicians is the ineffective communication styles of Black cancer patients, which have been criticized as being passive and less interactive (Eggley et al., 2013; Gordon et al., 2006a; Gordon Street, Sharf, & Soucek, 2006b). In their review of video-recorded clinic interactions between 109 Black and White cancer patients (30 of the cancer patients were Black) and their White oncologists, Eggly et al. (2011) determined that there was a significant difference ($p = .008$) between the mean total number of questions asked by Black cancer patients (7.83 questions, $SD=7.81$) and the mean total number of questions asked by White cancer patients (11.56, $SD=9.23$). The researchers concluded that the difference amounted to less information being sought by Black cancer patients and less information being shared with them by their White oncologists.

However, as noted by the focus groups conducted in Williams et al. (2008), Black cancer patients and their families have their own communication expectations

surrounding quality of life. The members of the six focus groups identified two domains of communication the participants felt were essential: effective communication and decision-making. The themes of personhood and tailoring communication were embedded within the domain of effective communication. Inherent in personhood was the admonition that, as a prerequisite to effective communication, physicians must establish a relationship with a patient in order to acquire knowledge about the patient and her family (Williams et al. 2008). The patients and family caregivers expected the physicians to initiate, maintain, and monitor the effectiveness of communication existent in the relationship. In terms of tailoring communication, the focus group members expected oncology physician to use language appropriate to their education and literacy levels and to control the amount and timing of information based upon the needs of the patient, the complexities of the patient's care, and where the patient was in terms of accepting or denying her disease state (Williams et al. 2008).

A few studies have considered the issue of CCT participation from the perspectives of Black cancer patients. Brown et al. (2013) and Wenzel et al. (2014) focused on Black cancer patients who had accepted, or declined, CCT enrollment. Wenzel et al. (2014) considered the processes and reasons influencing 32 Black cancer patients to accept, or to decline, CCT participation. Seven focus groups comprised of Black cancer patients who had been offered CCT participation were conducted. The focus group participants who refused CCT enrollment stated that their decisions were influenced by such factors as distrust of physicians, lack of awareness of CCTs, cost, transportation, discouragement by family and friends, and negative experiences with

healthcare providers. Some of the focus members expressed regret that they had allowed family and friends to persuade them to decline CCT enrollment. The focus group members who accepted CCT enrollment reported that participation was influenced by family and friend support and spiritual motivations.

The investigators in Brown et al, (2013) interviewed 22 Black cancer patients who refused participation in Phase 1-Phase 3 CCTs, the researchers found that participants cited more than one factor underlying their decision to decline CCT participation. The top four factors were (1) increase in burden related to CCT treatment (12, or 55%), (2) possibility of increase in symptom side effects (11, or 50%), (3) concern surrounding the process of randomization (8, 36%), and (4) family members recommending non-participation (8 participants, 36) (Brown et al., 2013). Of the 22, only one participant declined due to mistrust of clinical researchers, and one participant declined secondary to concern of not receiving optimum care (Brown et al., 2013). In terms of prior knowledge or opinions of CCTs, only nine (41%) of the participants lacked prior knowledge or opinions of CCTs. Significantly, the researchers observed that the participants and their family members (accompanying participants) did not understand crucial CCT information during the CCT consultation. For this reason, Brown et al. (2013) suggested that CCT participation could be improved if interventions were developed which targeted the CCT information and decision-making needs of Black cancer patients *and* their families (Brown et al., 2013).

A more recent qualitative study by Robinson et al. (2016) investigated the perspectives and opinions regarding CCTs from eight focus groups comprised

exclusively of Black cancer patients, patient family members and caregivers, religious leaders in the relevant Black community, and healthcare providers. The Black cancer patients were undergoing chemotherapeutic treatment. The researchers did not indicate whether any of them were participating in CCTs. The Black cancer patients felt it was important for Blacks to be involved in CCTs, since Blacks were disproportionately affected by disease, and it was very important to include all racial, socio-economic, age, and gender groups in research. In discussing ways to encourage to CCT participation among Blacks, they suggested the CCT participants should talk about their experiences in CCTs, physicians should educate their patients about CCTs as a way of encouraging participation, and information should be disseminated in the Black community in churches, social workers' offices, elevators, and hospitals. In order for them to enroll or to encourage other Black cancer patients to participate in CCTs, the Black cancer patients stated that they needed to trust the physician and to understand all of the CCT information, the side effects of the CCT intervention, and the effects of the CCT intervention on their existing comorbid conditions.

Family Member Factors

Family members have been mentioned tangentially as “companions” being present during physician-patient CCT discussions and/or interactions in the outpatient setting, with no mention of their roles in the lives of Black cancer patients external to the clinical setting (Albrecht et al., 2008; Albrecht et al., 2009; Eggly et al., 2006; Eggly et al., 2011; Penner et al., 2012). Several studies have begun to acknowledge the vital roles of Black family members (spouses, partners, children, etc.) in CCT discussions. Eggly et

al. (2011) found that White cancer patients were more likely to have a companion present at their appointments than Black cancer patients ($p < .000$). There was a significant difference ($p < .000$) between the number of questions asked at clinical interactions by patients and their companions (22.50 questions per interaction with a $SD=14.65$) versus questions asked by patients who came alone (9.50 questions per interaction with a $SD=9.23$).

Studies have noted that Black cancer patients expect oncology healthcare providers to exhibit respect for their family members, as well as to tailor cancer information to the health literacy and education needs of family members (Song, Hamilton, & Moore, 2012; Williams et al., 2008). Clearly, the Black cancer patients' expectation of familial inclusion espouses participation of their family members in the CCT process, despite such familial inclusion being absent from the research literature. Family members are more than just individuals in the periphery of CCT decision-making.

Wenzel et al. (2014) confirmed the valued status of family members and friends in CCT decision-making. The researchers reported that Black cancer patients who had accepted, or declined, CCT participation relied on family and friends as sources of CCT information and as participants in shared CCT decision-making. Brown et al. (2013) noted the strong influence of family members of Black cancer patients on CCT decision-making. In this study, 14 of the 22 participants reported discussing CCT information with family members during and after the initial CCT consultation—eight participants' family members advised declining CCT participation. Clearly, researchers have found that the presence of “companions” (most of whom were identified as spouses, partners, or

children) increased the information received by Black cancer patients during their clinical interactions with oncologists. This finding has bearing on the relevant impact of their presence during CCT discussions.

Physician Factors

Attitudes of oncologists towards CCTs significantly affect accrual of cancer patients to CCTs. Somkin et al. (2013) surveyed 77 oncologists and followed their accrual patterns over a two-year period. Oncologists who had high CCT accrual saw perceived value in CCTs ($p = .023$) and indicated awareness of open CCTs and specific eligible patients with whom they initiated CCT discussions ($p < .0001$). Indicators of oncologists with low accrual patterns included appreciation that patients initiated CCT discussions ($p = .04$), did not offer CCTs to patients who they feel are likely to do well on standard treatment ($p = .0092$), and perceived CCTs to be an inappropriate use of resources ($p = .023$).

Oncologists' attitudes and perceptions of Black cancer patients figure prominently in whether they are deemed eligible for CCTs. Oncology physicians have denied Black cancer patients CCT participation because of anticipated non-compliance, perceived mental status or cognitive impairment, and the presence of comorbidities (Penberthy et al., 2012; Simon et al., 2004). In Penberthy et al. (2012), the researchers reported that Blacks were more likely than Whites to be deemed ineligible for CCTs by oncologists (47.8% vs. 40.8%, $p < 0.004$) because of expected non-compliance and perceived inappropriate mental status. Prospective enrollees were deemed non-compliant by oncologists due to (1) consistent failure to attend appointments, (2) active substance

abuse, and (3) perceived instability. Inappropriate mental instability signified the perceived inability of Black cancer patients to understand and provide informed consent (Penberthy et al., 2012). In fact, oncology physicians have also declined to offer CCT participation to Black cancer patients based on physician preference for standard care versus CCT care, concern for patient inability to tolerate CCT treatment secondary to comorbidities, and likelihood of being ineligible (Langford et al., 2014; Simon et al., 2004; Somkin et al., 2013).

Simon et al. (2004) surveyed oncologists at an urban, NCI comprehensive cancer center to determine practice patterns for referral and enrollment of Black women to breast cancer CCTs. The sample included 319 self-identified Black, White, or other (Asian Pacific, Arab/Chaldean, and Hispanic) women who had new patient visits with oncologists. At the time of the survey, ten breast cancer trials were available. Using univariate analysis, the researchers determined that oncologists enrolled approximately 33% of the sample who were offered enrollment in a CCT—with White women being more likely to be offered CCTs than Black women (42% vs. 21%). Moreover, Black women were more likely found to be ineligible in comparison to White and other race patients (61% to 53%), and Blacks were more likely to be considered ineligible because of poor performance status and unsatisfactory organ function.

Kehl et al. (2014) surveyed a large cohort of lung and colorectal patients (or their surrogates, if the patient had died or were too ill to respond to the survey) three to six months after their cancer diagnosis to investigate their discussions pertaining to CCTs. Of the 7887 respondents surveyed, 1114 (14%) reported having discussions about CCTs

as a treatment option. The researchers ascertained that specific factors were significantly associated with occurrence of CCT discussions: (1) increasing educational level ($p = .01$), higher income ($p < .001$), possessing no self-reported comorbidities ($p < .001$), and being White ($p = .01$). Moreover, respondents who had these CCT discussions were less likely to enroll in CCTs, if CCT decision-making were physician-controlled (13.4% enrolled), as compared to shared CCT decision-making (35% enrolled) or patient-controlled CCT decision-making (29.2% enrolled, ($p < .001$)).

Finally, as discussed previously, research indicates significant differences in cancer information communication between oncology physicians (predominantly White in the reported studies) and Black and White cancer patients (Gordon et al., 2006; Eggly et al., 2013; Siminoff et al., 2006; Song et al., 2014). In support of these findings and as discussed previously, oncologists have been shown to have shorter appointments with Black cancer patients and discuss CCTs with Black cancer patients less often than with White cancer patients (Eggly et al., 2011; Eggly, et al., 2013). Instead of solely laying the burden on the interactive style of Black cancer patients, Eggly et al. (2013) suggested that the problem may lie with physicians. They posit that the differences in cancer communication may reflect oncologists' concerns about Black cancer patient distrust, or the oncologists' racial attitudes and beliefs which make the discussions less patient-centered (Eggly et al., 2013).

Protocol Factors

Inherent in all CCTs are eligibility criteria which define the targeted patient sample, as well as safeguard subject safety and make CCT results precise and meaningful

(NCI, 2014). Establishment of eligibility criteria challenges investigators to define accurately sample qualifications without excluding potential subjects who may contribute significantly to the generalizability of CCT outcomes. Studies have reported statistically significant exclusion of Black cancer patients from to CCTs due to the presence of comorbidities, multiple primary cancers, poor performance status, prior chemotherapy, and poor compliance (Penberthy et al., 2012; Simon et al., 2004; Adams-Campbell et al., 2004). Adams-Campbell et al. (2004) examined 13 CCTs to understand the influence of study design on recruitment and accrual of African Americans in these trials. The study found that exclusions included presence of co-morbidities, multiple primary cancers, high serum testosterone levels for participation in prostate cancer clinical trials, poor performance status, prior chemotherapy, and poor compliance.

By contrast, CCT protocols are more likely to recruit Black cancer patients, if the protocols seek subjects with advanced stage (or regional spread of) cancer, are therapeutic in nature, and/or possesses accrual targets (Diehl et al., 2011). These findings are consistent with existent literature indicating that Black cancer patients tend to experience more cancer treatment delays than White cancer patients and present for initial cancer treatment with later stage disease (Hines & Markossian, 2012; Nurgalieva et al., 2013).

Costs of clinical trials and cancer care.

Looking beyond the physiological characteristics and the disease profile of the Black cancer patients, there are other protocol factors that adversely affect CCT enrollment. CCTs do not necessarily include all costs related to medical treatment and

diagnostic tests secondary to CCT participation. The presence of routine medical costs incident to CCT participation poses a financial dilemma to potential and existing Black cancer, especially where state policy mandates do not exist to require insurance coverage (Chun & Park, 2012; Klamerus et al., 2010). Chun and Park (2012) compared the presence of CCTs (2001 to 2007) in predominantly Black areas in the United States after implementation of state law mandating insurance coverage for routine costs associated with CCTs. They were interested in determining whether adoption of the insurance law mandates resulted in CCT sponsors locating more CCTs in low income and predominantly Black areas, thereby increasing access to these populations. Interestingly, they reported no difference in the availability of CCTs in low income areas. However, the researchers cited a 36% increase ($p = .05$) in the location of Phase 2 CCT³s in predominantly Black areas, after the insurance mandate.

Klamerus et al. (2010) explored the association between CCT denial and insurance coverage for cancer patients denied and accepted for CCTs at Johns Hopkins Medical Center. There were no statistically significant relationships between CCT denial and sex, race, cancer stage, or prospective subject comorbidities. However, CCTs were denied to prospective subjects who were younger (mean age= 54.9; $p = .0001$) and lived in Pennsylvania ($p = .0009$). The mean age of subjects accepted for CCTs was 59.2 and reflects the proportionately larger number of CCT participants in this group who had Medicare, which authorizes payment of routine CCT related costs. John Hopkins

³ Phase one clinical trials are the first use of a drug in a small sample humans; as result, the goal is to determine safety, a safe dose range, and side effects resulting from use the drug. By contrast, Phase two clinical trials evaluate the effectiveness and safety of a drug in a larger number of humans, with the already established dosage range.

recruited most of its CCT subjects (81.3%) from Pennsylvania, Maryland, and Virginia. The latter two states had state law mandates that require insurance organizations to cover medical costs associated with CCTs. Pennsylvania did not have such an insurance law mandate at the time of the study.

Prior to passage of the Patient Protection and Affordable Care Act (PPACA) of 2010, approximately 29 states had policy mandates to require payment of routine costs associated with CCTs (Klamerus et al, 2010). The absence of these insurance mandates have a chilling effect on access to CCTs, since prospective subjects living in states lacking the CCT insurance mandate are denied insurance coverage for CCT participation at disproportionate rates (Klamerus et al., 2010). The PPACA with its minimum requirement of insurance coverage for therapeutic clinical trials has offered a glimmer of hope for improving access to CCTs (Kircher, Benson, Farber & Nimeiri, 2012; Martin et al., 2014). Unfortunately, room still exists to address the financial burden associated with CCTs and associated cancer care.

Zafar et al. (2013) indicated that despite the presence of insured cancer patients, they nevertheless experienced high financial burden. The data was collected from 254 participants in a state with mandated insurance coverage for routine cancer costs, following enactment of the PPACA. The median monthly out-of-pocket expenses for cancer care-related expenses for the samples were \$456 (interquartile range was \$213-\$827). The majority of the sample ($N = 190$) was recruited from a non-profit organization providing financial assistance for payment of cancer care-related costs; the remaining participants were recruited from an academic cancer center. Seventy-five

percent of the sample received financial assistance for costs associated with their cancer care, including payment for prescription copays, insurance premiums, and coinsurance. They were more likely to employ a host of cost-saving strategies to ease the financial burden accompanying payment of their prescription medication and cancer treatment,⁴ than the other 25% of the sample who did not apply for financial assistance. The use of at least one of these cost-saving strategies was correlated positively with high subjective financial burden ($p < .01$). Although, not correlated significantly with race, high financial burden was correlated significantly with younger age ($p < .001$), large household size ($p = .008$), communications with physicians regarding costs ($p = .020$), and applying for financial assistance ($p = .007$).

The financial toxicity, or financial distress resulting from cancer treatment, extends to CCT decision-making (Nipp et al. 2016; Wong et al., 2016; Zafar et al., 2013). Although the sample in Wong et al. (2016) was broadly defined as “White” and “Non-white,” the financial concerns expressed by the 1,211 participants were glaring and indicated distress and decisional conflict in CCT decision-making. Prospective subjects who expressed financial concerns had lower self-efficacy ($p = .004$) and were less prepared ($p < .001$) for CCT decision-making, as well as had greater distress ($p < .001$) and decisional conflict ($p < .001$) pertaining to CCT decision-making (Wong et al.,

⁴ The cost-saving strategies used by the participants to offset prescription medication, who also received financial assistance included: (1) receiving medication samples from oncologists (used by 63%, $p < .001$), (2) reduced spending on food and clothing (used by 53%, $p < .001$), (3) used credit or borrowed funds to pay for medication (used by 49%, $p < .001$), and (4) filled only a portion of the medication prescription (used by 24%, $p = .029$). The cost-saving strategies used by participants to offset cancer care costs, who also received financial assistance included: (1) reduced spending on leisure activities (used by 73%, $p = .005$), (2) reduced spending on food and clothing (used by 51%, $p = .021$), and (3) used credit or borrowed funds to pay for medication (used by 42%, $p = .001$).

2016). Clearly, barring changes to all CCT protocols affording coverage of all costs, the PPACA and the state laws mandating insurance coverage for CCT costs have not shown consistent association with access to CCTs. Ambiguities exist in financial coverage for cancer care that permit insurers to deny coverage to CCTs offered by providers outside of a patient's insurance network, to deny applicability of CCT insurance mandates to patients who are members of self-insured insurance groups, and permit insurers to determine what they consider standard, routine, and/or customary CCT care and costs (Martin et al., 2014). Where the CCT insurance coverage mandates are lacking or inconsistently applied and when CCT protocols fail to cover all costs associated with participation, prospective CCT participants may be incapable of shouldering the CCT out-of-pocket costs (Chun & Park, 2012).

Review of Research on Real-time Data Capture

Real-time Data Capture

The last section of this literature review will focus on a discussion of Real-time Data Capture (RTDC) as a methodological strategy to improve our understanding of the experiences of Blacks as they consider enrollment and participation in CCTs. RTDC is the acquisition of self-reported health information “in real time in the real world” (Stone et al., 2007). It is a data collection methodology which seeks to collect participants' experiences as they unfold—thereby minimizing the occurrence of recall bias (Stone et al., 2007). RTDC is facilitated by the use of several participant data collection methods,

such as experience sampling or ecological momentary assessment (EMA).⁵ Typically, EMA is characterized by frequent and intensive acquisition of self-reported information and experiences as they occur within the individual's own environment (Stone et al., 2007). RTDC via EMA has been used by a multitude of research disciplines to study pain, depression, drug use, cancer-related pain and fatigue, smoking cessation, and sexual risk behavior as well as incident sexually transmitted infections (Hachizuka et al., 2010; Hacker & Ferrans, 2007; Hensel, Fortenberry, Harzelak & Craig, 2012; O'Connell et al. 1998; Palmier-Claus et al., 2010; Shiffman et al., 2008). It comprises a constellation of research methods and methodologies united by the following characteristics (1) recordation of participant behaviors and experiences as they occur in the natural environment, (2) assessment of a participant's current, or most recent, behavioral or experiential state, (3) collection of data at strategic points in time, either random or centered on particular features or events of interest, and (4) use of multiple assessments to capture varied participant behavior and experiences over time or within situational contexts (Shiffman et al., 2008).

Considerations Regarding the Use of Elements of EMA

EMA facilitates recording of the dynamic interaction of a participant with his environment, as well as how individual experiences and behaviors vary per environmental influences, contextual associations, or the concurrent interaction of phenomena (Shiffman et al., 2008; Stone et al., 2007). Recording a participant's immediate experiences in the context of their environment produces ecologically valid

⁵ Experience sampling requires participants to stop at specified times during the day and describe or record their experiences and behaviors (Stone et al., 2007).

data potentially generalizable to the participant's daily life and, possibly, to the real-world experiences of similarly-situated individuals (Shiffman et al., 2008). EMA's strength is its ability to reduce recall bias, or systematic errors in retrospective data self-report, by focusing on a participant's current emotional, mood, physiological, symptom, or psychological state (Shiffman et al., 2008; Stone et al., 2007).

Researchers utilize EMA in order to avoid the biased, imperfect memory constructed by individuals who typically summarize and aggregate their experiences, rather than recollect their experiences as discrete moments (Palmier-Claus et al., 2010; Shiffman et al., 2008; Stone et al., 2007). Memory retrieval is influenced unconsciously and involuntarily by momentary moods, emotional states, and physical symptoms (Shiffman et al., 2008). For example, researchers have found that individuals (1) in a negative mood are more likely to recall negative experiences, (2) experiencing pain have more difficulty remembering pain-free moments, or (3) are more likely to recollect events or experiences that occur more frequently and, therefore, are more readily available for self-report (Hacker & Ferrans, 2007; Shiffman et al., 2008; Stone et al., 2007). As a result, questionnaire and interview methods which seek retrospective attitudinal and detailed self-report information are subject to recall bias.

There are three types of data sampling with EMA: time-based, random, and event-based. Time-based sampling seeks to capture phenomena which may vary, occur continuously, or occur at fixed time intervals (Shiffman et al., 2008; Stone et al., 2007). Data collection may occur at fixed intervals, in order to acquire a summary of a participant's experiences during the course of a day, while avoiding interruption of

desirable events such as meals (Hacker & Ferrans, 2007). Researchers may choose random, or variable, intervals in order to obtain representative examples of participant behaviors, experiences, and psychological or mood states (Badr, Basen-Engquist, Taylor, & De Moor 2006). Event-based sampling centers data collection on the occurrence of a specific event, behavior, or phenomenon, such as the urge to smoke, the intensity of pain during and after self-administration of pain medication, or the occurrence of risky behavior (Hachizuka et al., 2010; O'Connell et al., 1998). In addition, researchers have combined both methods of data collection in order to capture not only the occurrence of specific phenomena, mood states, behaviors, or experiences, but also to document the environmental milieu and antecedent events surrounding their occurrence (Hachizuka et al., 2010).

Use of EMA in Cancer Research

EMA has been used in studies involving cancer patients to assess pain and mood states, measure fatigue preceding and following intensive chemotherapy, and evaluate sleep, mood, and physical symptoms in the period surrounding a chemotherapy cycle for breast cancer (Hachizuka et al. 2010; Hacker & Ferrans, 2007). In Hachizuka et al. (2010), the investigators' tested the use of a personal data assistant (PDA) (a small, hand-held device utilized for computational and information storage/retrieval purposes) to collect real-time information on pain and associated symptoms (i.e., anxiety, nausea, depression, drowsiness, and fatigue) from 15 terminally-ill cancer patients, who were receiving home hospice care. Their purpose was to devise a means of effectively assessing pain, and its associated symptoms, in order to improve the quality of life of

terminally-ill cancer patients. The investigators used this method to avoid patient use of retrospective recall to assess pain, since they felt retrospective recall produced biased data. Moreover, there was concern that physicians' personal assessments, and patients' self-reports, of the pain experience were equally unreliable (Hachizuka et al. 2010). As a result, the terminally-ill cancer patients used the PDA to record pain and associated symptoms several times a day over a one-week period at three distinct times: (1) at two random times during the day, (2) two to three times proximal to regularly scheduled pain medication administration, and (3) whenever the patients required additional pain medication for breakthrough pain. The response rates for the random and regularly scheduled assessments were 90.3%; the response rates for the acute pain exacerbations were 80.2%. The researchers acknowledged that limitations included small sample size, unclear true compliance rates since the pain medication system was run voluntarily by the study participants, and only pain intensity was measured.

Hacker and Ferrans (2007) described their use of EMA as a data collection methodology to evaluate fatigue among cancer patients prior to, and subsequent to, a hematopoietic stem cell transplant (HSCT)⁶. The researchers sought to determine the intensity, incidence, and timing of cancer, or cancer treatment-related, fatigue, in order to assist in its management and/or to enable the development of interventions to ameliorate its effects. They acknowledged the biasing effects of such factors as other intense symptom experiences and negative mood on accurate retrospective recall of fatigue

⁶ Patients who receive a HSCT receive high-dose chemotherapy prior to instillation of the stem cells, either furnished by the patient or by another individual, in order to eradicate their immune system. The stem cells function to replace the patients' immune system with a new immune system free of cancer.

(Hacker & Ferrans, 2007). The cancer patients used an Actiwatch three days before and three days after a HSCT, in order to measure their fatigue at baseline and when they were likely to experience the most severe effects of cancer treatment-related fatigue (Hacker & Ferrans, 2007). The Actiwatch prompted the cancer patients to enter self-report fatigue data three times a day (at 10:00 a.m., 2:00 p.m., and 6 p.m.), as well as stored their self-report data. Using a repeated measures design, the researchers assessed that the patients were willing and able to provide real-time fatigue data. For the first three days, the response rates were 90%, 83%, and 92%. During this period, the patients experienced mild fatigue. The patients had response rates of 82%, 94%, and 82% for the last three days, and reported moderate to severe fatigue. Limitations included small sample size ($N = 20$ before HSCT, and $N = 17$ after HSCT) and measurement of fatigue at three set times during the day—other episodes of fatigue may have been missed,

Summary and Gaps in the Literature

The purposes of this study were to identify and to describe the patient, family member, physician, and protocol factors Black cancer patients consider in CCT participation, as well as to understand their daily experiences as they navigate the CCT process. There is no existing research explicating the daily experiences of Black cancer patients in CCTs. Further, there is neither a theoretical framework, nor a study or group of studies, which definitively provides guidance for identifying and describing the complex level of factors that assist Black cancer patients in their research participation decisions. Albrecht's Model lists a select number of factors as influential in CCT enrollment, but does not define the nature or the specific attributes of these factors. In

addition, there are a few qualitative research studies involving Black cancer survivors and their families and Black cancer patients who refused CCT participation, however, none of these studies include actively enrolled Black CCT patient-participants in their samples (Brown et al., 2013; Kehl et al., 2014; Owens et al. 2013; Somayaji & Gates, 2015).

Although trust and distrust is discussed extensively in the research literature as a barrier to CCT participation, it does not state to what extent CCT-enrolled Black cancer patients trust or distrust their oncology physicians, healthcare providers, and/or CCT teams, or how trust is engendered, just that distrust exists. It is also not known whether CCT-enrolled Black cancer patients continue to exhibit cancer information-seeking behaviors prior to, during, or after CCT participation. The impact of insurance, financial and economic pressures, and educational knowledge on potential out of pocket costs associated with CCT research participation needs more study, particularly with Black cancer patients, to better understand their needs in such trials. Family member issues also remain an important component of CCTs. For example, the reviewed studies did not address how CCT-enrolled Black cancer patients feel their family members support them at their initial CCT consultation, advocate for them during the CCT process, and enable them to cope with the daily emotional, physical, symptom, and financial pressures of living with cancer while participating in a CCT. Neither did the reviewed studies for this dissertation address the challenge that Black cancer patients might feel by disclosing a cancer diagnosis along with ensuing CCT participation to spouses, companions, children, and employers. Some literature discusses transportation issues and other logistical burdens as well as fear of physical burdens of research participation (Ulrich, et al, 2016)

such as side effects. But, a gap still exists in understanding Black CCT cancer patients', balancing of symptom burden, CCT treatment appointments, and on-going employment with caregiving responsibilities for children and parents.

Interventions responding to these questions would do much to close the gap between Black cancer patient mortality and CCT participation. Arguably, until these and many other questions are answered, how can researchers hope to understand why Black cancer patients enroll in CCTs in numbers inconsistent with the cancer burden they bear? Rather than relying on surveys with predetermined answers, the qualitative descriptive design of this dissertation study along with some elements of RTDC will help give voice to CCT-enrolled Black cancer patients. This will afford Black CCT participants an opportunity to share their experiences in their own words and to answer the many un-asked questions regarding the influence of patient, family member, physician, and protocol factors on their CCT research participation activities. Qualitative description plumbs the perceptions and sensitivities of a target population (here, Black cancer patients), absent transformative interpretation by the researcher—since its purpose is to describe an event or phenomenon (Sandelowski, 2000; and Sullivan-Bolyai, Bova, & Harper, 2005). Finally, this dissertation study has begun to fill slowly the cavernous gaps in nursing research concerning how the daily experiences of Black cancer patients impact their continued CCT participation and how these experiences can be used to develop patient-, family- and community-based resources for future Black cancer patients seeking to navigate the CCT process.

CHAPTER III: METHODOLOGY

Introduction

The primary purposes of this dissertation study were to identify and describe the patient, family member, physician, and protocol factors that Black cancer patients consider important when participating and remaining in CCTs and to record in real-time their everyday experiences as Black cancer patients navigate the CCT process. This chapter will present the research design, sample and setting, sampling procedures, data collection procedures, data analysis, and human subject protections.

Research Design

This study used a multimethod approach and primarily focused on a qualitative descriptive design with semi-structured face-to-face interviews⁷ and cell phone interviews with Black cancer patients involved in CCTs, and secondarily, descriptive quantitative items of the sample's sociodemographics and a measure of symptom burden (the Memorial Symptom Assessment Scale-Short Form). Elements of real-time data capture were also used to understand patient-participants' everyday qualitative experiences in CCTs. A multimethod approach is appropriate when the researcher uses two types of data collection methods to understand the research problem; and, the data are not usually combined (Tashakkori & Teddlie, 2003). As stated, the qualitative descriptive design

⁷ The "face-to-face" interview was defined, and intended, to be the initial interview conducted and immediately proximal to completion of the Informed Consent form, the HIPAA Authorization, the Sociodemographic form, and the Memorial Symptom Assessment Scale-Short Form. For this reason, it was considered the face-to-face interview. It was conducted in the patient-participants' private infusion room or in a private room in the Radiation Oncology department. Three patient-participants requested the initial interview to occur at a later time in their homes. Since the patient-participants routinely used cell phones, the initial interviews were conducted via cell phones. These three initial "face-to-face" interviews were included only in the Specific Aim One data.

was primary in this study and is appropriate when one wants to describe the perceptions and experiences of the target population, as well as an accurate accounting of the phenomena and events surrounding occurrence of the phenomena (Sandelowski, 2000; Sullivan-Bolyai et al., 2005). Qualitative description enables a “straight descriptive summary of the informational contents of data organized in a way that best fits the data (Sandelowski, p. 338-339, 2000).” A broad range of data may be used to describe the phenomenon, or event, under study. However, the descriptions must depict accurately the event in the proper sequence and have descriptive validity, or present an event in a manner that individuals observing the event would state is truthful (Sandelowski, 2000).

Qualitative description is the preferred method for this dissertation study for several reasons. First, it provides a rich description of the experiences of Black cancer patients during the CCT process; second, it identifies and explains the nuances of external and internal influences on treatment decision-making; third, it grounds the patient-participant’s experiences and perceptions within the context of a specified event—CCT participation, and; fourth, it ascertains the elements of a patient-participant’s intra- and inter-personal experience which cannot be quantified by a questionnaire (Hsieh & Shannon, 2005; Kearney, 2001; Sofaer, 1999). Use of qualitative description permits chronicling of CCT experiences in the everyday language of the patient-participants, while shedding light on what was happening outside of the clinical setting as the patient-participants navigated through the clinical trial process and the daily events of their lives. Qualitative content analysis, the preferred method of analysis for qualitative description, is used to analyze the semi-structured face-to-face interviews and the semi-structured cell

phone interviews with both a deductive and inductive lens (Sandelowski, 2000). This is described later in the chapter.

Setting and Sample

A large northeastern Cancer Center, a National Cancer Institute-designated (NCI-designated) comprehensive cancer center, was the setting for this dissertation study. In 2010, this Cancer Center enrolled 1,322 individuals in therapeutic cancer clinical trials. Of this number, 242 individuals who self-identified as Black or African American were enrolled in these specific types of cancer clinical trials. For the purpose of this dissertation study and as defined by the Cancer Center, a therapeutic cancer clinical trial was defined as a cancer clinical trial with curative intent that uses "drugs, radiation, surgery, other biological agents, or behavioral or other interventions" (Vicki Sallee, personal communication, July 8, 2011).

The sample for this study was drawn from a purposive sample of Black cancer patients enrolled in CCTs at the Cancer Center's outpatient oncology departments. The outpatient setting was chosen to minimize the likelihood of severe symptom burden. Patient-participants who were 18 years of age or older were drawn from the following types of CCT: breast, colorectal, lung, prostate, multiple myeloma, leukemia, cervical, pancreatic, head and neck (oral cavity, pharynx, and esophagus), gastric, liver, and uterine. Of these cancers, breast, prostate, lung, and colorectal cancer are the four leading causes of cancer death among Black cancer patients and have the highest incidence among Black adults with cancer (National Cancer Institute, 2012). In the remaining cancer types, Black men and women had higher incidence rates than White

men and women (DeSantis et al., 2016). Both men and women were eligible to participate in the dissertation study. Transgender individuals were not excluded from the study. Children were not included in this study, because the study was focused on adults with cancer.

Sample Size

The projected sample size for this study was 30 patient-participants who self-identified as Black. This original sample size was estimated to be 30 for two reasons: first to gather data qualitatively from a heterogeneous sample of cancer patient-participants, and second, to quantitatively compare symptom burden at two different time points (see below for discussion of this approach). First, qualitative researchers have agreed that there is no principal rule for absolutely determining the appropriate sample size for a qualitative study (Patton, 2002; Sandelowski, 2000; Waltz, Strickland & Lenz, 2010). However, the sample size chosen must provide the relevant information to answer the research questions being posed and provide information-rich qualitative data to describe the phenomenon being studied (Malterud, 2001; Sandelowski, 2000; Patton, 2002, Waltz et al., 2010). Based on leading qualitative methodologists, 20-30 patient-participants usually are adequate to reach saturation, or when no new themes or patterns emerge from the data (Graneheim & Lundman, 2004; Hsieh & Shannon, 2005; Im & Chee, 2006; Sandelowski, 1995). Second, to quantitatively compare participants' symptom burden at two different time points, a sample of 30 achieved 80% power to detect a mean of paired differences equal to 0.4 with an estimated standard deviation

equal to 0.7 and with a significance level (alpha) of 0.05 using a two-sided paired t-test (Hofso et al., 2012)

Inclusion criteria for the study included cancer patients who were male, female, or transgender and who self-identified as Black and were 18 years of age or older; had a diagnosis of any of the following cancers: breast, gynecologic (uterine, cervical), gastrointestinal (colorectal, gastric, liver, pancreatic), lung, genitourinary (prostate), hematological (multiple myeloma, leukemia), and head and neck (oral cavity, pharynx, and esophagus); subjects actively participating in a CCT occurring in the outpatient setting for a minimum of one month; able to speak, read, write, and understand American English; and able to provide informed consent. Exclusion criteria included participation in a CCT as a palliative measure, enrollment in hospice or palliative care, inability to speak, read, write, or understand American English because of a physical, cognitive, or anatomic impairment, and inability to provide written consent.

A total of 21 patient-patient-participants successfully were recruited. The 21 patient-participants provided a total of 21 semi-structured face-to-face interviews and 45 semi-structured cell phone interviews. The face-to-face interviews range in length from 30 minutes to 120 minutes, while the cell phone interviews range in length from 15 minutes to 60 minutes. Nine patient-participants answered the items on the symptom burden (MSAS-SF) scale at baseline and again at the completion of all four time points for the cell phone interviews. Data saturation was reached for the qualitative portion of this study with 21 participants, when no new information emerged from the qualitative data (Guest, Bunce, & Johnson, 2006).

Data Collection Procedures

Once approval was acquired from the IRB, the Clinical Trials Scientific Review and Monitoring Committee (CTSRMC), and the oncology attending physicians, eligible prospective patient-participants were contacted in person in order to acquire their assent to discuss this study. If assent was given, the doctoral candidate described this study to the prospective patient-participant, who was given the Informed Consent and HIPAA Forms to take home to review at their leisure with their families. A minimum of two attempts were made to re-connect with prospective patient-participants to discuss the Informed Consent and HIPAA Forms in person on the day of an outpatient appointment at the Cancer Center. If these attempts were unsuccessful, she attempted to contact them by cell phone or by their home telephone, where applicable. As stated, five prospective patient participants could not be contacted.

For those who chose to participate, the prospective patient-participants were met at their next appointment at the Cancer Center to discuss further the study and to obtain formal, written informed consent and HIPAA approval. Also, during this meeting and after acquisition of Informed Consent and HIPAA, a semi-structured face-to-face interview was performed and socio-demographic and symptom burden data were collected, when possible. Occasionally, due to the patient-participants' schedules, personal preference, or symptom burden, the semi-structured face-to-face interview, socio-demographic data, and/or symptom burden data were collected at another meeting or by cell phone. Twenty of the twenty-one patient-participants completed the face-to-face semi-structured interview, socio-demographic form, and the MSAS-SF. As stated, a

modification was sought and received to retain only the face-to-face interview of one patient-participant. This participant did not complete the socio-demographic form and MSAS-SF. Cellphones were also used in this study as a means to speak with participants about their everyday experiences related to cancer clinical trials over time and within their situational contexts (this is discussed under Elements of RTDC) (See Figure 3-2 in Section Discussing Real Time Data Collection).⁸

Semi-structured Interview, Demographics, and Assessment of Symptom Burden

A socio-demographic form and symptom burden measure, the Memorial Symptom Assessment Scale, Short Form (MSAS-SF), were administered to each patient-participant following acquisition of informed consent and HIPAA approval. The MSAS-SF measure provided information about physical and psychological symptom burden (e.g., fatigue, loss of appetite, irritability, feeling sad). The MSAS-SF was given a second time to patient-participants who completed all four cell phone interviews. The intended purpose was to perform an assessment of symptom burden at baseline and then following completion of the four cell phone interviews for all enrolled patient-participants. Twenty of the twenty-one patient-participants completed the MSAS-SF at baseline. Only nine patient-participants completed the MSAS-SF at both time points (see Chapter 4 for baseline descriptive data).

The face-to-face interview was expected to last approximately 45-60 minutes. It was comprised of several open-ended questions, approved by the IRB, and adapted from

⁸ At the time the doctoral candidate applied successfully for F31 funding (1F31NR013847-01A1) from the dissertation study from the National Institutes of Health in 2012, the use of cell phones to collect qualitative data was considered novel.

Ulrich et al. (2012) (e.g., “I would like to start by having you tell me in your own words what made you decide to enroll in a CCT”) accompanied by spontaneous and planned probes to clarify patient-participants’ thoughts on the relevant aspects of CCT participation (See Appendix A). The semi-structured face-to-face and cell phone interviews were conducted by the doctoral candidate.

Adapted Use of Element of Real-Time Data Capture (RTDC) and Procedures for Cell Phone Interviews

Adapting elements of RTDC via EMA enabled patient-participants to self-report their present, or most recent, (1) thoughts and experiences about participation in clinical trials in their own words, (2) advantageous and disadvantageous factors influencing their continued participation in their specific clinical trial, and (3) experiences navigating the clinical trial process. By using elements of RTDC, recall bias was reduced by focusing on patient-participants’ immediate, or most recent, experiences as they occurred within the context of their environment. During the course of their CCT enrollments, patient-participants self-reported symptom distress, such as fatigue and pain—all of which may have influenced their self-report. RTDC afforded the ability to gather self-report data in each patient-participant’s environment

Figure 3-1: Brief Telephone Interview Questions for Real-Time Data Capture

1. How are you today? Can you briefly describe how you are feeling today? How long have you been in the trial at this point?
2. Would you briefly describe (in your own words) ONE EVENT today that stands out in your mind related to your participation in the CCT. The event you describe can be positive, negative, or neutral.
3. In your own words, briefly describe your experience with the clinical research team. What has been helpful or not so helpful in your care and treatment?
4. Can you share and describe any symptoms that you have been experiencing and how you are managing them. This can be of any type that is important to you.
5. What are the challenges that you have been facing as you continue to participate in the cancer clinical trial? Can you share a few of these that are most important to you?

and to identify contextual associations, or the concurrent interaction of phenomena such as events or experiences, which may have impacted decisions to participate or remain in CCTs. This was done through the use of cell phone interviews with a combination of random and event-based data collection methods. Event-based sampling involves data collection concentrated around a specific occurrence or experience; in this dissertation study, it was centered on patient-participants' scheduled CCT outpatient appointments (Stone et al., 2007). The four cell phone interviews were also conducted randomly, (i.e., at variable intervals in order to collect representative examples of experiences), during a patient-participant's waking hours and ideally within 24-48 hours of a patient-participant's outpatient appointment with a member of the CCT team (i.e., oncologist, nurse practitioner, or clinical trial research nurse) (Badr, Basen-Engquist, Taylor, & De Moor, 2006). Patient-participants were instructed to self-report information, impressions, and/or experiences as of that moment, rather than provide a summary of this information. By using cell phones to collect qualitative experiential data in real-time, instances of recall bias may have been avoided.

The five basic questions in Figure 3-1 were used initially during the first real-time telephone interview to gather the patient-participants' real-time life issues associated with their participation in their respective trial. These questions were sufficiently general to elicit a broad range of responses, which could be narrowed or clarified through the use of spontaneous and planned probes. For example, the questions ascertained how the patient-participants' were feeling and their general thoughts on their participation in the trial. In addition, the patient-participants were asked questions about symptoms that might impact

their thoughts on continued participation and also any challenges they were currently facing. Each subsequent real-time interview was uniquely representative of the patient-participant's experiences and perceptions of CCT decision-making factors for that day. As is standard in qualitative methodology, the cell phone interview questions changed slightly each time a patient-participant was called to reflect the effect of on-going data analysis and the acquisition of new information regarding patient-participants' experiences.

Each patient-participant was called four times over a two-month period (i.e., six to eight weeks). If the patient-participant was non-responsive when called, the doctoral candidate attempted three more times at five minute intervals to contact the patient-participant. If the patient-participant remained non-responsive, she attempted to contact the patient-participant again 24 hours later—using the same procedure. If the patient-participant continued to remain non-responsive, the doctoral candidate attempted to contact the patient-participant 24-48 hours proximate to when their next outpatient appointment was performed. At the end of the two-month study period, each patient-participant was given an opportunity to ask any final questions, and to review several portions of their interviews to confirm they were accurate representations of their responses. Patient-participants who were unable to complete all four cell phone interviews (and who were not lost to follow-up) also were given an opportunity to ask any final questions.

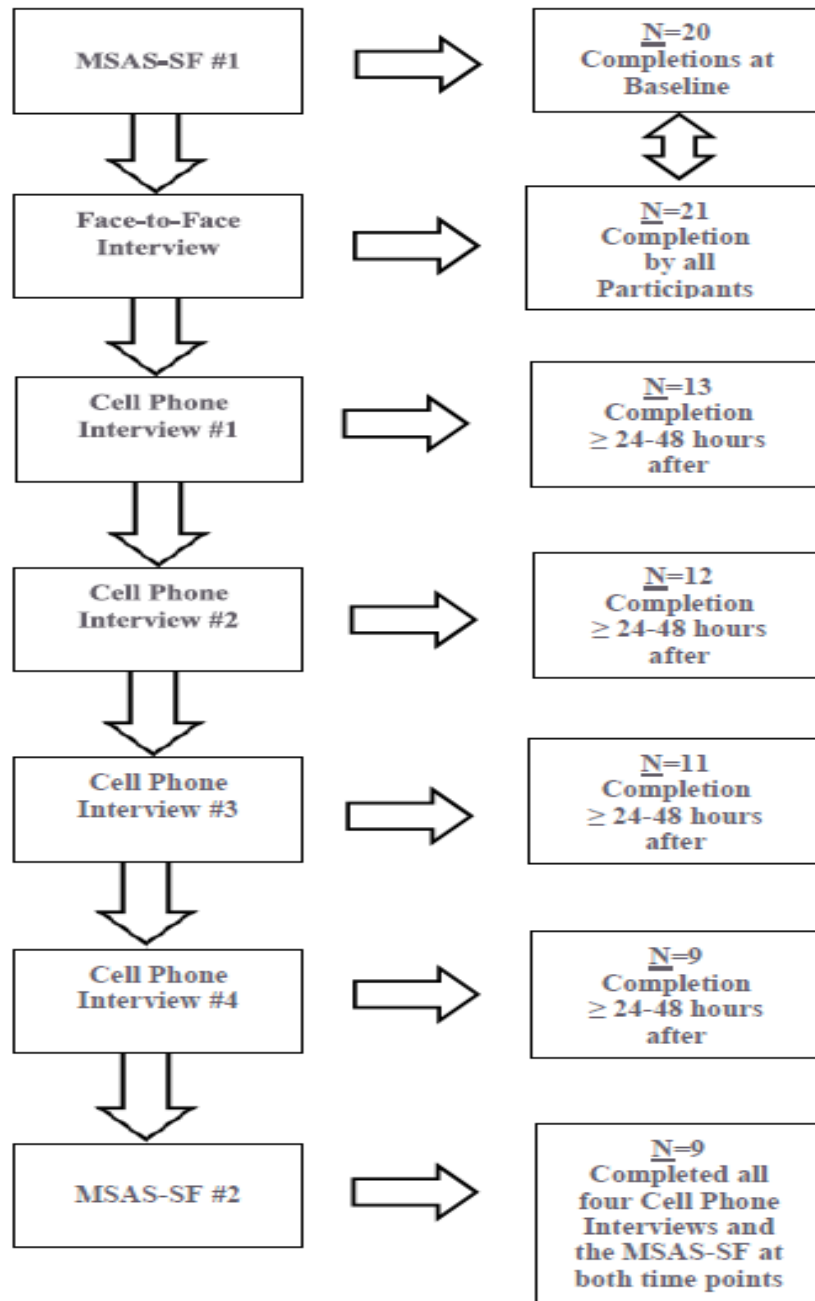


Figure 3-2: Data Collection Procedure

Privacy During Data Collection

Initial semi-structured interviews were administered in private rooms where patient-participants received their CCT treatment, or in a private room in the radiation oncology department provided by the Director of Clinical Research (for the patient-participants receiving radiation therapy). Three patient-participants' requested that their initial interview be conducted via cell-phone while they were in their homes. For all interviews, privacy procedures were maintained.

For any cell phone interview (initial, if requested, and for those that took place as part of the second aim), the doctoral candidate ascertained (according to the subject's willingness to provide this information) (1) where the patient-participant was located and whether a secondary telephone number at the location was available, (2) who was present in close proximity and their contact information, (3) whether the patient-participant felt safe and secure where they were located, (4) whether the patient-participant felt comfortable sharing private information and/or information related to their cancer clinical trial over the phone, (5) whether the patient-participant had any resources in close proximity or readily available in case of severe symptoms (e.g., oxygen or bronchodilators for breathlessness or shortness of breath, or the telephone number of their physician or a caregiver who can be contacted immediately), and (6) in case of a medical emergency, whereby the patient-participant was unable to respond to first responders on the scene and provide medical information, the doctoral candidate had permission to provide the patient-participant's private medical information.

To address privacy⁹ concerns, the doctoral candidate also developed a formal, verbal script to be used during the course of cell phone interviews that included the following sample queries prior to the initiation of the interview as required by the IRB:

- “Are you comfortable talking to me at this point? Are you by yourself or are there other individuals present? Is this okay with you? Would you like me to call you back at another time to protect your privacy?”
- “At this moment where are you located? Is someone close enough to you to hear your conversation with me? If someone is close enough to hear our conversation, are you comfortable with that person listening to our conversation?”

“If yes, do you want me to start our conversation about your experiences in your cancer clinical trial?” “If no, would you like me to call back at another time? Would you like to move to a place where you can answer my questions without anyone listening nearby?”

To further ensure the privacy of the patient-participants, the doctoral candidate included the formal, verbal script in the IRB application and collected all information in the aggregate so that personal information was not identifiable. In addition, prior to initiating the cellphone interviews, each patient-participant was told that the cellphone conversation was being audio-recorded and asked their permission to audio-record the conversation. Finally, HIPAA requirements were followed for the collection of private information during the course of the cellphone interview

⁹ Privacy is the right of an individual to control access to their personal, or private, information. Private information is inclusive of information occurring in the context that the individual would not expect recording or observation to occur, is provided for a specific purpose, and is provided with the expectation that the information will not be made public.

Human Subjects Protection

This study involved data collection from individuals actively involved in a therapeutic CCT. Approval from the IRB and the CTSRMC were obtained on August 13, 2013, and June 27, 2013, respectively, before the proposed study was initiated. Upon agreeing to participate and completing the Informed Consent and HIPAA documents, each patient-participant was assigned a patient-participant number for confidentiality purposes. Further, each patient-participant received a pseudonym to be used throughout the entire study as part of all qualitative interviews. Patient-participants were permitted the opportunity to choose their pseudonym. Two patient-participants refused pseudonyms; they were assigned a pseudonym. The patient-participant number and pseudonym were matched and recorded on a document. This document and all data (hard copies of written documents, including field notes, transcripts, and audio-recordings) in the proposed study, were stored at the University of Pennsylvania School of Nursing in a locked drawer in a locked office specifically dedicated for research files. Only the doctoral candidate and members of the Dissertation Committee (Study Personnel) had access to the data.

A telephone located in a locked, secured office at the University of Pennsylvania School of Nursing was used to call the patient-participants for this study. The interviews (face-to-face and cell phone) were audio-recorded using a password-protected digital audio-recorder. A research database was created and stored on a password protected secured drive at the University of Pennsylvania School of Nursing. Access to the database was available only to Study Personnel. All interviews were transcribed by a

professional transcription service. The transcribed interviews were scanned into a dedicated, password-protected, research computer drive for review by the doctoral candidate and her sponsors. All research drives are backed up daily by OTIS. The data on the research drive will be housed for five years and then destroyed. Finally, anticipation of the possibility of severe symptoms occurring during the cell phone interviews was addressed by developing an Emergency Action Plan to deal with any situation in which a patient-participant experienced severe symptoms during the cell phone interview. The Emergency Action Plan was not implemented during the course of the study.

Compensation

Patient-participants were compensated the equivalent of a \$5.00 gift card for the initial face-to face interview, the initial MSAS-SF assessment, each successfully obtained cell phone interview, and the final MSAS-SF assessment. Use of personal time and the risk of temporary fatigue were the most reasonably foreseeable burdens of this research study. For the entire study period, a patient-participant had the opportunity to receive \$35 for their involvement. This mode of payment was consistent with the wage-payment model which is based on the premise that research patient-participants should be paid on a payment scale commensurate with unskilled labor, provided that the payment is augmented for uncomfortable or burdensome procedures (Dickert & Grady, 1999).

Instrumentation

Demographic and Clinical Characteristics

A socio-demographic form collected demographic information from the patient-participants, such as age, gender, educational level, insurance status, and marital status. (See Appendix D). Clinical factors gathered included items such as medical history, cancer diagnosis, stage of cancer, healthcare coverage and benefits, caregiver and social supports, and communication with healthcare providers. Data from the socio-demographic form were supplemented by data from the patient-participants' electronic medical record.

Memorial Symptom Assessment Scale-Short Form (MSAS-SF)

The MSAS-SF is a shortened form of the Memorial Symptom Assessment Scale (MSAS) (See Appendix E). The MSAS-SF is a 32-item, patient-rated instrument that measures the most common physical and psychological symptoms experienced by cancer patients during cancer treatment; it also includes a global distress scale (Chang et al., 2000; Portnoy et al., 1994; Trammer et al., 2003; Kirkova et al. 2006). The benefits of using the MSAS-SF were three-fold: (1) it contained one-third the number of items of the original measure; (2) it took approximately five minutes to complete; and, (3) it captured the important components of physical and psychological burden (Chang et al., 2000). The MSAS-SF had subscales measuring physical symptom distress (PHYS), psychologic symptom distress (PSYCH), and a 10-item global distress index (GDI). Also, a total score was calculated and represented an average of the symptom scores (TMSAS). Items in the MSAS-SF were measured on a Likert scale from 0 (no symptoms) to 4 (symptom present

and causes very much distress) for the PHYS symptoms and from 0 (symptom is absent) to 4 (symptom is present and occurs constantly) for PSYCH symptoms (see Appendix). For the PHYS and PSYCH scales, a higher number indicates greater symptom distress and increased presence of physical and psychological symptoms, respectively.

Psychometric Properties of the MSAS-SF

The psychometric properties of the MSAS-SF include both reliability and validity testing. Internal consistency Cronbach alpha coefficients for the MSAS-SF subscales were: 0.80 for the GDI; 0.82 for the PHYS; 0.76 for the PSYCH; and 0.87 for the TMSAS (Chang et al., 2000). It also had been shown to exhibit convergent validity with extent of disease, performance status, and inpatient status (Chang et al., 2000). The GDI has an internal consistency reliability of 0.87.

The MSAS-SF also has demonstrated convergent validity with the Functional Assessment Cancer Therapy General (FACT-G), a general, validated 28-item measure of quality of life for all cancer types (Chang et al., 2000). It has been used among patient-participants in cancer clinical trials and has demonstrated sensitivity for determining performance status and extent of disease (Chang et al., 2000). For criterion validity, assessment of the MSAS-SF subscales with the FACT-G subscales showed the following correlation coefficients: -0.74 ($P < 0.001$) for the MSAS-SF physical symptom subscales and the FACT-G physical well-being subscales, -0.68 ($P < 0.001$) for the MSAS-SF psychological subscales and FACT-G emotional well-being subscales, and -0.70 ($P < 0.001$) for the MSAS-SF global distress scale and the FACT-G summary of quality-of-life subscales (Chang et al., 2000).

Qualitative Data Analysis

Qualitative data for this study were analyzed using qualitative content analysis (Graneheim & Lundman, 2004; Hsieh & Shannon, 2005). Qualitative content analysis is a qualitative research method that is used for the “subjective interpretation of the content of text data through the systematic classification process of coding and identifying themes or patterns (Hsieh & Shannon, p. 1278, 2005).” It can be employed to validate an existing conceptual or theoretical framework (directed content analysis) or to elucidate phenomena for which a paucity of research exists (inductive content analysis) (Hsieh & Shannon, 2005). Content analysis of the text-based information from the audio-taped interviews was instrumental in identifying and describing the decisional factors that influenced the patient-participants research decisions (deductive approach), as well as their everyday experiences in CCTs (inductive approach). The face-to-face interviews and cell phone interviews were audiotaped, transcribed verbatim by a professional transcription service, and loaded onto a computer for analysis using ATLAS software. Field notes were entered in ATLAS software and analyzed, as well. Confidentiality of the data was maintained at all times consistent with IRB guidelines and HIPAA requirements (see Human Subjects). Content analysis began with reading the text data in their entirety repeatedly, in order to get a sense of the data. From this point, the analytic path diverged, depending upon whether directed content analysis, or inductive content analysis, was employed (See Figure 3-3).

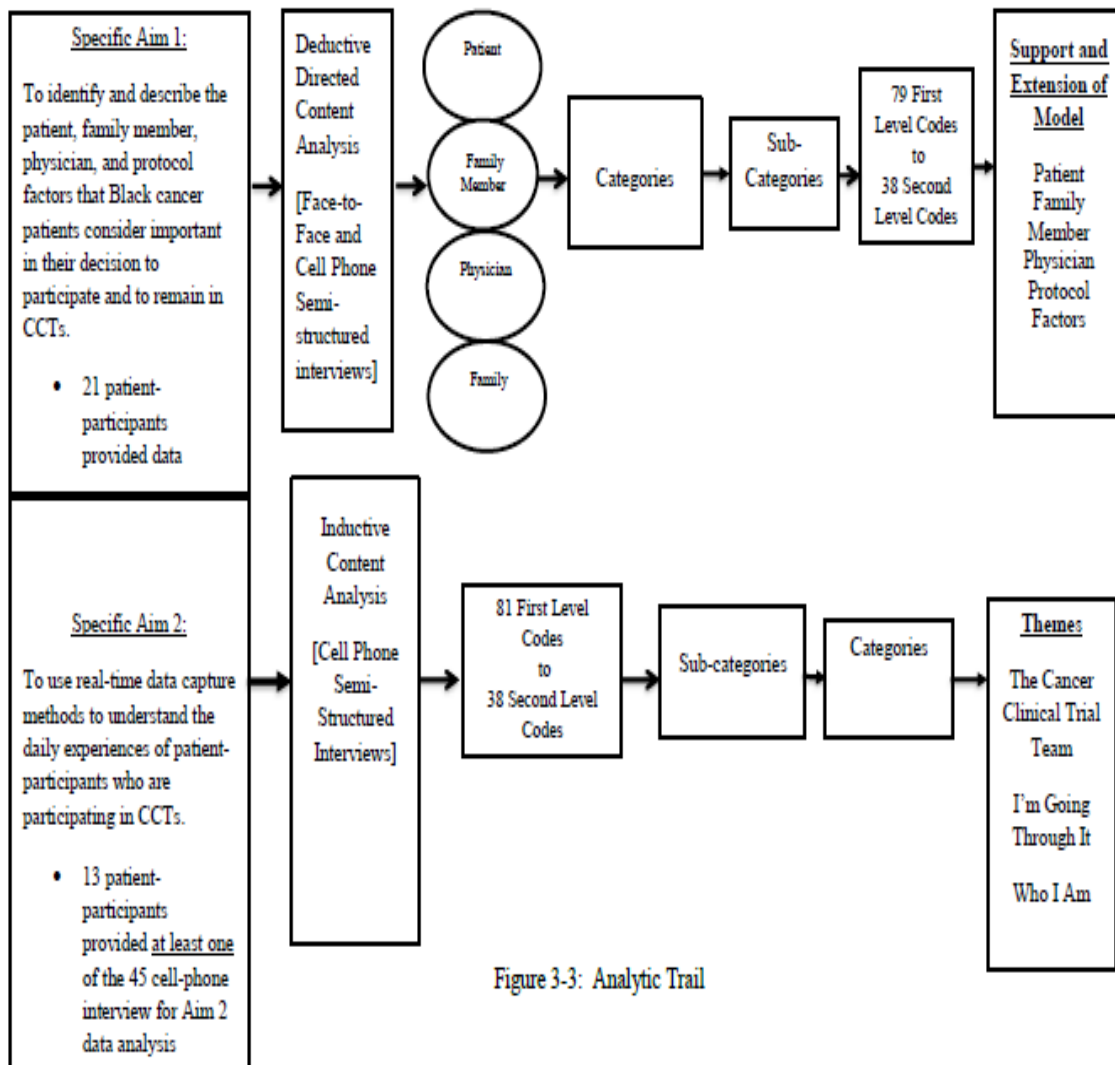


Figure 3-3: Analytic Trail

Directed content analysis was used for analysis of data for the first specific aim. Characterized by a more structured process based upon existing theory or theoretical framework, Coding was begun by using the four factors of the Albrecht Model (patient, family member, physician, and protocol) as initial coding themes (Hsieh & Shannon, 2005). Coding of the initial semi-structured interviews continued based upon the four themes and moved on to the two categories for this aim: CCT participation and CCT retention (Elo & Kyngas, 2008). From there, analysis progressed to sub-categories where the depth and breadth of the data permitted—then, the data was coded (first level codes were collapsed into second level codes) according to the categories and sub-categories (Elo & Kyngas, 2008; Hsieh & Shannon, 2005).

Inductive content analysis was used for Specific Aim Two. Text was extracted from the four cell phone interviews that took place after the initial interview at baseline and was divided into content areas, characterized by common patterns, phrases, and important features. The language was categorized into groups with similar meanings and themes emerging from the categories were identified (Graneheim & Lundman, 2004; Hsieh & Shannon, 2005). Last, commonalities and differences between the data were identified and extracted for further analysis, formalization of themes from the data were drawn, and the themes were analyzed and compared. The following also were formulated from the data: (a) meaning units, (b) condensed meaning units, (c) codes (first level codes were collapsed into second level codes), (d) a list of codes, (e) codes with quotes or exemplars, (f) a frequency table for the occurrence of codes, (g) sub-categories (where applicable) and categories, (h) themes, and (i) matrices displaying the themes,

categories, sub-categories (where applicable), and codes (Curry, Nembhard, & Bradley, 2009; Elo & Kyngas, 2008; Graneheim & Lundman, 2004). Codes were *in vivo* for both directed and inductive content analyses. Data were reviewed by the Dissertation Chair, the Qualitative Methods Consultant, by senior members of the Advanced Qualitative Collective (Sarah Abboud, PhD, RN; Elizabeth Froh, PhD, RN; and Kim Mooney-Doyle, PhD, RN), and the Advanced Qualitative Collective, a group of doctoral and post-doctoral students from the University of Pennsylvania School of Nursing and other academic departments of the University of Pennsylvania who, facilitated by a faculty member of the University of Pennsylvania expert in qualitative research, met on a regular basis to provide support and study of qualitative inquiry.

Scientific Adequacy and Rigor

Scientific adequacy and rigor in qualitative studies required adherence to well-established practices that ensured trustworthiness. Trustworthiness, or what is considered the reliability and validity of qualitative research, was measured by credibility, dependability, and transferability (Curry, Nembhard & Bradley, 2009; Graneheim & Lundman 2004). Credibility was the certainty that the data and analytical processes address the phenomenon being studied and in this case reflects patient-participants' experiences in CCTs (Graneheim & Lundman, 2004; Sandelowski, 1986). Member checks were an acceptable means of ensuring credibility by confirming that the respondents' accounts were accurate representations of their experiences (Curry, Nembhard & Bradley, 2009). At their final meetings, the nine patient-participants who completed all four cell phone interviews reviewed portions of their qualitative data for

accuracy. At the completion of data collection and following completion of the data matrices, member checks were conducted with three patient-participants to determine whether the data accurately represented their experiences and the factors that influenced their decisions to participate and to remain in their CCT. Credibility also was maintained because the individuals comprising the sample were heterogeneous¹⁰ and provided a variety of thoughts on the issue under study (Graneheim & Lundman, 2004).

Confirmability was achieved by leaving a clear decision trail during the research process for others to review. An audit trail was maintained by providing clear descriptions of the doctoral candidate's progression throughout the research process (from IRB application through data analysis). This includes the data collection process and outcomes, decisions and judgments in data analysis (formulation of meaning units, codes, categories, etc.), and scheduled meetings with the Dissertation Chair and the senior members of the Advanced Qualitative Methods. An additional independent coder was not used as part of this dissertation study.

The use of independent coders to verify qualitative analysis was not strictly required. As noted by Wu, Thompson, Aroian, McQuaid, and Deatrck (2016), the goal of qualitative analysis is the training of qualitative researchers to be rigorous in data gathering, as well as using systematic procedures to document decision-making. Moreover, rather than "evaluating if two independent raters came to the same numeric rating, reviewers of qualitative manuscripts should judge to what extent the overall process of coding, data management, and data interpretation were systematic and

¹⁰ Although all patient-participants self-identified as Black, they were heterogeneous in areas such as cancer type, cancer stage, age, education level, and place of residence.

rigorous” (Wu et al., p. 500, 2016). To this end, the formulation of codes, sub-categories (where applicable), categories, themes, and data matrices were reviewed and refined at various points during analysis of the data with the Dissertation Chair, the Qualitative Consultant, the senior members of the Advanced Qualitative Collective, and the other members of the Advanced Qualitative Collective. Memoranda of the meetings with all relevant parties also were kept to ensure auditability or replication of the same study results by another researcher (Graneheim & Lundman, 2004; Sandelowski, 1986).

To ensure dependability of the research, there was consistency in the data collection methods and, again, scheduled meetings with the Dissertation Chair to assess consistency, similarities, and differences in the data (Graneheim & Lundman, 2004). Finally, to ensure transferability, the doctoral candidate provided clear descriptions of the sample characteristics, sample selection methods, and data procurement methods and analyses (Graneheim & Lundman, 2004).

Data Management and Quality Control

To maintain data quality and control, there were scheduled meetings with the Dissertation Chair to address any issues that might arise in the course of the study. Here, issues surrounding the consistency of the face-to-face and cell phone interviews, data saturation, development of key themes and patterns related to the data, and data classification, summarization, categorization, and coding were discussed. In addition, any ethical considerations (such as informed consent or respondent burden) that arose were discussed and addressed (See Human Subjects section).

Quantitative Data Analysis

Descriptive statistical analysis is used to summarize the information from the socio-demographic form and the MSAS-SF. Representative statistics include measures of central tendency, including means, variances, standard deviations, and frequencies. A descriptive analysis of the MSAS-SF data is presented in Chapter 4 and provides important information for future research and hypothesis generating questions. SPSS was used to store quantitative data reported in the aggregate. Data was housed on a research database created and stored on a password protected secured drive at the University of Pennsylvania School of Nursing. Data were entered twice in SPSS and checked for accuracy and completeness. Furthermore, data were reviewed with a statistician at the School of Nursing (Dr. Alexandra Hanlon) for completeness, processing, and interpretation. There were no missing data for the MSAS-SF and the socio-demographic form.

Summary

In summary, this chapter presents the research design, methodology, data collection procedures, data analysis, and human subjects protections used to address the purpose of the dissertation research. Qualitative description methodology captures the rich experiences of Black cancer patients actively enrolled in therapeutic CCTs. Analysis of data collected from semi-structured face-to-face interviews and semi-structured cell phone interviews via RTDC presents a rich, descriptive accounting of the patient-participants' CCT and every day cancer experiences, as well as a more complete representation of the Black cancer patients' symptom experience.

CHAPTER IV: FINDINGS

This chapter describes the findings of the research. It begins with an overview of the sample, wherein demographic information and descriptions of the members of the sample are provided. There will also be a presentation of the data results of the MSAS-SF. Next, an overview of the qualitative findings will be presented. Last, the two specific aims are addressed individually through explanation of the themes, categories, and sub-categories that emerged from the data. Supporting evidence from interviews is included. **Themes** are in bold font and underlined, **categories** are in bold font, *sub-categories* are italicized and underlined, and components (codes) are italicized.

Recruitment of Sample

Following receipt of approval from the Institutional Review Board at the University of Pennsylvania and the CTSRMC, the doctoral candidate sought and received email approval from oncology attending physicians to access and to recruit their patients enrolled in outpatient therapeutic CCTs. A meeting was held with the Cancer Center's clinical trial coordinators and clinical trial research nurses to discuss the purpose of the dissertation study. At this meeting and in the emails sent to the oncology attending physicians, written IRB and CTSRMC approval and appropriate supporting documents describing the dissertation study were provided. The Cancer Center's Regulatory Affairs Program Manager and the Director for Clinical Research for Radiation Oncology assisted the doctoral candidate in identifying the Black cancer patients who were enrolled in, or would be accruing to, eligible CCTs.

Both administrators provided lists of prospective patient-participants from October 2013 to November 2014, who were enrolled in CCTs in the cancers and cancer types eligible for recruitment for the dissertation study. The 48 prospective patient-participants identified by the two administrators were reduced to 46, following removal of duplicate records. The doctoral candidate reviewed the records of the 46 prospective patient-participants, individually as the lists were received, to determine eligibility for the dissertation study. Nineteen patient-participants were deemed ineligible on the following bases: (1) physically unable to participate secondary to laryngectomy (n = 1); (2) withdrawn from CCT before recruitment made by doctoral candidate (n = 3); (3) administrator listed prospective patient-participant enrolled in non-therapeutic CCT(n = 8); (4) self-identified as White (n = 2); (5) not enrolled in CCT (n = 1); (6) less than two appointments per month per CCT protocol (n = 2); and (7) died before recruitment attempt by doctoral candidate (n =1).

The doctoral candidate submitted successfully a modification to the dissertation study to include the face-to-face interview of one prospective patient-participant enrolled in a Phase 0, non-therapeutic CCT. This patient-participant only provided a face-to-face patient interview. Because she was a clinical trial coordinator at another nationally-ranked, Philadelphia healthcare/research institution, her participant perspective was singularly unique, as was her interview. Further, her understanding of the factors influencing clinical trial accrual and retention was unparalleled and her comments were candid and very insightful. With the addition of this face-to-face interview, there were 28 patient-participants eligible for recruitment. Of this number, two-patient participants

refused participation and the doctoral candidate was unsuccessful in her attempts to contact five patient-participants (See Figure 4-1).

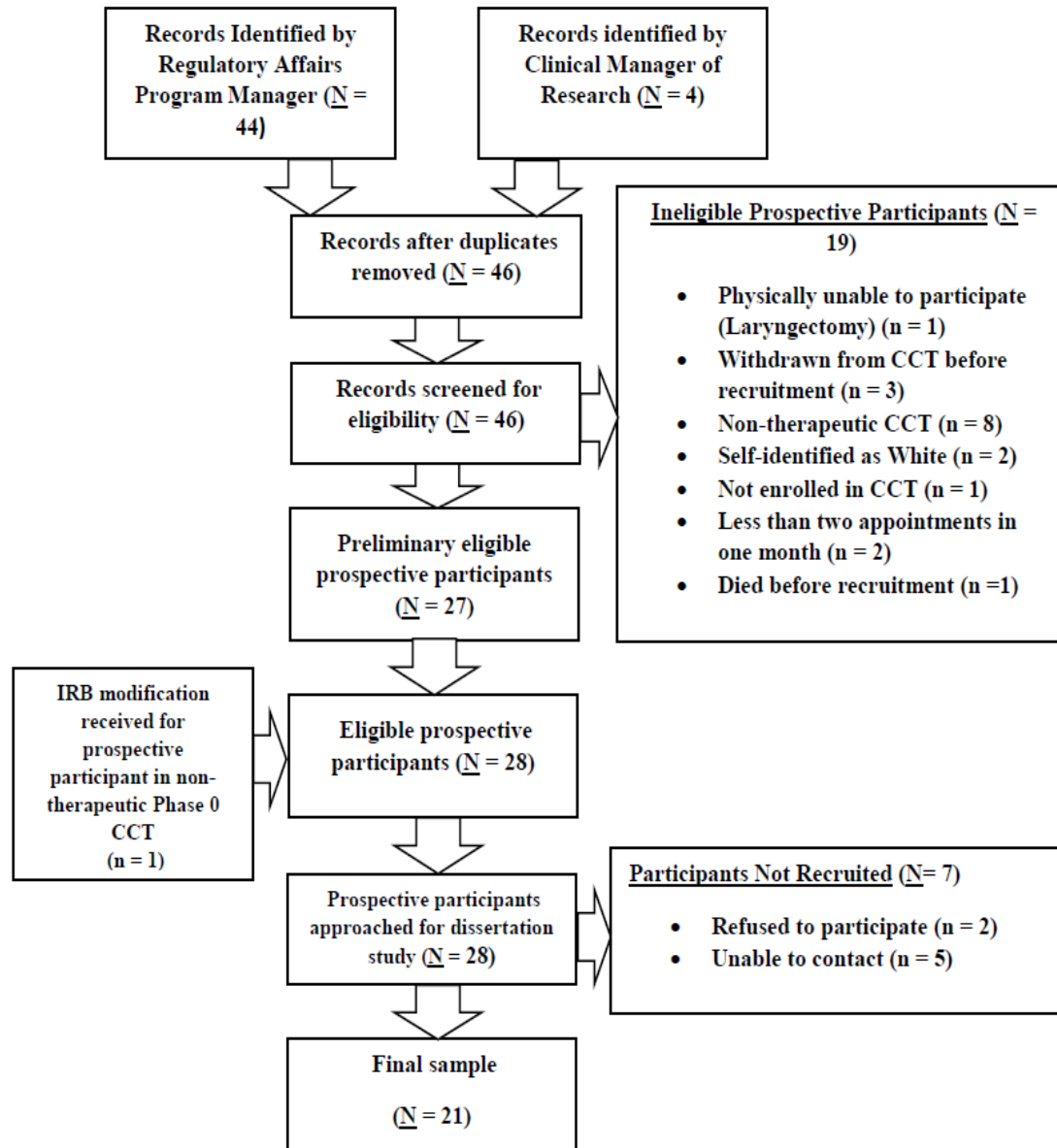


Figure 4-1: Recruitment Flowchart

Overview of the Sample

Demographic Information

A total of 66 interviews were completed with 21 patient-participants who met the inclusion criteria. Of the 66 interviews, 21 were face-to-face interviews and 45 were cell phone interviews. As discussed in Chapter 3, the first cell phone interview for each patient-participant began with the same five general questions. Each subsequent cell phone interview was uniquely representative of the patient-participant's experiences and perceptions of CCT decision-making factors for that day. Nine patient-participants (43%) completed the proposed dissertation study interview total: one face-to-face interview and four cell phone interviews. The remaining 12 patient-participants (57%) completed one face-to-face interview and zero to three cell phone interviews.

Patient-participants were drawn from a purposive sample of Black cancer patients enrolled in therapeutic CCTs at The Cancer Center. Of the 23 Black cancer patients approached, twenty-one agreed to participate and signed the requisite Informed Consent and HIPAA documentation. Consistent with the inclusion criteria, all of the patient-participants self-identified as Black. However, the 20 individuals whose demographic data were collected more specifically self-identified in the following manner: one Black/Other (5%), three Black/African (15%), and 16 Black/African American (80%). One patient-participant self-identified as Hispanic or Latino. The Black cancer patients comprising the sample were a demographically diverse group. They ranged in age from 42 years to 74 years ($SD = \pm 9.19$), had educational attainment from grade school to post-

graduate school, and had been receiving cancer treatment for less than one year to over ten years.

To acquire the richest data and to increase study accrual, patient-participants were drawn from the following cancer types: breast, colorectal, lung, prostate, multiple myeloma, leukemia, cervical, pancreatic, head and neck (oral cavity, pharynx, and esophagus), gastric, liver, and uterine. The 21 patient-participants were diagnosed with the following cancers types: breast (25%), prostate (25%), lung (15%), colorectal (15%), pancreatic (10%), and multiple myeloma (10%). Forty percent of patient-participants reported a stage four cancer status. All patient-participants had insurance coverage and reported spiritual or religious beliefs. Seventy percent of the sample had comorbid conditions. The sample was either equally, or nearly equally equivalent (55%-45%) on employment status and place of residence (suburban versus urban). Seventy-five percent of the Black cancer patient-participants reported having a caregiver, or caregivers, who supported them during their CCT participation—this percentage increased to nearly 100% when the data of the cell phone interviews were analyzed. Caregivers took various forms; they were spouses, children (below and above 18 years of age), close friends, cousins, and daughters-in-law.

The patient-participants comprising the sample valued information regarding their cancer diagnosis and CCT treatment. Eighty-five percent felt that it was extremely important to receive information about their cancer diagnosis and treatment. Sixty-five percent felt it was extremely important to receive information regarding their CCT treatment. Forty percent reported they had excellent communication with their oncologist

and rated their ability to get information from their oncologist about their cancer treatment and cancer diagnosis as excellent. Conversely, 45% of the patient-participants reported their ability to receive information regarding their cancer diagnosis and treatment from their nurse practitioner as excellent. For more detailed information regarding the sample's demographic characteristics, see Table 4-1 below:

Table-4-1: *Demographic Characteristics of Patient-participants*

Characteristic	Patient-participants (N=20) ^a
Age (Years)	56.70 (SD: +/- 9.19) (range: 42-74)
Gender (% male)	30% (<i>n</i> = 6)
Racial Background	
Black/African	15% (<i>n</i> = 3)
Black/African American	80% (<i>n</i> = 16)
Black/Other	5% (<i>n</i> = 1)
Ethnic Background	
Hispanic or Latino	5% (<i>n</i> = 1)
Education (Highest Achieved)	
8 th Grade or Less	5% (<i>n</i> = 1)
Some High School	5% (<i>n</i> = 1)
High School Graduate	15% (<i>n</i> = 3)
Some College	40% (<i>n</i> = 8)
College Graduate	15% (<i>n</i> = 3)
Graduate/Post-Graduate	20% (<i>n</i> = 4)
Marital Status	
Never Married	35% (<i>n</i> = 7)
Married	35% (<i>n</i> = 7)
Divorced	25% (<i>n</i> = 5)
Separated	5% (<i>n</i> = 1)
Cancer Type	
Breast	25% (<i>n</i> = 5)
Lung	15% (<i>n</i> = 3)

Colo-rectal	20% (<i>n</i> = 4)
Prostate	20% (<i>n</i> = 4)
Multiple Myeloma	10% (<i>n</i> = 2)
Pancreatic	10% (<i>n</i> = 2)
Years Living With Cancer	
0 to 1 Years	55% (<i>n</i> = 11)
2 to 5 Years	35% (<i>n</i> = 7)
6 to 10 years	10% (<i>n</i> = 2)
Cancer Treatment	
Chemotherapy	70% (<i>n</i> = 14)
Radiation	25% (<i>n</i> = 5)
Chemotherapy and Radiation	5% (<i>n</i> = 1)
Cancer Stage	
Don't Know	25% (<i>n</i> = 5)
Stage 1	5% (<i>n</i> = 1)
Stage 2	15% (<i>n</i> = 3)
Stage 3	10% (<i>n</i> = 2)
Stage 4	40% (<i>n</i> = 8)
No Stage	5% (<i>n</i> = 1)
Comorbid Condition*	
Yes	70% (<i>n</i> = 14)
No	30% (<i>n</i> = 6)
High Blood Pressure	35% (<i>n</i> = 7)
Blood Clots	15% (<i>n</i> = 3)
High Cholesterol	25% (<i>n</i> = 5)
Diabetes	20% (<i>n</i> = 4)
Migraine Headaches	5% (<i>n</i> = 1)
Diverticulosis	5% (<i>n</i> = 1)
GERD	5% (<i>n</i> = 1)
Living Area (Place of Residence)	
Urban	55% (<i>n</i> = 11)
Suburban	45% (<i>n</i> = 9)
Insurance*	
Yes	100% (<i>n</i> = 20)
Private Insurance	65% (<i>n</i> = 13)
Out of Pocket/Self Pay	5% (<i>n</i> = 1)

Medicare	40% (<i>n</i> = 8)
Medicaid	10% (<i>n</i> = 2)
VA	0% (<i>n</i> = 0)
Other	15% (<i>n</i> = 3)
Spiritual or Religious Beliefs	
Somewhat Important	5% (<i>n</i> =1)
Important	15% (<i>n</i> =3)
Very Important	35% (<i>n</i> =7)
Extremely Important	35% (<i>n</i> =9)
Employment	
Yes	50% (<i>n</i> =10)
No	50% (<i>n</i> =10)
Caregiver	
Yes	75% (<i>n</i> =15)
No	25% (<i>n</i> =5)
Importance of Caregiver	
A Little Important	10% (<i>n</i> =2)
Somewhat Important	5% (<i>n</i> =1)
Important	5% (<i>n</i> =1)
Very Important	25% (<i>n</i> =5)
Extremely Important	30% (<i>n</i> =6)
Not Applicable	25% (<i>n</i> =5)
Caregiver Type*	
Spouse	30% (<i>n</i> =6)
Sibling	20% (<i>n</i> =4)
Parent	10% (<i>n</i> =2)
Child	35% (<i>n</i> =7)
Friend	10% (<i>n</i> =2)
Daughter-in-law	5% (<i>n</i> =1)
Cousin	5% (<i>n</i> =1)
Importance of Receiving Information	
About Cancer Diagnosis and Treatment	
Important	5% (<i>n</i> =1)
Very Important	10% (<i>n</i> =2)
Extremely Important	85% (<i>n</i> =17)
Importance of Getting Information About	

CCT Treatment	
Very Important	35% (n=7)
Extremely Important	65% (n=13)
Rate Communication with Oncologist	
Fair	10% (n=2)
Good	15% (n=3)
Very Good	40% (n=8)
Excellent	35% (n=7)
Rate Communication with Nurse Practitioner	
Fair	15% (n=3)
Good	10% (n=2)
Very Good	35% (n=7)
Excellent	40% (n=8)

Note. ^a One of the patient-participants was involved in a non-therapeutic Phase 0 CCT (a CCT non-curative in nature whose purpose is to determine the pharmacodynamics and pharmacotherapeutics of Bortezomib). Her demographic information does not appear in Table 4-1. *More than one choice was available; resulting percentage may not equal 100%.

Symptom Distress and Symptom Frequency (The MSAS-SF)

The MSAS-SF measured the symptom distress and frequency of symptoms experienced by the patient-participants. The MSAS-SF data were collected at baseline (following receipt of Informed Consent and always prior to the face-to-face interview) for each patient-participant. As stated in Chapter Three, there were three symptom distress subscales which encompassed measurement of physical distress (PHYS), psychological distress (PSYCH), and global distress (GDI). The PHYS distress scale measured physical symptom burden and was calculated by the average of 12 symptoms (i.e., lack of appetite, lack of energy, pain, feeling drowsy, constipation, dry mouth, nausea, vomiting, changes in taste, weight loss, feeling bloated, and dizziness). These and the remaining physical symptoms were scored in increments of 0.8 (indicated that a symptom was

present and caused no distress) up to 4.0 (indicated a symptom was present and resulted in very much distress). Zero was assigned when a patient-participant did not experience a symptom. The PSYCH scale assessed the distress corresponding to the following six psychological symptoms: worrying, feeling sad, feeling nervous, difficulty sleeping, feeling irritable, and difficulty concentrating. The PSYCH scale is scaled in increments of one up to four, with one indicating the patient-participant experienced a symptom “rarely” and 4 indicating a symptom was experienced for “almost constantly.” Zero represents that the patient-participant did not experience a symptom. The GDI was calculated by averaging the frequency of four prevalent psychological symptoms (i.e., feeling sad, worrying, feeling irritable, and feeling nervous) and six prevalent physical symptoms (i.e., lack of appetite, lack of energy, pain, feeling drowsy, constipation, and dry mouth).

The PHYS distress scale values for patient-participants ranged from 0 to 2.93. The mean PHYS distress scale value was 1.09—zero signified that patient-participants did not experience any overall symptom distress, while 2.93 represented a moderate level of symptom distress. The PSYCH distress values ranged from 0 to 2.43. The mean PSYCH value was 0.77. For the patient-participants, the GDI ranged from 0 to 2.90. The mean GDI for the sample was 1.09. Overall, patient-participants were mildly to moderately distressed with their physical symptoms and minimally distressed with psychological symptoms. Patient-participants experienced the following symptoms the most frequently: “Lack of Energy,” “Pain,” and “Change in Taste.” The following symptoms were tied for the fourth most frequently experienced symptom: “Changes in

Skin,” “Numbness and Tingling,” “Lack of Appetite,” and “Feeling Irritable.” “Hair Loss” and “Changes in Skin” were the most distressing symptoms for the study sample. “Difficulty Swallowing” was the least distressing symptom. The only symptom not experienced by at least one member of the sample was “Mouth Sores.” Patient-participants’ symptom experience will be discussed in more detail when reporting their real-time experiences. For more detailed information regarding the sample’s symptom distress and symptom frequency, see Table 4-2 and Table 4-3 below:

Table-4-2: *Physical Symptom Frequency (MSAS-SF) (n=20)^a*

Symptom	Did not Experience Symptom N (%) ^b	No Distress N (%)	Little Bit Distress N (%)	Somewhat Distress N (%)	Quite a Bit Distress N (%)	Very Much Distress N (%)
Difficulty Concentrating	16 (80)	1 (5)	1 (5)	2 (10)	--	--
Pain	7 (35)	1 (5)	2 (10)	5 (25)	3 (15)	2 (10)
Lack of Energy	4 (20)	--	3 (15)	7 (35)	4 (20)	2 (10)
Cough	14 (70)	--	2 (10)	1 (5)	2 (10)	1 (5)
Changes in Skin	10 (50)	1 (5)	2 (10)	3 (15)	--	5 (20)
Dry Mouth	12 (60)	--	5 (20)	1 (5)	2 (10)	--
Nausea	12 (60)	--	5 (20)	1 (5)	1 (5)	1 (5)
Feeling Drowsy	10 (50)	1 (5)	3 (15)	3 (15)	3 (15)	--
Numbness/Tingling (Hands/Feet)	9 (45)	--	2 (10)	3 (15)	3 (15)	3 (15)
Difficulty Sleeping	11 (55)	--	2 (10)	3 (15)	2(10)	2 (10)
Feeling Bloating	13 (65)	--	4 (20)	1 (5)	2 (10)	--
Problems with Urination	15 (75)	--	--	3 (15)	1 (5)	1 (5)
Vomiting	17 (85)	--	--	1 (5)	--	2 (10)
Shortness of Breath	12 (60)	--	5 (25)	--	3 (15)	0
Diarrhea	11 (55)	1 (5)	2 (10)	2 (10)	2 (10)	2 (10)
Sweats	10 (50)	1 (5)	5 (20)	2 (10)	1 (5)	1 (5)
Mouth Sores	20 (100)	--	--	--	--	--
Prob. Sexual Interest/Activity	14 (70)	--	2 (10)	2 (10)	1 (5)	1 (5)
Itching	13 (65)	--	3 (15)	1 (5)	2 (10)	1 (5)
Lack of Appetite	9 (45)	1(5)	4 (20)	3 (15)	2 (10)	1(5)

Dizziness	16 (80)	--	3 (15)	--	--	1 (5)
Difficulty Swallowing	17 (85)	1(5)	--	--	2 (10)	--
Changes Food Taste	8 (40)	1 (5)	2 (10)	3 (15)	3 (15)	3 (15)
Weight Loss	13 (65)	--	2 (10)	3 (15)	1 (5)	1(5)
Hair Loss	14 (70)	--	--	2 (10)	2 (10)	2 (10)
Constipation	12 (60)	--	2 (10)	1 (5)	1 (5)	4 (20)
Swelling Arms or Legs	16 (80)	1 (5)	--	--	1 (5)	2 (10)
Don't Look Like Self	15 (75)	--	--	2 (10)	3 (15)	--

Table 4-3: *Psychological Symptom Frequency (MSAS-SF) (n=20)^a*

Symptom	Did Not Experience Symptom N (%)	Rarely N (%)	Occasionally N (%)	Frequently N (%)	Almost Constantly N (%)
Feeling Sad	11 (55)	5 (25)	3 (15)	1 (5)	--
Worrying	12 (60)	4 (20)	3 (15)	--	1 (5)
Feeling Irritable	10 (50)	6 (30)	3 (15)	--	1 (5)
Feeling Nervous	11 (55)	5 (25)	2 (20)	1 (5)	1 (5)

Note: Table 4-2 and Table 4-3 are derived from the MSAS-SF, Portenoy, R. K., Thaler, H. T, Kornblith, A. B., Lepore, J. M., J. M., Friedlander-Klar, H., Kiyasu, E., Sobel, K., Coyle, N., Kemeny, N., Norton, L., & Scher, H. (1994). The memorial symptom assessment scale: An instrument for the evaluation of symptom prevalence, characteristics, and distress. *European Journal of Cancer, 30A(9)*, 1326-1336.

^a One of the patient-participants was involved in a non-therapeutic Phase 0 CCT (a CCT non-curative in nature whose purpose is to determine the pharmacodynamics and pharmacotherapeutics of Bortezomib). Due to her uniqueness as a study patient-participant (she was a clinical trial coordinator at another institution), only her face-to-face interview data and cancer diagnosis were included in the dissertation study. Her demographic information does not appear in Table 4-2 and Table 4-3. ^bIn Table 4-2 and Table 4-3, the “N” value signifies the number of patient-participants who experienced a distress level for a particular symptom. The percentage sign (%) represents the associated percentage of patient-participants who experienced a distress level for a

particular symptom. The dashes represent the absence of distress for a particular symptom in the sample of patient-participants

Description of the Patient-Participants

As stated, the sample participants were twenty-one Black cancer patients spread over six cancer types: breast, prostate, lung, colo-rectal, pancreas, and multiple myeloma. The members of the sample are described here, in order to facilitate ease of identification during the presentation of the dissertation findings later in this chapter. They will be presented according to cancer type, although there was no commonality of experience based upon cancer type. The following descriptions are meant to provide a cursory introduction to each participant; additional details will be provided during the presentation of the data.

Breast cancer.

The patient-participants who participated in breast CCTs were among the youngest in the study sample. They had a mean age of 48.8 years and ranged in age from 44 years to 58 years. Three of them were participants in the I-SPY II CCT, a multi-arm adaptive CCT that utilizes biomarkers to guide determination of trial eligibility, screen the use of novel therapies, and determine treatment therapy effectiveness based upon tumor subtypes. Mrs. Washington was a newlywed with two adult children. She postponed her honeymoon in lieu of beginning initial treatment of her breast cancer via CCT participation. Her husband provided her immeasurable support. In turn, Mrs. Washington became a valuable source of support for other women diagnosed with cancer, who turned to her for information and support. Kit was a mother of three teenagers, and an education administrator trying to juggle home, work, and her pursuit of a doctoral degree. Katie, a

divorced mother of two teenagers, had just fully recovered from a motor vehicle accident, when she received her cancer diagnosis. She reacted with shock and dismay, when she learned that that her older female relatives shared an extensive (but hidden) history of breast cancer.

The remaining two women with a breast cancer history were participants in a randomized yoga/radiation therapy CCT, where the participants were randomized to yoga or supportive care for symptom management. Both women shared strong family support, but differed in support from their employers. Lee, a nurse, had an extensive support system among her family and friends. Her employer supported her during her cancer treatment. She received treatment during her work hours. Reecy was supported predominantly by her teenage sons. Her employer was unsupportive and terminated her from her position, secondary to work days missed for cancer and CCT treatment. As a result, she lost her home and sought living arrangements with supportive relatives.

Prostate cancer.

Four patient-participants were diagnosed with prostate cancer and had a mean age of 59.5 years. Three of them participated in a yoga/radiation CCT, where yoga was taught to assist the men in managing symptoms associated with radiation therapy: Steed, Ro, and RR. Two of the men, Steed and Ro, received proton therapy as part of the CCT. RR and the remaining prostate cancer participant, Eric, both received standard external beam radiation. Steed was the only participant in the sample who articulated initial distrust for research. His distrust was overcome by having a racially concordant oncologist and CCT research coordinator (his oncologist CCT research coordinator were

both Black) and by the open communication he shared with his oncologist. Ro came to the Cancer Center for a second opinion, because he was dissatisfied with his first oncologist. He was very pleased with his experience and with his oncologist and at the Cancer Center.

RR came to the Cancer Center for treatment five years after a cancer diagnosis, when he finally had qualified for Medicare coverage. He stated that he could not afford the co-payments required to receive proton therapy. RR frequently discussed his symptoms and symptom management and declined to discuss his CCT participation with certain members of his nuclear family and his church family. Eric did not participate in the yoga/radiation CCT. He was receiving external beam radiation therapy along with a phase 1 medication, following a prostatectomy. Per his words, Eric freely questioned the care he was receiving and “pushed the issue” on symptoms he was experiencing that he felt were not being addressed (Eric, Face-to-Face Interview).

Lung cancer.

The patient-participants with lung cancer had a mean age of 60.7 years. Niecy had participated in more than one CCT. She had a deep and abiding faith in her spiritual beliefs and in her family and fully expected her family to support her during her CCT participation. She had a close and trusting relationship with her oncologist. Due to disease progression, Jill was removed from her CCT soon after completion of her initial face-to-face interview, which occurred during a hospitalization. Soon after her interview, she was placed on home hospice. She repeatedly voiced indications that she was overwhelmed by the financial burden of fees related to medication costs and “usual and

customary care” fees related to her CCT participation. Diane had been a participant in several CCTs for lung cancer. She felt that she received support from her children and husband, as well as her church cancer support group.

Colo-rectal cancer.

The four participants with colo-rectal cancer ranged in age from 48 years to 74 years and had a mean age of 63.3 years. Mrs. L was enrolled in a CCT contemporaneous with being informed of her cancer diagnosis. As a result of CCT medication, she experienced debilitating pain and peripheral neuropathy. Mrs. L was the primary caregiver for her adult daughter who suffered from a chronic illness, while receiving scant support for herself. Jay was concerned with living as normal a life as possible, as well as with how he was perceived by others. For this reason, he preferred the CCT oral chemotherapeutic agent over the standard treatment intravenous agents administered continuously through a portable infusion pump, which he had previously received.

Willie was diagnosed with stage four colo-rectal cancer six months short of her next screening colonoscopy. She came to the Cancer Center for a second opinion. Her daughters were very supportive and did research for her, regarding treatment of her colo-rectal cancer; she was recently separated from her husband. Ellie had an extremely supportive family, comprised of her husband and children. Her youngest adult daughter and husband were committed advocates for her and routinely were present at all of Ellie’s oncologist appointments and CCT treatments.

Pancreatic cancer.

Bob and Mrs. S were diagnosed with pancreatic cancer. Their mean age was 61 years. Mrs. S was the wife of a minister, who also was being treated at the Cancer Center for multiple myeloma. Her children and their spouses supported her participation in the CCT and formed a vigilant support network that ensured that she was never alone and had everything she needed. Bob actively sought randomization prior to CCT accrual. He viewed CCT participation as an opportunity to receive optimal care for a life-limiting cancer. Bob acknowledged that he felt that he “was pretty much the aggressor,” when it came to inquiring about CCTs at the Cancer Center (Bob, Face-to-Face Interview). Moreover, his husband constantly was seeking promising pancreatic CCTs for him, as well as bringing them to the attention of Bob’s oncologist.

Multiple myeloma.

Finally, three patient-participants were diagnosed with multiple myeloma and had a mean age of 52.7 years. Each had lived with multiple myeloma for at least four years. Previous to CCT participation, Tammy had received only standard treatment. She relied primarily on her father for tangible and emotional support and described him as her “number one” (Tammy, Face-to-Face Interview). Tammy reported having good support from her family. Although, she admitted that only her parents, an aunt, and her children were aware of her CCT participation, because she felt that other members of her family would not understand. Gina had enrolled in several CCTs in order to forestall progression of her multiple myeloma. Gina was very well-informed of the multiple myeloma disease process and treatment options, pursuant to self-study, attendance at

multiple myeloma conferences and participation in support groups wherein multiple myeloma patients shared information. During her CCT accrual, she continued to work full-time while she received her lengthy CCT treatment (four to five hours once a day during the week), and was the sole caregiver for her elderly mother who suffered with moderate to advanced dementia. Nellie worked full-time during her CCT participation; she scheduled early CCT visit appointments in order not to disrupt her work schedule. She was enrolled in a non-therapeutic CCT. Nellie was supported by her friends during her previous standard and CCT treatment. She was very knowledgeable of CCTs and chose CCT participation to help other Black cancer patients.

Findings

Specific Aim One: Identify and Describe the Patient, Family Member, Physician, and Protocol Factors that Black Cancer Patients Consider Important in Their Decision to Participate and to Remain in CCTs

Consistent with Albrecht's Model, the four themes for Specific Aim One are:

Patient Factors, **Family Member Factors**, **Physician Factors**, and **Protocol Factors**.

Patient Factors concerns the patient-participant decisions, preferences, and expectations that influenced their enrollment (**Why I Came Here**) and retention (**My Treatment**) in CCTs at the Cancer Center. **Why I Came Here** has three sub-categories that more fully describe the patient-participants' reasons for arriving at the Cancer Center and choosing CCT participation: *Get a Second Opinion*, *To Help Myself*, and *To Help Others*. **My Treatment** describes the treatment expectations of patient-participants who remained in CCTs and has two sub-categories: *How I Want to Be Treated* and *Managing My*

Treatment. **Family Member Factors** explicates the influence of family members on CCT participation and retention. It has two categories: **They Helped Me Decide (Participating)** and **Family and Friends Support Me (Remaining)**. The latter category treats the various ways in which family members and friends assisted CCT retention. **Physician Factors** describes the manner in which oncologists influenced patient-participants to enroll and to remain in CCTs at the Cancer Center. **Why I Participated** explains the oncologist characteristics that prompted patient-participants to choose their respective oncologist (*Doctor I'm Dealing With (Choosing My Doctor)*) and the role of oncologists in CCT enrollment (*He Asked Me and Told Me (Enrolling in the Cancer Clinical Trial)*). **Why I Remain** conveys the continued influence of oncologists on CCT retention from the perspectives of the patient-participants. (See the matrices below for **Patient Factors**, **Family Member Factors**, **Physician Factors**, and **Protocol Factors**; all matrices serve as a guides for the discussion of each theme.)

Table 4-4: *Patient Factors*

<u>Theme</u>	<u>Patient Factors</u>				
Category	Why I Came Here (Participation)			My Treatment (Remaining)	
<i>Sub-category</i>	<i>Get a Second Opinion</i>	<i>To Help Others</i>	<i>To Help Myself</i>	<i>How I Want to be Treated</i>	<i>Managing my Treatment</i>
<i>Code</i>	“unhappy where I was” “go somewhere else”	“I’m a pioneer or a trailblazer” “help somebody else” “our ethnicity”	“go to the study for you” “help me” “give myself the best possible”	“like a person” “have some kind of compassion” “push the issue”	“they have to get answers for you” “weighing the options” “I tell everything”

			<i>chance”</i> <i>“learn more</i> <i>about my</i> <i>condition”</i> <i>“if one trial</i> <i>doesn’t</i> <i>work”</i>		<i>“tap into</i> <i>the</i> <i>resources”</i>
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Patient factors. The Black cancer patients enrolled in this dissertation sample were demographically diverse in several aspects (e.g., age, education, marital status, and cancer status, yet shared many commonalities of experience). The majority of patient-participants were forthright in their choice of seeking cancer treatment at the Cancer Center. Many of study participants came to the Cancer Center for a second opinion, before enrolling in a CCT. Once enrolled, they regarded CCT participation as a means of helping themselves and others. Moreover, during their continued enrollment in their CCT, they had expectations of how they wanted to be treated and how they wanted to share management of their CCT treatment.

Why I came here. **Why I came here** represents patient-participants’ personal reasons for coming to the Cancer Center. This category depicts the conditions under which some patient-participants came to the Cancer Center seeking second opinions for treatment of their cancer, as well as the altruistic and self-interested reasons they gave for their CCT enrollment.

Get a second opinion. Some patient-participants experienced discontent or displeasure with an oncologist physician prior to going to their present oncologist physician for a second opinion (*unhappy where I was*). This discontent motivated them

to seek cancer treatment elsewhere for cancer treatment at another medical facility or with another oncologist (*going somewhere else*). In so doing, the patient-participants found their present physician and enrolled on the present CCT. For the patient-participants in the dissertation study sample, a diagnosis of cancer was a necessary precursor to their experiences in clinical research at the Cancer Center. However, some of the patient-participants sought out a second opinion at the Cancer Center after being diagnosed with cancer at another healthcare institution (*go somewhere else*)

That's, you know, I had some, uh, bleeding one morning from the rectum. It was pretty bad, so my husband rushed me to the hospital, which was _____ here in T_____. Um, so. And, um, that's where they detected it there. They kept me in the hospital for a week. All kind of test they ran. So, um, they found it. They were gonna give me chemo there, but I wasn't really happy with what they wanted to do, so I wanted to get a second opinion. And that's why I went to [the Cancer Center]. And I'm, and I've been with [the Cancer Center] since. (Willie, Face-to-Face Interview).

Diane did the same:

No, I was at _____ when they diagnosed it, and I just felt like I needed to *go somewhere else* more knowledgeable. So that's why I came to the [Cancer] Center. They worked on that and everything was good for about a year and a half. I was on maintenance [chemotherapy] and everything. (Diane, Face-to-Face Interview).

After leaving other oncologists and other cancer centers, patient-participants purposively sought consultations with oncologists at the Cancer Center. At these consultations, standard treatment options (the customary treatment for a cancer type) and cancer clinical trial participation (voluntary involvement in a medical research study to test new methods of treating their cancer type) were discussed. In general, the patient-participants were discerning in their decisions to undergo treatment with an oncologist following a second opinion and consultation.

Ellie arrived at the Cancer Center after visiting three other cancer centers for initial treatment recommendations and decided to stay, because she was impressed by the time spent by the oncologist to perform a thorough evaluation of her cancer (Ellie, Face-to-Face Interview). By contrast, Bob chose the Cancer Center because his oncologist, ironically the same oncologist treating Ellie, expediently began treatment. Gina came to the Cancer Center for a second opinion after her initial oncologist had suggested a cancer regimen for her progressive multiple myeloma:

And, uh, so now I've been going for a series of thing. I was going—I actually participated in a study before the study I'm now on. Dr. _____ suggested it. I came to him for a second opinion because they wanted me to take like a, a cyto—Cytosan with decadron and something else. I'm like, 'Look, before I do this,' 'cause I said, 'Okay, I know the devil that I'm dealing with as far as drugs are concerned.' I said, 'So I still got to work every day.' I said, 'That might throw me into something else.' I said, "Let me get a second opinion," so I actually came here and talked to Dr. _____ to get a second opinion. (Gina, Face-to-Face Interview).

Ro expressed intense displeasure (*unhappy where I was*) with the oncologist who initially diagnosed him with prostate cancer, because of prior experience with another physician. He related sitting in the first physician's office and hearing him say, "If you came in here with a PSA 20, or something I would tell you I can't do nothing for you (Ro, Face-to-Face Interview)." So, after he was told ten months later by another physician that his PSA was 20, he went to the Cancer Center for a second opinion following a referral from a friend who had been treated there for prostate cancer. His comments are below:

I was recommended by a friend of mine who had prostate cancer. And he was working with Doctor _____. And um you know he told me to come down you know, cuz I was very *unhappy where I was* at before so. Uh I didn't like the way my um doctor handled the situation, and I didn't like—like the way the

oncologist at Einstein handled the situation. So I came down here and I—I met Doctor _____. And uh then Doctor _____ put me in touch with Doctor _____. (Ro, Face-to-Face Interview).

RR's dissatisfaction stemmed from an oncologist's rush to perform robotic prostatectomy surgery for his prostate cancer, without discussing other treatment options (RR, Face-to-Face Interview). He felt that the oncologist was rushing him to treatment, rather than considering his quality of life following the surgery:

No, I didn't do it. I—the reasons were the doctor was too much in a rush. He didn't give me both sides of things. He was, you know, just, “Oh, yeah, you want to save your life?” [Chuckles] It—he didn't - he didn't seem to have any concern with quality of life. He was just tryin' to sell me on getting the thing. At least, that's my perception. (RR, Face-to-Face Interview).

Ellie shared the same experience of being unhappy with her previous oncologist, because she felt that she was rushed to treatment:

like the oncologist at _____ it seemed like he was in a hurry to get me in the operating room or...whatever he was gonna do. Excuse me. But Dr. _____'s people, they were careful. They-they wanted more information that I already had. Cuz I had all my information from _____ sent to _____. And they-they were...very, very good at-at making sure that they were on the right track. (Ellie, Face-to-Face Interview).

By contrast, Bob felt an urgency to receive cancer treatment. Initially diagnosed with stage four pancreatic cancer at another comprehensive cancer center in the area, Bob's displeasure with his prior oncologist stemmed from her slowness in beginning treatment. He was impatient with the sheer number of diagnostic tests he had to undergo, before he could be treated (Bob, Face-to-Face Interview).

To help others. The sub-category, *To Help Others*, reflects the shared, personal altruistic reasons the patient-participants provided for enrolling in CCTs, once they came

to the Cancer Center. Gina viewed herself as a trailblazer (*I'm a pioneer or a trailblazer*) assisting in the development of science intended for the benefit of future cancer patients:

I told my friends, I'm not a guinea pig. Um, *I'm a pioneer or a trailblazer*. Somebody...went through something before I even got here—to take us to this point. So now I wanna be able to not only help myself, but help other people in the process, because it might be somebody that's going through the exact same thing that I'm going through. (Gina, Face-to-Face Interview).

CCT participation was viewed as a means to *help somebody else*:

So I don't look at it on the lines of 'No, I'm not gonna do dis,' cuz there's something out of all this that you're doin' that you're gonna get, it may *help somebody else* somewhere down the line. But if we say no to everything like this how do you get the information to help the next person. (Reecy, Face-to-Face Interview).

Implicit in the patient-participants' altruism was the recognition that they may not benefit from their respective CCTs. Helping others by participating in CCTs was viewed as a refusal to be selfish, an appreciation for the importance of research, as well as a duty owed to document cancer information for all individuals with cancer. Lee shared a widely expressed need to do more for others:

I mean, I'm a nurse as well. I do research. I think it's important. I think research is important. I think that's how we get our information that can help the person, benefit the person, or it helps other people for the future. I think that's the main reason. I think that if I can help someone else, even if it doesn't personally benefit me, then it's okay. (Lee, Face-to-Face Interview).

However, as a patient-participant in a CCT and a member of a CCT team in a different medical discipline, Lee had a unique perspective:

I'm a patient. I know from my experience when we gather information from patients that are in clinical trials, it gives us feedback and information that can help us with future things. I just wanna be able to see a positive, a plus. (Lee, Face-to-Face Interview).

Recognizing the symptom burden they experienced, the patient-participants hoped that enrollment in CCTs could lessen symptoms such as fatigue, aches and pains, and hair loss for future cancer patients. For this reason, Katie felt that enrollment in a CCT was perceived as an opportunity to spare others from the symptom burden she was experiencing:

That, you know, even though I'm always thinkin' about the next person but that would be satisfying to me knowing that—that they can get something out of it, That this won't be so harsh, as far as all this other stuff that you have to go through. You know, every time you get the infusion, of the fatigue, of the aches, the pains, the hair loss, all that stuff—*Interviewer:* Mm-hmm. *Interviewee:* – will be alleviated a little for the next person. (Katie, Face-to-Face Interview).

Steed and Katie viewed CCT participation as a chance to help *our ethnicity*, or other Black cancer patients:

We need to have a-we need to have a-a collection of information—and data that *our ethnicity* has on record. So that the medical profession will know how to treat, um, diseases. The-the things that we are afflicted with. And, not only that, just our concerns. (Steed, Face-to-Face Interview).

Hence, Steed viewed his CCT participation as an opportunity for researchers to collect information on a Black individual, in order to assist the medical profession in treating other Blacks with cancer. Katie viewed CCT participation as a way to help another Black patient-participant like herself:

That whatever they find out, whatever the results are, whatever they're looking for to find out, you know, in a person, maybe a African—maybe based on just me, African-American female, 45 years old, that may be similar to me or, you know, may be at the same stage or presented at the same, you know, during the same time, that it would benefit them. (Katie, Face-to-Face Interview).

To help myself. Although the patient-participants shared altruism as a motivation for CCT enrollment, the desire to help themselves was expressed by all patient-

participants as a motivating factor for CCT enrollment. Ro voiced the necessity to *go to the study for you*, or for Black cancer patients to make a personal decision to participate in CCTs

But if somebody come tell you, ‘Yeah man, you know it’s really good and everything.’ Yeah, listen to them, but *go to the study for you*. Because if you go to the study saying, ‘Cuz somebody said this and that and everything,’ then you’re not goin’ for yourself. And you’re not gonna pay attention the way you should. (Ro, Face-to-Face Interview).

This sentiment was shared by Lee:

It’s your personal decision. Something that the person has to feel comfortable with. I don’t think there’s anything wrong with participating in a clinical trial. That’s my opinion, but it is still that person’s personal decision. I’ll tell them it’s how comfortable you feel about it. If you don’t feel comfortable then you don’t do it. (Lee, Face-to-Face Interview).

In making the decision to participate in a CCT, the patient-participants were motivated by the desire to help themselves (*help me*):

Interviewer: Why - why did you decide to participate in the research that you're participating in? **Interviewee:** Because I - I - I feel as though, uh, that it can *help me* more than it could hurt me, I think. I asked the question, would it hurt me? Would it hurt me? And the doctor said, no, it wouldn't. So the only thing it could be is a plus. (Eric, Face-to-Face Interview).

For the patient-participants, helping themselves through CCT participation was an attempt to save their lives and to prolong their lives as long as they could. Jill viewed her decision to enroll in a CCT as taking a chance to help herself:

I said let me take a chance because maybe it will help. Maybe they'll find somethin'. It—it'll help or maybe it won't help. But if it helps that’s—I'm two points ahead in the game. (Jill, Face-to-Face Interview).

Participation in a CCT was more than a taking a chance for some patient-participants to help themselves. Wanting the best care was the reason given by the vast majority of participants for CCT enrollment. They ascertained that CCTs provided better treatment

for their cancer. Mrs. S stated very frankly, “Plus I would like to get the best of care and best of what I could get, out of what I could get, as long as I could get” (Mrs. S, Face-to-Face Interview). Hence, from the perspective of the individual patient-participant, it was a desire to *give myself the best possible chance* to treat my cancer. Gina wanted a CCT targeted medication which specifically attacked her cancer cells and which did not have secondary cancers as a side effect, as did many medications for multiple myeloma. As conveyed by Gina:

Right, because it’s targeted therapy. So that interested me, because with all the other stuff, and especially with Revlimid...you can develop a cancer in another part of your body. That’s the chance that you kinda, sorta, have to take, you know, when you’re on these drugs...So I realized that [*pause*]—I still needed to *give myself the best possible chance*. (Gina, Face-to-Face Interview).

Several participants reported that CCTs afforded the opportunity to *learn more about my condition*. Participation in the I-SPY II CCT with its additional diagnostic tests and genetic testing appealed to Mrs. Washington’s willingness and need to learn more about her cancer, “I want to *learn more about my condition*, what's goin' on and everything, which I probably could get from my Doctor ____” (Mrs. Washington, Face-to-Face Interview). Diane was a veteran of other lung CCTs, before enrolling in her present CCT. Enrollment in subsequent studies permitted her to acquire additional diagnostic information and become knowledgeable about her cancer status and treatment, as well as motivating her to seek enrollment in other available CCTs whenever her cancer progressed:

They had some other—maybe three more things they could try. But they weren’t working, and two clinical trials that I was under they didn’t work, either. It seemed like it grew. And I actually told them you can stop this one because it’s—whatever these pills are they’re not working with me. So then, um, each—

between each one you still have to wait, like, six weeks or whatever before they'll start so it can get out of your system. So this came along, and she offered it to me, and, um, so far it—it hasn't been growing so it's already big enough, so it hasn't grown. And as long as we can keep my fluid retention under control—I will—I should be okay. (Diane, Face-to-Face Interview).

Finally, a few participants with late stage cancer were frank in their use of CCTs as a means of prolonging their lives and, who hoped, *if one trial doesn't work*, there could be another CCT which could work. Reecy, who had newly diagnosed stage four breast cancer with multiple metastases, saw her CCT as the first of many CCTs in which she would be enrolled for the remainder of her life, because of her tumor burden:

...and it was like too much cancer areas throughout my stomach and, and back, so they really, they didn't wanna operate....so they thought the best thing for me to do is just to live with it, and, um, and take the, the chemo treatments. And like I did have radiation for, I guess it was about six or eight weeks. So they're not gonna give me any more of that. So now they told me I would be on chemo for the rest of my life...And, and when, *if one trial doesn't work*, you know, they'll just keep putting me on different ones until it works. (Reecy, Face-to-Face Interview).

For several years, Gina had monitored the progression of her multiple myeloma by following the levels of certain laboratory levels of her blood (her “numbers”) (Gina, Face-to-Face Interview). She had been enrolled in at least two prior CCTs, until her numbers indicated that her cancer was no longer responding to the medication. She had hoped the oncologist:

could make a cocktail and it might do something for a while, but I felt as though I had a good shot of getting my numbers down far enough or just to eradicate the disease. You now, itself. So that's why I agreed. (Gina, Face-to-Face Interview).

The CCT in which Diane was participating had halted the growth of the large tumor in her abdomen, although she still experienced side effects such as acute shortness of breath from the ascites (extra fluid accumulating in her abdominal cavity as a result of the

metastases). She knew the CCT in which she participated was her last chance to manage her cancer:

they were saying that they don't have anything else as far as treatment that they can give me. Because they've tried everything. So they wanted to, you know, try this one in particular... it's not really a cure, but if—in the meantime, if they can stop the growth of it, who knows down the line? They might find something else that can get rid of it. (Diane, Face-to-Face Interview).

My treatment. Except for the few patient-participants who had participated in other CCTs as a means of prolonging their life, the patient-participants perceived the CCTs as, and the CCTs were, the first medical intervention for their cancer:

Oh, um, I initially found out from the radiologist and then, um, she was telling me about the clinical trial. And then when I got diagnosed and met with the oncologist, they, um, the oncol – oncologist talked to me about it again. And, um, then I met the researcher and it went from there. (Kit, Face-to-Face Interview).

The patient-participants had expectations of how they wanted to be treated and how they wanted to manage their cancer treatment. Fulfillment of these expectations kept them in their CCTs.

How I want to be treated. The participants had an expectation of how, and in what manner, they expected to be treated while they were enrolled in the CCT. Kit voiced the shared expectation of many of the participants of being treated with respect, or treated with positive regard for them as individuals (*like a person*):

like a person with cancer who needs help, but also like a person. And a person who needs information and who needs to be, uh, treated like, what's the word—I need the people who take care of me to be knowledgeable. I need them to be intelligent. I need them to know me. If I don't get that, it's not happening. (Katie, Face-to-Face Interview).

Kit was treated like a person:

Interviewer: Okay? Um, one question. Um, tell me about your experience? So, I mean over the last two months. **Interviewee:** Um. It's been fine. Um,

they've been very thorough with everything. Um. The team, like I said, continued the same, with the same consistency they were always at every appointment. (Kit, Cell Phone Interview #4).

Patient-participants wanted their decisions to be accepted and respected, especially as it pertained to additional CCT participation—as explained by Lee:

I work in this and this is what I often have to say sometimes to people in my department. They'll say, 'I don't know why this person is—' They'll identify a patient. Of course, we need patients to participate on the trials because that's how we're grant funded. We need people to participate in order to, so to speak, in reality keep our jobs. You still have to respect the person. If the person says, 'No. I don't wanna do it.' Just let her go. (Lee, Face-to-Face Interview).

At the most basic level, Niecy expressed the desire that her healthcare providers *have some kind of compassion* when they communicated with her:

I mean you have to—you can't be so cocky that you know you just come off to people like—'This is what you need to do.' **Interviewer:** Right. **Interviewee:** You know you may get better, you may not get better, and I mean fighting this disease, I mean— **Interviewer:** Mm-hmm. **Interviewee:** - you've gotta *have some kind of compassion*, some kind of—some kind of, "If it was me," or, "If it was my daughter, if it was my aunt. If it was my mother, how would I want them to talk to her?" (Niecy, Face-to-Face Interview)

Niecy found this compassion in her oncologist, as she describes a discussion she had with him, "I says, 'The feeling I get, the feeling in my stomach, I can't shake it. I don't want to mess with you.' I just found a good oncologist. Wherever we go from here, you know I'm okay" (Niecy, Face-to-Face Interview).

There were times when a patient-participant, or family member, wanted to have an important health problem or issue addressed (*push the issue*). Eric was concerned about his persistent rib pain:

I told him last week that, uh—that my ribs were swollen, and I'm gonna tell him again this week. And I'm gonna not demand, but I'm gonna *push the issue* on, okay, it still hurts. It's still hurting. It's still hurting. Let's do something about it. I

mean, like, this week or whatever or next week, check me out for something to see what's going on here because it's been swollen for two weeks. (Eric, Face-to-Face Interview).

Eric addressed his pain with his oncologist and was given medication. Bob's husband was a stalwart advocate for him. When he noticed that Bob had begun losing weight on the CCT, Bob husband began asking the nurse practitioner questions at an appointment:

Um, I can't say that she mentioned it like it was—she just said—because I mean - I think because Tom was so focused on—he was asking questions, so she mentioned that there was an eight-pound weight loss difference between the last month... And she's, like - she's, like, 'You're not really like in a danger zone, but you don't wanna continually, you know, keep losing weight, you know, each month.' (Bob, Cell Phone Interview #4).

As a result of Bob's husband directing his concerns to the nurse practitioner, Bob began to understand the importance of maintaining his weight:

Which kind of surprised me because I was, like, 'What? I mean I am eating.'

Interviewer: Mm-hmm. **Interviewee:** But, um, you know, I guess I just have to, you know, keep it up. Tom wants me to, you know, talk to a nutritionist so—I guess it wouldn't hurt... (Bob, Cell Phone Interview #4).

Managing my care. Patient-participants had a clear idea about how they wanted their care to progress and assertively advocated for themselves, or had family members who advocated for them (*Managing My Care*). *They have to get answers for you* meant seeking information about the CCT in which an individual was enrolled:

But uh, you know, just-just put them in a position where *they have to get answers for you*. Because what happens is, I think, is they get answers for themselves, as well. **Interviewer:** Yeah, that's true. **Interviewee:** They do. I really do believe they-they get answers for themselves, because people ask questions that they don't have answers to. And they—and they know they wanna keep their-their patient, they're gonna have to come up with—they're gonna have to get some reliable answers to your questions. (Ellie, Face-to-Face Interview).

It enabled participants to ask relevant and meaningful questions during the CCT. Katie began while she was deciding on CCT participation:

And I asked questions about, you know, ‘How many people are participating? Is—is it just done here at Penn? Where else is it done? Like, is it done at the other local Philadelphia hospitals?’ Um, um, ‘Are there mostly just people my age? Um, are there other ages that participate? Um, is it ethnic-based [*inaudible 07:19J*?’ Uh, we had a lot of dialogue.... (Katie, Face-to-Face Interview).

Her questions continued throughout the CCT:

Um, I just know that I just have like some questions I am gonna ask about like, you know, far as reconstruction is, like, surgery, reconstructive surgery and um, therapy and all that stuff. Not, not just—I didn’t even like really know about the therapy until I went to therapy for my ankle and found that it, that there’s a therapy, therapist there that works with people after they have um, like mastectomies. (Katie, Cell Phone Interview #4).

Ellie’s continued participation depended upon whether the CCT treatment was reducing the size of her tumor (Ellie, Face-to-Face Interview). By staying informed about the status of her cancer and asking questions about her progress during the CCT, she remained in the CCT:

Interviewer: I remember—actually, I remember you had said that you and your husband had talked about not continuing on if there wasn’t a change, you know, in—**Interviewee:** Mm-hmm. **Interviewer:** Are you still having that discussion? **Interviewee:** No because we have seen a change for the better. And, uh, uh, because when we took the other CAT scan, where there was this mass in my belly had already shrunk by 40 percent. (Ellie, Cell Phone Interview #3).

Participants were always *weighing the options* of continued CCT enrollment, i.e., considering the advantages and disadvantages of cancer clinical trial treatment and/or cancer treatment. Niecy had been with her oncologist through more than one CCT and had followed him to the Cancer Center from another comprehensive cancer center. Her decision to not remain in her CCT was based upon her consideration of the advantages of the treatment versus the symptom burden that she was experiencing. She explained very simply, “He’s gonna listen to my point, and I’m a listen to his point, and I’m gonna *weigh the options*” (Niecy, Face-to-Face Interview). Ultimately, when Niecy felt that the

“medication wasn’t workin,” (Niecy, Face-to-Face Interview) Niecy weighed the options, communicated her decision to her oncologist, and withdrew from the CCT after only two CCT cycles.

Patient-participants wanted to be informed of their progress in the CCT—and, in furtherance of that goal, communicated everything that they experienced to the CCT team (*I tell everything*), as exemplified by Kit:

Interviewee: I tell everything. **Interviewer:** Okay. **Interviewee:** [*Inaudible*] blurry vision. **Interviewer:** Okay. **Interviewee:** Everybody knows everything. Numb – tingling fingers. (Kit, Face-to-Face Interview).

The information shared between the patient-participants and the Cancer Clinical Trial Team (CCT Team) varied. Participants, such as Niecy, notified the oncologist or the nurse practitioner when the CCT medication was not resolving the symptom burden associated with their cancer (Niecy, Face-to-Face Interview). Lee informed the CCT Team of her wound care needs and received non-adherent dressing for her breast wound (Lee, Face-to-Face Interview). Gina and Ellie were concerned about possible reactions to their treatment. Gina was experiencing “hot flashes” again, after having experienced a natural menopause ten years earlier:

...I’ve gone through all of that before, so I, I don’t know what this is, but I have to make sure that I tell, um, the, uh, the clinical nurse what’s going on because, because this is such a, you know, a new drug, they need to know peoples’ reactions to things. (Gina, Cell Phone Interview #1).

Ellie was experiencing severe peripheral neuropathy in both of her hands, which prevented her from touching anything for several days (Ellie, Face-to-Face Interview).

After notifying the clinical trial research nurse, one of the CCT chemotherapeutic agents was eliminated.

Last, patient-participants were referred to internal resources (offered by the Cancer Center) and sought external resources (*tap into the resources*) in order to ensure their continued participation throughout the CCT. Seeking and using these resources to support them during CCT participation was an integral part of the patient-participants' managing their CCT treatment. Patient-participants were referred to resources for transportation, counselling, nutrition, and stress management. Gina required more than one type of resource. She balanced a full-time job, visits to the Cancer Center twice a week, and was the sole caregiver for her mother who had dementia. For stress management and counselling services, she received external support from her employer. She received the services of Carebridge, an employee assistance program provided by her employer, which provided five free counselling and stress management sessions (Gina, Face-to-Face Interview). Later, she was referred by the Cancer Center to the Breathing Room Foundation, a local non-profit organization which provides care and support to individuals and families affected by cancer. Gina received \$200 which enabled her to offset transportation costs and pay for respite services for her mother's care:

And there's—the Breathing Room Foundation gives you a one-time stipend of \$200.00—**Interviewer:** Okay. **Interviewee:** - to, you know, to help you out with whatever. So I faxed her—I talked to her today, and um, they're willing to pay this lady for the time that she's gonna stay with my mom, which is good, 'cause I don't have to do out of pocket. And they'll just, you know, cut the lady a check. But I'm trying to find out as many organizations as I can to assist, and there's so many out here as far as cancer patients are concerned—**Interviewer:** Right. **Interviewee:** - that people are not aware of that will help you. So just trying to *tap into the resources* that are available. (Gina, Face-to-Face Interview).

Transportation resources were needed by Reecy and Mrs. L, both of whom had limited financial means. Absent these resources, neither one of them would have been able to

continue to come to the Cancer Center. Initially relying unsuccessfully on social work at Cancer Center, Reecy arranged her own transportation through Medicaid:

I got a—they gave me a monthly TransPass. The social workers here didn't fix that for me. I fixed it for myself. *Interviewer:* You t—how'd you do that? *Interviewee:* I went to Welfare and I got my Welfare situated. I caught the transportation people. I fixed that myself. *Interviewer:* Okay. *Interviewee:* Waiting for the social workers, nothing was getting done—. (Reecy, Face-to-Face Interview).

The Cancer Center referred Mrs. L to a taxi service funded by a non-profit cancer organization, to transport her and her disabled daughter to the Cancer Center for her CCT appointments (Mrs. L, Cell Phone Interview #1). Despite feeling that the taxicab service was burdensome, she continued to use it during her CCT enrollment.

Table 4-5: *Family Member Factors*

<u>Theme</u>	<u>Family Member Factors</u>		
<u>Category</u>	They Helped Me Decide (Participating)	Family and Friends Support Me (Remaining)	
<u>Sub-category</u>		<u>My Family</u>	<u>My Friends</u>
<u>Code</u>	<p>“my children heard” “he talked to all my children”</p>	<p>“my family is close” “we support each other” “my rock” “they’re in my world”</p>	<p>“friends that support me” “we’re like sisters”</p>

Family member factors. Family members were integral elements in the lives of the patient-participants. They accompanied them to initial oncology appointments, sat with them through innumerable hours at the Cancer Center, offered heart-felt

encouragement to carry them through the CCT process, and provided needed home care for them. However, very few of the patient-participants discussed the influence of family members in their CCT enrollment decisions (**They Helped Me Decide (Participating)**). Most of their discussions centered on the tangible and intangible ways that family members sustained them during their CCT participation (**Family and Friends Support Me (Remaining)**).

They helped me decide. Only two patient-participants mentioned their family members' involvement in CCT enrollment decision-making. Mrs. L had little recollection of her initial discussion with the oncologist regarding her CCT; she relied on her children to listen for her (*my children heard*). When asked how she decided to participate in her CCT, she stated, "I don't know that I did. [*Laughter*]. They just automatically, like I said, handed me the papers, told me what was what and, of course, like I do, I'm being the airhead so *my children heard*" (Mrs. L, Face-to-Face Interview). Niecy's oncologist actively involved her and her children in CCT decision-making (*he talked to all my children*):

From Dr. ____'s standpoint, this is uh, the best thing that he has—I guess, far as trial medicine, for me with the lung cancer—so he wanted to try it, and I mean he—he just didn't talk to me. *He talked to all my children*, and— **Interviewer:** Oh good, so he talked to all—everybody? **Interviewee:** Right. **Interviewer:** Okay. **Interviewee:** Right, it's—and when—there's somethin' and— 'bout changin', and what's goin' on with me—he tells me that you know, 'I need all your kids to come in, and we can talk about this.' (Niecy, Face-to-Face Interview).

Family and friends support me.

My family. The influence of family members on the participants' CCT participation emerged early in the face-to-face and cell-phone interviews. As described,

“family member” was broadly defined to include members of participants’ nuclear family, friends, significant others, spouses, and ex-spouses. Gina discussed the constant presence of her friends, since she was estranged from her siblings (Gina, Cell Phone Interview #2). For Ro, a family member included not only individuals who shared consanguineous ties, but also his ex-spouse (Ro, Cell Phone Interview #3; Ro, Face-to-Face Interview). Many patient-participants described the “closeness” with their family members and, how they gathered around them following their cancer diagnosis and during their CCT participation (*we’re very close*). Lee shared how her family had rallied around her and offered emotional support:

We’re very close. I guess we don’t mind talking and sharing because that’s how we help to educate each other.... We just—I mean my family, when they learned that I had this everybody was calling. Everybody was calling, everybody was coming. That’s just how we are. Even my Auntie who’s 93 years old. I was just talking to her yesterday. She calls me every week. My cousin who lives down south called to check on me. The one’s that’s in New York. They call to check on me, make sure I’m okay. My cousin Earl reminds—my Aunt Cleo, she didn’t have daughters. She had two sons. My cousin Earl. He’s 60—I’m 56, he’s at least 10 years older than me. When he got the news he called me. He was like, ‘Cousin I heard.’ He says, ‘Don’t worry about it. You know Mama had it and she lived all those years cancer-free after that.’ He told me, reminded me. He just went on, ‘You’re gonna be alright. You’re gonna be alright. Just like mom.’ (Lee, Face-to-Face Interview).

This closeness was indicative of the strong family relationships existing within the patient-participants’ families. Reecy expressed the sentiment shared by many of the sample of an expectation of family closeness as she discussed her sons, “I think this is what we supposed to do. I think we’re supposed to stick together. I think we’re supposed to help each other, you know” (Reecy, Face-to-Face Interview).

At the most basic level, being present was the first line of support and was valued greatly by the participants (*we support each other*). Ro expressed the importance of his family members during his CCT participation:

So I mean my family, my family has had illnesses, but we have always said you know you gotta fight. And we, and *we support each other*. That supportin', that's a lot—comin' down here every day and you see the ones who have support with 'em, the people who have support with 'em. You know, it's just incredible when you have somebody sittin' beside you, your brother, your sister, your mother, your father, your aunt and uncle, somebody down there with you. (Ro, Cell Phone Interview #3).

Ro and many of the participants were not alone, as they waited for their oncologist appointments, radiation treatments, or CCT medication infusion visits. Being present for the participants extended into the oncologist and nurse practitioner appointments, where the participants' family members asked questions the participants may have forgotten and made requests for consults, such as Bob's husband who requested a nutrition consult following concern surrounding Bob's eight-pound weight loss. Ellie felt that the presence of her family members positively impacted her CCT treatment:

I really am very satisfied with uh, the way—the kind of treatment I'm getting. But you let—I'll just say this on the side. I think, if I were just me coming in there all the time—**Interviewer:** Right. **Interviewee:** I don't know how good it would be. **Interviewer:** Okay. **Interviewee:** But because it's my daughter and my husband, and he never, ever lets me come alone—**Interviewer:** Right. **Interviewee:** - um, because they're there asking the questions that I don't think of to answer—to ask—**Interviewer:** Mm-hmm. **Interviewee:** I think—I think it encourages a little more attention than I would get otherwise. (Ellie, Face-to-Face Interview).

When family members were not able to be physically present, the participants could expect a call or text to remind them of family members' support (Mrs. Washington, Cell Phone Interview #2). As shared by Mrs. Washington, support could come in a call:

What do my sons do for me? They'll call me up...and ask me, 'Do you need me to come and stay with you? Or, do you need me to, um, go to the store? Do you need anything to eat?' (Mrs. Washington, Face-to-Face Interview).

Diane affirmed the power of a call. Her sisters called her “all day and night” inquiring about her needs and offering her rides from the Cancer Center to home, as did her sons (Diane, Face-to-Face Interview).

Participants noted that family members would do whatever they could to support them through the CCT. Bob explained that his husband acted as a “buffer” between him and the prying questions of other members of his family, regarding his CCT and his health status (Bob, Cell Phone Interview #3). Katie’s sister helped her by assuring that her two sons’ clothes were ironed for the week (Katie, Cell Phone Interview #3). During the summer of 2014, Katie had been spending at least one day a week receiving chemotherapy and/or diagnostic testing at the Cancer Center, secondary to her CCT participation (Katie, Cell Phone Interview #2). This made it difficult for her to plan a summer getaway with her two sons. In addition, her sons had been choosing to spend more time with their father (Katie is divorced) that summer. Katie acquiesced, since she felt that they were trying to adjust to her cancer diagnosis. Katie received much-needed assistance from a paternal aunt, who gave her a summer timeshare at the New Jersey shore (Katie, Cell Phone Interview #2). In this way, Katie was able to spend time with her sons before the school year began.

Some family members were actively involved in many aspects of the patient-participants’ lives during their CCT participation (*they’re in my world*) as exemplified by Steed’s comments regarding his family, “And they are in my world all the time. You

know, cross-examining me, asking me—everything. There’s nothing off limits to my family, because they’re-they’re in there. *They’re in my world*’ (Steed, Face-to-Face Interview). Diane’s husband had supported her through several CCTs. Diane recalled during one CCT that he had questioned whether it was helping her and whether she should consider withdrawing from it:

when I was doing the one before this my husband actually did say to me—but I was already thinking anyway. He knew it. He said, ‘It’s just not working. It’s not working for you. It’s not working for you, baby.’ And I said, ‘Yeah, I understand and I am going to say something,’ and I did. I stopped it, stopped it altogether. (Diane, Face-to-Face Interview).

Ellie’s daughter and husband were constant fixtures at her CCT appointments. They accompanied her to every appointment, asked the clinical trial research nurse, nurse practitioner, and oncologist questions regarding her progress in the CCT, and made recommendations to Ellie about her treatment and assessing her involvement in the CCT (Ellie, Cell Phone Interview #3). Like Diane, Ellie’s family members talked with her about her CCT participation and gave her “feedback from their point of view” which she valued (Ellie, Cell Phone Interview, #2).

Receiving CCT treatment at home was common among the participants and offered another opportunity for family members to be involved in the patient-participants’ lives during their CCT participation. In order to deliver at-home chemotherapy and anti-nausea medications associated with her CCT, Ellie’s husband and daughter were trained how to use a mini-infusion pump (Ellie Cell Phone Interview #1).

As stated previously, Bob's pleural effusions¹¹ required insertion of a pleur-x-catheter¹² to drain his lungs. After insertion, a home nurse made a few visits to continue to drain pleural fluid and to instruct Bob's husband on the pleural effusion draining procedure. Bob's husband took over care and draining of the pleur-x-catheter indefinitely (Bob, Cell Phone Interview #3).

The Black cancer patients invariably described one person they called *my rock*, or that individual who provided unwavering support, or more than one type of support, during their cancer and CCT experiences. Diane's rock was her older son:

... he's *my rock*, but I do have other people that are there for me. In fact, during most of the time when I first started coming and—and getting chemo and stuff like that, my older son was the one would be here all the time. (Diane, Face-to-Face Interview).

Ellie's twin rocks were her daughter and husband who never wavered in their support—at least one of them was constantly present at Perelman, in the home to assist and care for her in any manner necessary, and emotional support (Ellie, Cell Phone Interview #1; Ellie, Cell Phone Interview #2; Ellie, Cell Phone Interview #4). Kit's rock was her boyfriend who was with her at every chemotherapy appointment, as well as everywhere she needed to go (Kit, Cell Phone Interview #1). Diane described how her husband had adjusted to being a caregiver and now did everything for her when she returned home exhausted from work—a role reversal which redefined their thirty-year marital

¹¹ A pleural effusion is the presence of excess fluid in the fluid-filled lining surrounding each lung. The excess fluid prevents the lung from expanding, thereby resulting in shortness of breath and impaired oxygenation.

¹² A pleur-x-catheter is a flexible plastic tube inserted through the chest into the pleural space. It remains in place until no longer needed and permits drainage of pleural effusions in a patient's home.

relationship (Diane, Face-to-Face Interview; Diane, Cell Phone Interview #2). He cooked for her, cleaned the house, and assisted her in making decisions about her CCT treatment (Diane, Cell Phone Interview #2; Diane, Cell Phone Interview #4). Tammy's father was her "number one" who drove her to every appointment and cared for her grandchildren when she could not care for them (Tee, Face-to-Face Interview). Reecy depended on her oldest son who stayed overnight with her during hospitalizations and came with her to every appointment (Reecy, Cell Phone Interview). Finally, Ro turned to his ex-wife, a breast cancer survivor, who understood his cancer experience more than anyone:

She knows how I am. We laughed. We joked. We talked. Cuz she had cancer. She beat breast cancer, my ex-wife. I was with her then when she was fighting that. And uh so she knows. So she sat down here with me. (Ro, Face-to-Face Interview).

My friends. When a patient-participant explained he had *friends that support me*, they were describing the ways in which their friends assisted them during their CCT participation. Friends did not differ from family members in their support of members of the sample. They accompanied the participants to their appointments, sent them cards and flowers, called them every "damn" day, and laughed, cried, and prayed with them (Gina, Cell Phone Interview #3; Katie, Cell Phone Interview #2; Mrs. L, Face-to-Face Interview; Mrs. S, Face-to-Face Interview). Gina's friends were essential for her, because of her estrangement from her family. They offered the support she would have received from family members:

Yeah, I do have *friends that support me*. They, you know, call me on a daily basis. How are you doing? How are you feeling—are you feeling medically? You know, how are you feeling emotionally? You know, what is it, you know,

that, you know, um, while this is going on, why don't we go out and do this or, you know, how about this or what's happening in the house? That kinda thing. So, I mean, I'm-I'm-I'm fine as far as that's concerned, you know. (Gina, Cell Phone Interview #2).

Ro described a moment early in his CCT treatment, when he was despondent. A friend who lived across the street, who was a prostate cancer survivor, spoke to him and provided the support he needed:

And he told me, 'First of all, Ro, take a deep breath and settle down.' He said, 'You don't know how bad it is...God is usin' you to-to put this out there.' He said, 'Look at it that way.' He said, 'Don't-don't be with that grueling look on your face and everything.' And I thought about it, and I said, 'You know what? You're absolutely right.' And I still to this day talk to everybody the way I do is because he-he told me that. He told me that when I was feelin' like really down. Like he just told me that, you know, you got prostate. Your PSA is high. I was feelin' really bad. And I felt bad for ten minutes, and then as I talked to him, I said, 'You know what? He's absolutely right.' (Ro, Cell Phone Interview #3).

Ro's interaction with his friend gave him hope and cemented Ro's resolve to share his experience with the men of his social circle—as his neighbor had done for him (Ro, Cell Phone Interview #3).

Friends helped them to understand and to endure the silence of family members and their unspoken questions about their cancer. Katie's best friend was her "rock" and more like a sister (*we're like sisters*):

And then, my best friend, we've been friends since high school, M____. She's excellent—excellent support. You know, we—*we're like sisters*. We're like sisters. We talk a lot, share a lot. We cry. We laugh. We—we do everything. She's—she's um, she's always there. She's always there. (Katie, Face-to-Face Interview).

Since many of her family members were unprepared to discuss her cancer and CCT experiences, her best friend filled the void by talking and praying with her as often as Katie needed (Katie, Cell Phone Interview #1; Katie, Cell Phone Interview #3). Katie

related her discussions with another friend who had sisters who were breast cancer survivors. Her friend shared a personal experience and asked a pointed question:

... some of her siblings, she had to ask them about another sister, like, do you think that she's gonna die? Do you think that she's not gonna survive this? And she said, 'Maybe that's what they feel like.' Maybe...she said, 'Maybe that's what they're feeling.' (Katie, Cell Phone Interview).

With her friends' assistance, Katie began to learn to cope with her family's reticence to share their opinions and feelings about her cancer and CCT participation. She began to talk about her cancer and CCT experiences with her family, whether or not they asked, in response to their discomfiture

Table 4-6: *Physician Factors*

<u>Theme</u>	<u>Physician Factors</u>		
<u>Category</u>	<u>Why I Participated</u>		<u>Why I Remain</u>
<u>Subcategory</u>	<u><i>Doctor I'm Dealing With (Choosing My Doctor)</i></u>	<u><i>He Asked Me and Told Me (Enrolling in the Cancer Clinical Trial)</i></u>	<i>"Trust"</i> <i>"He's in the ethnic group"</i>
<u>Code</u>	<i>"Doctor was very careful"</i> <i>"He took time out to explain"</i> <i>"Seemed to have more going on"</i>	<i>"She mentioned the trial"</i> <i>"Offered me other treatments"</i> <i>"Handed a paper to sign"</i> <i>"He thought it was a good idea"</i>	<i>"They have people that address things"</i>

Physician factors. Patient-participants shared how their positive perceptions of their oncologists influenced their decisions to enroll and to remain in CCTs. They discussed trust in their oncologist, the ethnicity of the oncologist, the attentiveness of the

oncologist, and timely referral to other healthcare providers. Oncologists had active roles in motivating CCT enrollment and retention, whether by personally recruiting patient-participants or referring them to other oncologists managing CCTs.

Why I participated. The patient-participants in this study discussed their oncologists' diagnostic prudence, openness and candor, and willingness to evaluate thoroughly their disease process and available treatment and CCT options. These qualities attracted participants to their respective oncologist, encouraged them to choose treatment at the Cancer Center, and, ultimately, to enroll in a CCT. Participation in CCTs was effectuated principally by oncologists who recruited a large number of the participants, by either asking them to participate or by referring them to oncologists who were seeking participants for CCTs.

Doctor who I'm dealing with (choosing my doctor). Patient-participants cited the seriousness of purpose and thoroughness in their CCT treatment. Bob described it as having a type of tunnel vision where the oncologist appeared to be entirely focused on his treatment (Bob, Face-to-Face Interview). Also, Bob based his choice of oncologist on his perception that funding was readily available at the Cancer Center for cancer research:

There's more money being funneled in here. It seemed to have more going on with pancreatic cancer than _____. Even though _____'s an excellent hospital, it just seemed the [Cancer Center] had a little bit more going on with pancreatic cancer. (Bob, Face-to-Face Interview).

For Ellie, it was characterized by thoroughness in the initial evaluation of her disease and subsequent recommendations for treatment tailored specifically to the genetic structure of her cancer (*doctor was very careful*):

And I felt really—*Dr. _____ was very careful*. He wasn't in a rush to get me going. He told me, he-he said, 'I—what I wanna do is to do a gene—a genealogy [genetics] test.' You test your genes or something.... They went back and looked at all the pictures, everything. And that—only after that did he design a chemotherapy for me. And then that's when the chemo—then it was another month before I really got started with it. **Interviewer:** Okay, so—
Interviewee: But he—I-I-I-I like the idea that he wasn't in a hurry, like the oncologist at J_____ it seemed like he was in a hurry to get me in the operating room or whatever. (Ellie, Face-to-Face Interview).

Another important physician factor was the oncologists' ability to explain in an understandable manner the cancer diagnosis, cancer treatment, and/or cancer treatment options (*he took time out to explain*). Ro chose the Cancer Center, because the first oncologist he had consulted failed to offer him treatment options:

And we got to talking and you know he explained it. I think that the best part about it is that *he took time out to explain* it in laymen terms about everything that was going down as far as the regular radiation, the radiation, and chemo or protons... And then they explained to me that you know they found that uh women with breast cancer and some other types of cancer when they do yoga it seem to help them with them—with their symptoms. And uh you know gettin' past, or gettin' through some of the symptoms. And it's illness, and illness too. So I said, 'Okay, I'll give it a try.' (Ro, Face-to-Face Interview).

This sentiment was shared by Eric and Katie (Eric, Face-to-Face Interview; Katie, Face-to-Face Interview).

He asked me and told me (enrolling in the cancer clinical trial). Only one of the patient-participants related enrolling in a CCT based largely upon an oncologist's recommendations (*he thought it was a good idea*):

Interviewer: Um. I guess the first thing I'm gonna ask you about is what were some of your personal reasons for deciding to participate in a cancer clinical trial?
Interviewee: Because the doctor told me *he thought it was a good idea* and anything that will help. You know, help the cancer, to help shrink it and whatever. **Interviewer:** Okay. **Interviewee:** And I was a good, uh, client for it.
Interviewer: Uh. Okay. Um. Were there any other considerations besides what the doctor said? **Interviewee:** No. (Mrs. S, Face-to-Face Interview).

Many of the patient-participants related that their oncologist described the study objectives of the CCT and the risks and benefits associated with CCT participation. In nearly all instances, the patient-participants' oncologists were the principal investigators for the CCT. Katie, Kit, and Mrs. Washington were the only patient participants who were referred to the physician, who became their oncologist and administered the CCT. She was referred by the surgical oncologist who performed her breast biopsy (*she mentioned the trial*). Once referred, the oncologist and other members of the CCT team provided Katie with written information, discussed the details of the CCT, and answered her questions (Katie, Face-to-Face Interview):

after having the biopsy and then meeting with Dr. ____, she went over, like, *she mentioned the trial* also. And then she talked that—she said that she thought I would be—I may be a good candidate for the trial, but there was more information to come... But I remember just—I was—I was given the information. I know Dr. ____ talked to me about it, and I know the research team, um—at the time it was like L____ and the other girl, L____. (Katie, Face-to-Face Interview).

Kit related how she enrolled in her CCT. She was referred by her radiologist to her present oncologist, who, in turn, enrolled her in the breast CCT which has been her initial treatment (Kit, Face-to-Face Interview). Much like Katie, Kit's oncologist explained the details of the CCT, provided her with detailed written information, and answered Kit's questions:

I initially found out from the radiologist and then, um, she was telling me about the clinical trial. And then when I got diagnosed and met with the oncologist, they, um, the oncol – oncologist talked to me about it again. And, um, then I met the researcher and it went from there. (Kit, Sami-structured Interview).

As stated, participants' perceived CCT participation as a means of being given options for cancer treatment, rather than as opportunities to advance medical research

(*offered me other treatments*). For example, Steed related how his oncologist discussed proton radiation therapy, which was part of his CCT for his prostate cancer: “[t]hey *offered me other treatments*, and, um, I-I just said no. I said no to those other treatments. When protons was explained to me, and how effective the percentage, I said, I’m going with this” (Steed, Face-to-Face Interview).

Only one patient-participant reported not being asked to participate in a CCT. As stated previously, Mrs. L stated she was told that she was in a CCT, until she decided that she no longer wanted to participate. When asked why she decided to enroll in a colorectal CCT, Mrs. L explained that she was just *handed a paper to sign*, “And, um, next thing I was *handed a paper to sign* and was told that if I changed my mind about going through the trial, then they would destroy the paperwork” (Mrs. L., Face-to-Face Interview). Although, she admitted that the oncologist most likely did explain the details of the CCT (Mrs. L, Face-to-Face Interview). Following her cursory enrollment to her CCT, Mrs. L conceded that she did not know what to expect and characterized her participation as “...something like the lamb being led to slaughter cause you sure didn’t open your mouth. You just went along with things. That’s how I felt. Uh, I guess that’s how I still feel and, you know” (Mrs. L, Face-to-Face Interview).

Why I remain. None of the patient-participants readily fit the stereotype of the uninformed, distrustful Black cancer patient afraid to participate in cancer clinical research. The lack of trust that drove several of the participants to the Cancer Center to seek a second opinion was not typified by a general distrust of clinical research. It was epitomized by feelings derived from personal interactions with oncologists, such as

experienced by RR who felt pressured by an oncologist to undergo an unwanted surgery (RR, Cell Phone Interview #1) and by Niecy who encountered a flippant oncologist who was displeased by a refused surgical recommendation and told her regardless of her decision he was “gonna get paid either way” (Niecy, Face-to-Face Interview). In the same manner, trust in their oncologist kept the participants at the Cancer Center actively enrolled in a CCT.

In defining trust, the Black cancer patients offered various meanings. Ro described it as “strong faith in the doctors that you workin’ with...” (Ro, Cell Phone Interview #2). At its most elemental level, Bob described it as a “vibe” he felt when he met his oncologist for the first time, or a way of knowing experienced during that first handshake and first eye contact (Bob, Face-to-Face Interview). For Steed, it was something much more concrete—his oncologist was *in the ethnic group*:

He is—he is in the ethnic group. He’s in the ethnic group [laughter]...it’s a blessing. It is so wholesome to see this, you know, because, um, it really does something for the ethnicity. And, uh, we have to have beacons. We have to have beacons of hope. Educational beacons of hope. We have to have that. (Steed, Face-to-Face Interview).

He trusted his oncologist, because he was Black.

Also, there was a commonality of honesty and frankness noted by the patient-participants about their oncologists. In describing the reason she trusted her oncologist, Niecy shared that “he keeps it real (Niecy, Face-to-Face Interview).” Her trust in him prompted her to follow him to the Cancer Center, when he left another comprehensive cancer center. She went further to say that “he had talked me into things that I knew would have been “No” with any other doctor (Niecy, Face-to-Face Interview).” After

disclosing his decision to stop radiation treatment and rely on prayer to cure his prostate cancer, RR was silenced by the frankness of his oncologist's answer:

He says, 'Well, how would you know if God's healed you? I mean, we can't do another biopsy in at least—for a period.' But not within the period that we were talkin' about...So, he talked me out of that. He said—well, one, he said, this is a very, um, pressurized business. They're workin' with people to try to save them. And that he likes to feel that well, if the Lord's healin' them, then he may be one of the Lord's instruments. (RR, Face-to-Face Interview).

Despite his candor, RR opined later, "I think he's a trustworthy guy. He tries to give it the way it is" (RR, Cell Phone Interview #1).

In furtherance of their scrupulous treatment in the CCT, participants observed that their oncologists often referred them to other medical or rehabilitative services or healthcare providers secondary to continued CCT participation (*they have people that address things*). RR's oncologist had referred him to other healthcare providers secondary to his CCT; he accepted the referral as a corollary to CCT participation as issues arose, "So, but I mean, and anything you bring up they - *they have people that address things*" (RR, Cell Phone Interview #3). He was referred to a dietician for chronic constipation, which may have impacted his radiation:

Well, they just talked about the need to have regular bowel movements, and, um, yeah. They - they didn't really recommend that people use a lot of laxatives or artificial stuff. They try to use more natural stuff like yogurt (RR, Cell Phone Interview #3).

Other patient-participants were referred to otolaryngologists (physicians who specialize in evaluation and treatment of the ear, nose, and throat) for hearing loss, physical therapists to improve their functional status, and surgeons for placement of pleur-x-catheters to drain accumulating fluid in their lungs (pleural effusions).

Table 4-7: *Protocol Factors*

<u>Theme</u>	<u>Protocol Factors</u>
Category	Participation
<i>Code</i>	<i>“it’s more targeted”</i> <i>“help myself if I was randomized (randomization)”</i> <i>“extra treatment I’m Getting (additional surveillance)”</i>

Protocol factors. The data from the face-to-face and cell phone interviews indicated that protocol factors only had bearing on the patient-participants’ enrollment in CCTs. As reported previously by Gina, targeted therapy was a CCT feature that appealed to her, because it directly affected cancer cells instead of all of the cells in her body (Gina, Face-to-Face Interview). However, the patient-participants with prostate cancer also preferred the choice of more targeted radiation therapy (it’s more targeted):

It’s more targeted. **Interviewer:** Right. **Interviewee:** It is more targeted, and, um, I don’t need that-that other stuff, where it just goes everywhere.
Interviewer: Exactly. Exactly. **Interviewee:** And-and affects other organs.
 (Steed, Face-to-Face Interview).

Ro was determined to receive proton therapy, even though he knew that health insurance companies often withheld coverage:

Because I know that I went through a lot fillin' in that I wanted the proton. You know they just sayin', 'Well, the insurance probably don't like to pay for it for everybody,' and, you know, I thought, I thought that was crazy because here I had—I have never, ever used my medical insurance for anything, and now that I need it, you don't want me to get the best treatment possible for me. (Ro, Face-to-Face Interview).

Bob chose to participate in his CCT, because he wanted the opportunity to be randomized to an experimental treatment, hydrochloroquine. Diagnosed with life-limiting stage four pancreatic cancer, Bob articulated: “I thought maybe it would help, um, *help myself if I was randomized* to get the hydrochloroquine (Bob, Face-to-Face Interview).” He rationalized that randomization to experimental treatment would offer a better benefit than the standard treatment:

... just thinking that...if I had been randomized that it could possibility, um, have a positive outcome as opposed to just the regular standard, um. I don't know why I thought that but I did because it—they certainly never said that it was necessarily better, but I just assumed that anybody that's doing a—a study of something, they're leaning towards thinking or hoping that it would do some good or it's—it's better than the alternative. (Bob, Face-to-Face Interview).

The I-SPY II CCT interested Kit, because she wanted additional diagnostic surveillance. She viewed CCT participation as a vehicle to receive *extra treatment* that she otherwise might not receive. As participants in the I-SPY2 CCT, she, Mrs. Washington, and Katie would receive additional diagnostic surveillance beyond the standard of care for breast cancer treatment—at no cost to them:

So, the standard – the standard treatment would be two MRIs. Under the study, I get four MRIs. Um, standard, I think, for biopsy is one. With this, I get three. Uh, then, um, MRI, biopsy, um, I think that's it. Um, and then with all of my appointments, the – the researcher is there—making sure that things are going well. Um, just documenting and asking questions. Seeing how she can help and, um, so it's been a great experience for me. (Kit, Face-to-Face Interview).

Specific Aim Two: Describe the Everyday Experiences of Black Patient-Participants Living with Cancer as They Navigate the CCT Process.

Three themes address Specific Aim Two and embody the experiences of the Black cancer patients as they progressed through, withdrew, and/or were withdrawn from

their CCT. Data was gathered in real-time by cell phone interviews. Patient-participants provided vivid and poignant descriptions of their CCT treatment, expectations and events surrounding CCT participation, their symptom experience, personal thoughts and feelings of the effect of CCT participation on their daily lives, and their relationships with family members, the CCT team, and others during CCT participation. The three themes are: **The Cancer Clinical Trial Team, I'm Going Through It, and Who I Am.** **The Cancer Clinical Team** concerns the patient-participants' recognition of the contribution of the individuals involved in the screening, treatment, and oversight of the Black patient-participants during their CCT. The patient-participants described the roles of the individual members (*My Team*) and their activities during the CCT (*What They Do for Me*). **I'm Going Through It** describes the patient-participants' experiences prior to and during their appointments (*At My Appointment; Treatment Realities*) as well as their varying degrees of symptom burden (*How I Feel; It's Knocking Me Down*). **Who I Am** is the patient-participants' expressions of who they were and what was important in their lives. There are three categories: (1) *I Didn't Want To Be Different Than Who I Was*, (2) *Cancer Has Changed My Life*, and (3) *Getting the Word Out*. Consistent with the dictates of RTDC, the cell phone interviews were recorded in real-time, wherever the participants happened to be when the cell phone call was made. (Each matrix precedes its respective section and serves as a guide for the discussion of each theme.)

Table 4-8: *The Cancer Clinical Trial Team*

<u>Theme</u>	<u>The Cancer Clinical Trial Team</u>
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Category	I Have a Good Team	
<i>Sub-category</i>	<i>My Team</i>	<i>What They Do for Me</i>
<i>Codes</i>	<i>coordinator</i> <i>“nurse practitioner”</i> <i>“research nurse”</i>	<i>“They call me”</i> <i>“Showed concern”</i> <i>“Normally they alternate”</i>

The cancer clinical trial team.

I have a good team. Albrecht’s Model highlights the significant role of the oncologist in the CCT process. However, the participants indicated that the individuals who interacted with the patient and worked alongside the oncologist during the CCT, the *cancer clinical trial team*, were important, as well. Regarding her CCT team, Mrs.

Washington stated:

Uh, the—the team has just been wonderful. Uh, you know, they always tell me at the end of my appointment, uh, if I ever need anything just don't hesitate to call and let, uh, [*clears throat*]—excuse me—just don't hesi—hesitate not to call if I need anything. Um, so the team has been very helpful to me. There's no unhelpful. (Mrs. Washington, Cell Phone Interview #4).

My team. For most participants, other than the oncologist, the CCT team was composed of the clinical research nurse, and the clinical trial coordinator. However, the nurse practitioner also was mentioned as a member.

Only the participants in the Yoga Study mentioned interacting with a clinical trial coordinator. They mentioned the clinical trial *coordinator* by name, instead of by his role. This individual individually recruited and consented all of them.

S_____, when he approached me, um he said how was it—yeah he—he asked if I had the [inaudible 09:47], and I said yeah. And then he got into it you know. He explained it really good. Really nice guy. **Interviewer:** Mm-hmm.

Interviewee: So he—after talking to him, I felt comfortable.... (Ro, Face-to-face Interview).

The clinical coordinator's duties were focused solely on the research aspects of the CCT. He offered these patient-participants different CCTs in which they could enroll—all chose the Yoga Study. In addition, he reviewed the CCT protocol with them, administered the CCT questionnaires, and collected and evaluated the data related to the CCT (Steed, Cell Phone Interview #1; Ro, Face-to-Face Interview). He maintained the CCT paperwork and answered their questions, as needed (Steed, Cell Phone Interview #1). He was their point of contact with the CCT.

All of the patient-participants mentioned interacting with the *nurse practitioner* during outpatient research visits alone, or in tandem with the oncologist, such as Bob, “So I haven't see the doctor. Last time I saw the, um, nurse practitioner cuz the doctor—the last time the doctor was on vacation (Bob, Cell Phone Interview #4).” Mrs. L recounted how the rapidity of her nurse practitioner's response to her declining health status:

Well, she's gotten better. I mean, in the beginning, I just feel like she threw me to the curb cuz I had to go into the hospital the same day I met her. We met her across the street, and that was it. And I was in there a full week, so I was saying, ‘Wow, this is like weird. They just kicked me to the curb,’ you know. So, when I saw her again, I spoke on it, and I got very upset about it. I don't know why, and she says, ‘I'm sorry.’ She said, ‘But, yes, we did keep an eye on you, but, um, I'm sorry that things—you feel as though I just kicked you to the curb, but you were very sick.’ (Mrs. L, Cell Phone Interview #1).

Nurse practitioners made the participants feel secure as they progressed along in the CCT. Diane reported that her nurse practitioner is the “one that looks out for me, also,

like Dr. _____. She's good. She's good at what she does" (Diane, Face-to-Face Interview).

The members of the sample also felt the clinical trial research nurse was attentive to their informational needs:

Interviewer: For instance if you have questions about what comes next in your clinical trial who do you talk to? **Interviewee:** There's two people who you can talk to—who I talk to that would be the nurse or *[inaudible]*. **Interviewer:**

When you say the nurse you mean the nurse practitioner or the research nurse?

Interviewee: The *research nurse*, the person who I'm working with on the clinical trial I think would be the person who would have that information. That's the best person who I think who would have the information, the most information. (Lee, Face-to-Face Interview).

Mrs. Washington depended upon her clinical trial research nurse to provide calendars of her extensive CCT chemotherapy treatments (Mrs. Washington, Cell Phone Interview #4). Katie enjoyed meeting with her clinical trial research nurse, since she routinely inquired about the side effects of the CCT medication and how Katie was feeling, gave Katie an opportunity to ask questions, answered her questions, and discussed her experiences during the CCT (Katie, Cell Phone Interview #2).

What they do for me. Communication between the CCT team and the patient-participants (*they call me*) was common—as noted by Mrs. Washington, “Yeah, *they call me* at home (Mrs. Washington, Cell Phone Interview #4). A member of the CCT team called the patient-participants following their CCT treatments, following a biopsy, or on a weekly basis to see how they were doing (Mrs. Washington, Cell Phone Interview #4; Mrs. L, Cell Phone Interview #4; and Jay, Cell Phone Interview #1). Moreover, the CCT Team's show of interest or engagement in their CCT treatment (*showed concern*) was valued by the patient-participants:

It—it wasn't one of those things where, um, where the only way that I can describe for where they ignored me, or as we say in Duluth, quote/unquote, played me to the left. They—they absolutely, um, *showed concern*, continuous concern. (Steed, Cell Phone Interview #2).

Kit was very pleased with the interest exhibited by her CCT team:

Um, the researchers and nurse in charge of the clinical trial have been very supportive and very personal. Um, seem to be truly interested and vested in my Well- being. Um, it's just an overall positive experience. I can't say anything negative about it. (Kit, Cell Phone Interview #1).

The oncologist and the nurse practitioner coordinated the clinical care of the patient-participants by taking turns seeing them during their research visits (*normally they alternate*), as noted by Mrs. Washington, “Yeah, they *normally alternate*. So I either—I might see—even though they got me down for B _____ [nurse practitioner], I might end up seeing [Dr.] _____ on Thursday. But they had me down to see B _____ on Thursday” (Mrs. Washington, Cell Phone Interview#1). Further, nurse practitioners fulfilled their advanced nursing role as primary healthcare providers—seeing participants alone or in place of the oncologist as the need arose. Bob’s nurse practitioner saw him with and without his oncologist. She fulfilled the oncologist’s requisite clinical tasks, as well as administrative tasks such as completing work disability forms, to Bob’s relief:

I had a doctor's appointment, although Dr. _____’s on vacation. So I met with the nurse practitioner. So at first I was afraid. I said, “Oh, my gosh, she might not be able to fill these forms out," you know, cause it says "doctor" but thank God, she was able to fill out the form. (Bob, Cell Phone Interview #3).

Table 4-9: *I'm Going Through It*

<u>Theme</u>	<u>I'm Going Through It</u>	
Category	At My Appointment	Just Trying to Get Through It

<u>Sub-category</u>	<u>My Appointment</u>	<u>Treatment Realities</u>	<u>How I Feel</u>	<u>It's Knocking Me Down</u>
Codes	<p>“using some time” (Taking time for treatment)”</p> <p>“getting back and forth”</p> <p>“nice little wait”</p> <p>“being treated differently”</p>	<p>“they want me to get” (Care secondary to treatment)</p> <p>“going in the right direction”</p> <p>“and they told me”</p> <p>“withdrawal”</p> <p>“they want my system cleared”</p>	<p>“I feel good”</p> <p>“gettin’ myself together”</p> <p>“not feeling good day”</p> <p>“I’m miserable”</p> <p>“I’m angry”</p> <p>“I’m scared”</p> <p>“death”</p>	<p>“feeling the fatigue”</p> <p>“marked up pretty bad”</p> <p>“when the hair starts to come out”</p> <p>“pain”</p> <p>“shortness of breath”</p> <p>“neuropathy”</p>

I’m going through it. During their cell phone interviews, the patient-- participants invariably discussed a “typical” appointment day at the Cancer Center (**At My Appointment**) and the symptom burden that some experienced on a daily basis (**Just Trying to get Through It**).

At my appointment. Patient-participants’ experiences encompassed activities prior to arriving to the Cancer Center and prior to being seen by the oncologist or members of the CCT (*My Appointment*) and information received at the appointment (*Treatment Realities*). These experiences included mundane activities such scheduling time in their daily lives to attend CCT appointments (*using my time*) and transporting themselves (or being transported) to their appointment (*going back and forth*). However, the mundane activities were interspersed with moments of gravitas. Members of the sample discussed feeling that they were being treated differently because of their race (*being treated differently*), waiting interminably for treatment (*a nice little wait*), being

informed their cancer had progressed or metastasized (*and they told me*), and being notified that they had responded favorably to the CCT treatment (*going in the right direction*).

My appointment. Several of the participants discussed the impact of trying to schedule their CCT treatment around their work schedule (*using some time*). These participants micro-managed their work and personal lives. They actively sought cooperative relationships with supervisors, co-workers, and administrators in order to schedule and attend their CCT appointments with the modicum of disruption to their work responsibilities. Katie tried to schedule her CCT appointments at 11:00 a.m. in order to conserve her leave time:

They're usually either at 11:00. Most of the time they're at 11:00 or 1:00. Um, so I usually go to work in the morning just trying to save on using some time. Like, my sick time. So, um, I usually try to schedule them, like, mostly between, like, 11:00 and 1:00. Usually, um, my—I don't usually schedule it later than 1:00. (Katie, Cell Phone Interview #1).

As an administrator at a high school, Ro had accepted that stress and unexpected incidents would occur. Ro attended his nine-week proton therapy appointments after leaving his employment for the day (Ro, Semi-structured Interview). The two days he took yoga required that he leave slightly earlier. It was a pattern that soon became known to his staff and the students he supervised (Ro, Cell Phone Interview #1). However, his staff worked with him to make sure he was never late for his appointments.

Gina worked a full-time, professional salaried position, while receiving a six-hour CCT treatment once a week and caring for her mother who had a deteriorative cognitive condition. To offset the time she used for the CCT infusions, she had arranged with her

employer to work extra hours on Thursdays and Fridays (Gina, Cell Phone Interview #1).

In this way, she was able to save vacation and sick time, which she had exhausted with two prior autologous stem cell transplants. She felt well-supported at work:

You know, they know what I'm going through. So I really, you know, I've—I-I don't put any pressure on myself at work and they seem to be working with me, so I'm very happy about that. (Gina, Cell Phone Interview #2).

By contrast, Diane no longer felt supported. During her first cell phone interview, Diane was considering working part-time in order to have time for her CCT treatment.

As she progressed through her CCT, she began increasingly to request time off from work due to symptom burden and in order to attend CCT appointments (Diane, Cell Phone Interview #1; Diane, Cell Phone Interview #3; Diane, Cell Phone Interview #4).

By the time of her fourth cell phone interview, Diane's resulting symptom burden and the amount of work time she had lost (or had to make up at work) were taking a tremendous toll on her job security. Her once supportive manager was no longer supportive. She shifted from considering working part-time, to retiring, and, finally, to losing her job (Diane, Cell Phone Interview #1, Diane, Cell Phone Interview #3; Diane, Cell Phone Interview #4):

But I was, I will actually thinking...there's like a game changer going on around here. And I don't know whether I need to cut my hours or just stop working altogether. If I cut my hours, they can still, you know, check on my time card. I'm already maxed out, and I mean way maxed out, on my vacation time. And I still have a little bit of sick time left and maybe 13 hours of personal time. But I need to think about what I really want to do. (Diane, Cell Phone Interview #3).

The manner in which participants arrived at the Cancer Center varied (*going back and forth*). The task of finding transportation, or being transported, to the Cancer Center varied in difficulty. Three patient-participants used public transportation or a taxicab to

reach the Cancer Center. Gina, who used public transportation, applied for funding to assist her in travelling from her job, to the Cancer Center, and, finally, to her home:

But that would help me because some of these people come there and they drive and they're there all day. You know what I'm saying? Then they don't work and they don't do anything like that, you know, they're just in this program, but I'm *going back and forth*. I'm coming there and I'm going to work. I'm coming back out there, you know, and I'm going home, so if I don't have a ride, I'm dealing with all of this, this public transportation that I have to pay for. (Gina, Cell Phone Interview #3).

Participants who drove, or were driven, to their appointments generally had family support or were accompanied by their families at some or all of their appointments.

Participants who walked to their appointments worked in close proximity to the Cancer Center and usually had advantageous arrangements in their workplaces that allowed them to leave for treatment. Mrs. L was challenged repeatedly by financial concerns during her CCT participation. She lived several miles from the cancer center site and was physically unable to walk long distances to and from public transportation. As a result, she relied on taxicabs, funded by a non-profit cancer organization, to transport her to and from her every appointment. Her experiences were fraught with difficulty and frustration, as have been described previously in Specific Aim 1.

Patient-participants complained of waiting for extended periods before their healthcare provider and CCT treatment appointments (*nice little wait*). The delays caused the most consternation and frustration among the patient-participants. RR related waiting approximately one to three hours for individual radiation treatment due to machine malfunctions:

So they had five machines to handle six machines worth of customers.
Interviewer: Wow. Okay. **Interviewee:** Patience, I guess. [*Laughter*]

Interviewer: Yeah. So how long did-did you have to wait? **Interviewee:** Uh, my appointment was 10:00 to get my treatment. They finally finished it at around 11:53. **Interviewer:** Wow. Okay. **Interviewee:** Yeah. Yeah. It was a *nice little wait*. (RR, Cell Phone Interview #1).

Mechanical/instrument breakdown resulted in lengthy delays for participants receiving radiation, such as RR and Ro who related this type of delay in two or more of their four cell phone interviews (Ro, Cell Phone Interview #1; Ro, RR, Cell Phone Interview #1). Participants reported waiting several hours to be seen and arriving home late in the evening: “[b]etween leaving the office, going downstairs, and then having to wait for a cab, and not getting home until damn near eight—eight o’clock at night. That really, really got to me” (Mrs. L, Cell Phone Interview #1). Delays in treatment were caused by a variety of factors. Often, one delay contributed to subsequent delays. For example, before their appointments with their oncologist/NP or for CCT treatments, patient-participants had blood drawn to determine laboratory values. Hence, a delay in drawing or in processing the blood led to additional waits. Some long waits were due to over-booking patient slots, which resulted in long waits for patient treatment rooms.

The patient-participants dealt with delays in receiving treatment in varying ways. Patient-participants expressed their annoyance to the nursing staff or left their appointments without having been seen. Ellie came with the expectation of being seen late, so she brought reading materials (magazines and her Bible) and slept (Ellie, Cell Phone #2). Katie accepted the long waits as a trade-off for the exemplary treatment that she perceived she was receiving:

...you know like sometimes I feel like, okay, it’s taking too long. But the outcome is this and so it just makes me feel like you know that’s, that’s trivial. It,

it doesn't matter how long I need to wait or anything, because I feel like I'm getting great treatment. (Katie, Cell Phone Interview #4).

Three patient-participants discussed the issue of *being treated differently* because of race in their cell phone interviews. This question was never asked, directly or indirectly, during the face-to-face and cell phones interviews. The intent was for it to arise independently from the interviews. In her cell phone interview, Diane surmised that there may be fewer Blacks, because Blacks may not have insurance for oncology treatment (Diane, Cell Phone Interview #1). RR raised the issue, because he expected the question to be asked. He observed that he “didn't see anything that changed differently because of race (RR, Cell Phone Interview #4).” By contrast, Ellie believed that physicians treated black and white patients differently (Ellie, Cell Phone Interview #3). She posited that the doctors at the Cancer Center were like other physicians, except “[m]aybe they're trained better, or something. So, that if they do feel that way, you don't feel it coming from them” (Ellie, Cell Phone Interview #3).

Treatment realities. At CCT appointments, oncologists informed the patient-participants of additional imaging, laboratory testing, or physician referrals secondary to CCT requirements or response assessments¹³ (*they want me to get*):

But they happened to see a nodule on my, on my lung that was the size of a pinhead—and so I supposed to go through the pulmonary doctor on Tuesday, so *they want me to get* a CT scan tomorrow so I can take with Tuesday to the pulmonary doctor. (Ro, Cell Phone Interview #3).

¹³ A response assessment is an evaluation of whether the CCT treatment had stopped or decreased the growth of tumors and/or cancer in the body. It occurs approximately every three months (or, in some protocols, at the discretion of the investigator) and are done with the assistance of laboratory tests, physical assessment, and radiographic imaging, such as computerized axial tomography (CAT) scans, magnetic resonance imaging scans (MRIs), ultrasounds, and/or positron emission tomography (PET) scans.

They were directed to imaging assessment (MRI, CT scan, PET scan, and ultrasound) appointments, genetics consultations to assist in receiving targeted treatment, and interventional radiologists for central line replacement. CCT appointments were opportunities to share positive news about the outcome of CCT treatment (*going in the right direction*):

Interviewer: D-during your appointment with Dr. _____, um, how, how was that, how was that last meeting with him on Wednesday? **Interviewee:** Um, it was fine. It was positive, I felt. Um. Yeah, he had some positive things to say. I had, I mean, I had already spoken with Dr. _____—**Interviewer:** Mm-hmm. **Interviewee:** - um, before the meeting actually, earlier in the week. Um. Actually the end of last week, after I had my CAT scan. **Interviewer:** Mm-hmm. **Interviewee:** And, um, so it, well, I mean, it was good to corroborate with, uh, Dr. _____, you know, basically saying the same things as far as, um, you know, things were looking good and *going in the right direction*, and—. (Bob, Cell Phone Interview, #1).

Receiving good news at CCT appointments meant shrinkage of cancerous masses (Katie, Cell Phone Interview #3). Also, it meant laboratory values which were within normal ranges (Bob, Cell Phone Interview #3; Ellie, Cell Phone Interview, #2). Moreover, for some participants, receiving good news meant the possibility of receiving CCT treatment without side effects or being told definitively when their CCT treatment would end and their subsequent return to their normal life would begin (Ro, Cell Phone Interview #2; RR, Cell Phone Interview, #4; Steed, Cell Phone Interview #2).

Also, at their appointments, oncologists notified patient-participants of the development of a new medical condition during CCT participation, or the discovery of metastases from a primary cancer site (*and they told me*), as Jay had learned at a CCT appointment:

And they told me I—I had cancer in my back, like, three spots—on my spinal cord... Well, they said, like—it, like, a tumor in my back, you know, like it—they don't wanna, like, mess with it—so it might spread and shit, so they working on that, too, so. (Jay, Cell Phone Interview #1).

The participants remained knowledgeable of the nature of the new medical condition or metastases, as well as knew with certainty the resulting treatment plan. At a CCT, Kit was informed that she had developed Type 2 diabetes, secondary to steroids prescribed as anti-emetics for the CCT regimen (Kit, Cell Phone Interview #1). She reported that she would be weaned from the steroid and referred to her primary care physician for management of her diabetes (Kit, Cell Phone Interview #1). At a CCT appointment Gina, Diane, Mrs. L, and Willie were told that that their cancer had progressed and would have to be withdrawn from their CCTs.

Only four patient-participants discussed withdrawal from their CCT (*no longer involved in that last trial*) during the cell phone interviews, after receiving news of cancer progression during their CCT appointments: Gina, Diane, Mrs. L., and Willie. Gina's withdrawal was presaged by an increase in certain blood protein levels:

I did see—I did go in to, um, see Doctor _____ today because, um, my protein numbers started going up, so I'm—I'm *no longer involved in that last trial*.

Interviewer: Oh, you aren't? Did they propose something for you?

Interviewee: Um, we talked about a couple things, but, you know, I'm gonna stay in prayer that, um, they took some blood today, and if my numbers aren't—if my protein numbers don't shoot up rapidly, then he's thinking that maybe, um, for the next four weeks or so, you know, he'll just leave me off of it and, you know, everything and just see how I work, you know. (Gina, Cell Phone Interview #3).

Willie had begun experiencing increasing abdominal pain, which she had dismissed (Willie, Cell Phone Interview #1). Approximately two weeks later, she was informed that there was new tumor growth, as well as metastasis of the cancer to her liver (Willie,

Cell Phone Interview #2). The oncologist had assured her that she would be “on the list” for a new CCT opening in three to four months (Willie, Cell Phone Interview #2):

And-and then he said that there's a trial that will probably open up in January or February. And, um, he's put my name in for that one. But right now, he's gonna put me back on that saliparton [oxaliplatin] and I'll have to be infused there and come home with that pump again, which I'm not lookin' forward to, but it is what it is. (Willie, Cell Phone Interview, #2).

Following withdrawal from their CCT, each woman understood the need for the CCT medication to clear her body (*they want my system cleared*). Mrs. L was hesitant to take any medication:

It's like coming out of—out of my body. I didn't know that it would do that fast. The only thing is, my only complaint really was—now it's my leg and my foot. It's still—he said its neuropathy. **Interviewer:** Right. **Interviewee:** And, um, [*pause*] and yeah, okay, is it gonna go away? What? You know? But as far as he couldn't tell me—**Interviewer:** Well, did he give you any medication to help with it? **Interviewee:** No. No. I don't know if I have to wait, cause *they want my system cleared* of just about everything. (Mrs. L., Cell Phone Interview #4).

Gina confirmed her understanding:

And, um, I thought since I'm off of the um, the Dara [Daratumumab] for the last three weeks because if I—you know, if I need to get—you know, if I need to go on something else, I have to get the other stuff outta my system first, you know, so. (Gina, Cell Phone Interview #3).

Just trying to get through it. Just Trying to get Through It describes the symptom burden endured by patient-participants. During the cell phone interviews, it became readily apparent that patient-participants underwent symptom burden that affected their ability to continue working, care for their families, and care for themselves. Symptom burden affected emotional and physical aspects of the patient-participants' lives. They shared feelings of anger, fear, and misery and talked about good days and bad days (*How I Feel*). They described their physical symptoms, such as nausea, hair

loss, pain, and fatigue. Some of the physical symptoms were viewed as something to overcome, and enabled the participants to feel that they could get their “strength and health back together” (Mrs. Washington, Cell Phone Interview #4). Other physical symptoms were debilitating and, often, non-responsive to attempts to manage them. Some patient-participants were prepared for the symptoms, while other participants were wholly unprepared for the frequency and severity of the myriad symptoms they faced daily. Successful symptom management enabled many participants to achieve some measure of normalcy in their lives and to remain in their CCTs.

How I feel. Patient-participants experienced days, when symptoms and/or side effects from CCT treatment did not impede their daily activities (*I feel good*):

I feel good today. Uh, I’ve got off of the, uh, proton machine and, um, I was able to, you know, go directly to my car, jump in it, and pull some out of the, uh, Rapid Profile parking lot and, um—and just carry on with my—with my day.

Interviewer: Uh huh. **Interviewee:** Um, I had to do some running around but I wasn’t amiss for energy or anything like that. (Steed, Cell Phone Interview #2).

For Mrs. Washington, feeling good meant awakening, showering, cooking, and being able to eat “a nice sized portion” of food” (Mrs. Washington, Cell Phone Interview #1).

Then, there were days when patient-participants had to attempt to gather their resolve to begin the day or to begin an activity (*gettin’ myself together*). Ellie had difficulty starting her day for a few days after receiving her CCT treatment:

Interviewer: - 10:00 might be a little early for you. **Interviewee:** Yeah. I think so cuz I’m just really *gettin’ myself together* around that time, so. Especially this—especially the first few days. The first three or four days it seems like I’m kinda slow getting started [*Laughter*]. (Ellie, Cell Phone Interview #3).

Then, there were days the patient-participants stayed at home and barely moved from their beds (*not feeling too good*), as shared by Mrs. Washington, “Uh, I’m at home, but

I'm *not feeling too good* today" (Mrs. Washington, Cell Phone Interview #2). In an earlier cell phone interview, she elaborated, "Like, I'm tired, I can't get comfortable if I'm laying down. I'll have hot and cold flashes. Pretty much, I may eat something, but it won't be like a nice sized portion" (Mrs. Washington, Cell Phone Interview #1). Mrs. L shared:

I'm trying. Maybe not hard enough, you know. I need to sit out and get some sunlight in me and whatever, but it's—I come in here and the first thing I do is crawl up in my bed and go to sleep. (Mrs. L, Cell Phone Interview #3).

Feeling unhappy, or uncomfortable (*I'm miserable*), was mentioned by some of the patient-participants during periods of their CCT participation, when they were experiencing symptom burden:

Now the tumor's starting to hurt. But it's supposed to be shrinking. And I get, like, pain in my bones, like near the pelvis area. And I think I told her all of that last time I saw her, so she said she would try to cut back on the chemo a little bit, you know. But *I'm miserable* as heck. (Mrs. L, Cell Phone Interview #3).

The full impact of Katie's increasing alopecia (loss of hair) had the same effect on her, when she was discussing with her supervisor her remaining CCT treatments:

Oh, we got four down, you know. Seven to go on this cycle," and I was like, 'Yeah,' and then she was like, 'So how are you doing?' And I just, like, bust out crying. And she was like, 'Oh, what's going on?' She said, you know, 'cause everybody's so used to seeing a smile on my face, and I've been, you know, okay and then—so I was just like, I said, 'It's the hair.' I said, 'And today I just felt like, you know, I, I felt like I didn't look nice. I didn't feel good about myself.' And it's so, you know, just how I felt on Friday. (Katie, Cell Phone Interview #3).

Some cell phone interviews discussed anger, fear, and thoughts of death. Gina felt anger for being affected by cancer, while others around her did not have cancer and were "still living" (*I'm angry*). She described an interaction with a friend whose wife had recently died from pancreatic cancer:

He said, ‘This is the first time I really can talk to somebody without cryin’ and breakin’ down.’ And I realized—he says, ‘And *I’m angry* right now.’ He says, “I’m going to therapy,” he said, ‘Because she was a good woman. She wasn’t drinkin’, smokin’, out there.’ He said, ‘There are people out here that are abusing their bodies,” and he said, “They’re still here,’ and I realized when he said that I felt the same way. I had that same feeling sometimes. It’s like, I’m not doin’ the things that these people are doin’ but getting—still, they’re still living. (Gina, Cell Phone Interview #1).

Fear (*I’m scared*) was expressed by Gina, as well, when she thought about the effectiveness of her CCT treatment:

You don’t, you know, I mean it’s-it’s supposed to just target that area, but every person is different, so yeah, I’m-*I’m scared* because I don’t—I don’t know, um, what else could develop. I don’t—*I’m scared* because I want to—I want to be in remission and, you know, I don’t wanna have to do—you know, anything else that I might be on would be like a standard drug, and thus far standard drugs have not worked for me. (Gina, Cell Phone Interview #2).

Ro shared the same concerns, “So you’re still thinkin’, you know, I’ve gotta get chemo and this treatment, are they gonna work? And you know, is this treatment gonna be successful? Is this the best treatment” (Ro, Cell Phone Interview, #3)? Last, thoughts of death and mortality (*thinking about death*) were common among the patient-participants—although fear was not always associated with it:

I used to be scared. I used to wake up in cold sweat, um, because *thinking about death* and my dying, but now it’s like I don’t feel that way. It’s like if I, you know, I believe I’m going to heaven, so it’s—I-I-I don’t have that fear that I used to have. (Gina, Cell Phone Interview #2).

Ro commented,

Uh, well, first of all, you know when you’re newly diagnosed with—the first you hear the word cancer, the first thing that’s on your mind is how long I got, I’m gonna leave here [04:25], all that you know, that start goin’ through. (Ro, Cell Phone interview, #3).

It’s knocking me down. Nausea was mentioned by a few of the Black cancer patients who provided cell phone interviews—however, none of the participants reported

difficulty managing it. Similarly, diarrhea was discussed infrequently (Bob, Cell Phone Interview, #4; Mrs. L Cell Phone Interview #3; Mrs. Washington, Cell Phone Interview #3). Other symptoms discussed sparingly by the participants, included acid reflux, disequilibrium, and insomnia.

By contrast, many of the patient-participants discussed *feeling the fatigue*, or the subjective feeling of extreme tiredness, as expressed by Mrs. Washington, “Uh, Friday, Friday was good. Saturday was, Saturday was good, and then I started feelin’—it was Saturday night I started *feeling the fatigue* going on” (Mrs. Washington, Cell Phone Interview #2). Generally, fatigue occurred on the day of, or within a day or two of, receipt of CCT treatment (Ellie, Cell Phone Interview #1; Steed, Cell Phone Interview #4; Mrs. Washington, Cell Phone Interview #2). Typically, patient-participants described requiring several additional hours of sleep during their day (Kit, Cell Phone Interview #1; Mrs. L, Cell Phone Interview #1; Mrs. Washington, Cell Phone Interview #2; Steed, Cell Phone Interview #4). The degree to which fatigue interfered with their daily activities varied. Kit, who was adamant about compartmentalizing her CCT treatment from her daily life, stated that the fatigue “makes it hard to balance school and work and home” (Kit, Cell Phone Interview #1). Other participants surrendered to the extreme tiredness for a period of time, then resumed with the remainder of their daily activities:

I don’t know if it was me not wanting to push it or ran out of energy. I said, ‘No, I just don’t feel like doing this right now.’ I took the vacuum the cleaner and put it over on the side. I went upstairs and took a nap, came back down and that was it. Then I finished. (Steed, Cell Phone Interview #4).

Finally, a few, like Mrs. L and Eric were challenged severely by their fatigue. Eric freely admitted that, initially, the radiation had a limited effect on his physical constitution (Eric, Cell Phone Interview #1). However, at the time of his interview, he reported that he felt “very weak and tired” and had begun to “fall asleep all the time” (Eric, Cell Phone Interview, #1). He was finding it difficult to work—although, he was still able to work. Mrs. L was very challenged by fatigue. She recognized the seriousness of her fatigue, but felt unable to combat it:

I just get tired. That’s what’s bothering me I wanna be an adult now. I want to be able to do what I need to do in this apartment, and I just get, oh, like, wow. I’ll sit there and try to get myself together, and the next thing, I just come right on in here, crawl up on my bed and go to sleep. (Mrs. L, Cell Phone Interview #1).

The male participants in the Yoga Study, Steed, Ro, and RR, had been randomized to receive yoga instruction as a means to reduce the effects of fatigue from the radiation therapy administered as part of their prostate cancer CCT (RR, Cell Phone Interview #4). All the men spoke highly of the physical and meditative benefits of yoga instruction. It did reduce some of their fatigue. Yet, eventually, RR and Steed yielded to the effects of the radiation therapy (RR, Cell Phone Interview #1; Steed, Cell Phone Interview #4).

Symptoms tied to physical appearance, such as skin changes (*marked up pretty bad*) and hair loss (*when the hair starts to come out*), were very upsetting to the female patient-participants. Mrs. L had a rash on her neck. She stated that the nurse practitioner did not know the cause of the rash and had never prescribed any medication:

So it’s like, are you listening? I’m trying to tell you somethin’. And that’s when I get just tired and my skin breaking out. She still says she doesn’t know why that’s happening. Well, okay. All right. Whatever. You know. I don’t like it.

I've not had skin break out like this in *[laughs]* ever. You know. And it's—it's just annoying. But I'm *marked up pretty bad*, so I can just give up on the skin, you know. (Mrs. L, Cell Phone Interview #3).

Katie had blue-black discolorations on both of her hands (Katie, Cell Phone Interview #2). The nurse practitioner was aware of her hand discolorations; however, Katie was not given medication, or any recommendations on how to care for the discolorations.

Hair loss, mentioned by several of the women during their face-to-face interviews, continued to be an enduring and painful topic during the cell phone interviews (Diane, Semi-structured Interview; Gina, Cell Phone Interview #1; Katie, Semi-structured Interview; Katie, Cell Phone Interview #1; Katie, Cell Phone Interview #2; Kit, Semi-structured Interview; Mrs. S, Semi-structured Interview). Hair loss was one of the symptoms that could not be remedied. Katie was especially distressed and had difficulty adjusting to her hair loss. Her hair had been important to her; and she recognized that she would have difficulty when it began to “shed”:

I think I mentioned that to one of my friends, and I said, ‘I know *when the hair starts to come out* I'm gonna be, like, a mess because I'm big on getting my hair done.’ I used to go to the hairdresser like every week at one time. (Katie, Cell Phone Interview #2).

Her hair was an integral part of her self-image. Ultimately, Katie did buy a human hair wig and began to wear it (Katie, Cell Phone Interview #4). However, she remained inconsolable about her hair loss. Gina adjusted to hair loss by wearing wigs, while her hair grew naturally under her wigs as dreadlocks (locks).¹⁴ However, she had not come to terms with losing her new growth of locks which was fragile (Gina, Cell Phone

¹⁴ A dreadlock, or lock, is comprised of strands of hair that have been twisted or formed together and allowed to grow together as a single piece of hair.

Interview #1). The weight of the hair was causing the locks to break apart and fall off her head. She despaired that her new growth of locks would have to be cut (Gina, Cell Phone Interview #1).

Pain (*pain*) and peripheral neuropathy (*neuropathy*) were mentioned frequently as extremely distressing symptom experiences. Both symptom experiences affected the daily activities of the patient-participants and were not always amenable to effective control by the CCT team. Willie reported that the "...only thing that I have is the *pain*, and that's, that's the everyday thing. I don't think I'm gonna ever get rid of that pain" (Willie, Cell Phone Interview #1). A few patient-participants reported feeling no pain during their CCT (Bob, Cell Phone Interview #3; RR, Cell Phone Interview #3). For those who experienced pain, the participants varied in their description of the quality and the duration of their pain. The quality of the pain ranged from discomfort to feeling like "being hit in the back" (Ro, Cell Phone Interview, #1; Mrs. L, Cell Phone Interview #3). The duration of the pain varied. Some pain was episodic. Ro received Lupron injections which caused nipple and breast tenderness (Ro, Cell Phone Interview #1). His pain occurred only when his chest was touched. He described pain which nearly made him "drop to his knees," when a friend playfully punched him in his chest (Ro, Cell Phone Interview #1). Ellie experienced pain only when her portacath was accessed (Ellie, Cell Phone Interview #2).

For some patient-participants, the pain was continual and unremitting. Willie and Mrs. L had unrelenting pain secondary to their colo-rectal cancer (Mrs. L, Cell Phone Interview #3; Mrs. L, Cell Phone Interview #4; Willie, Cell Phone Interview #1).

Abdominal pain was a regular part of their lives, since each day began and ended with pain for both of them (Mrs. L, Cell Phone Interview #1; Mrs. L, Cell Phone Interview #4; Willie, Cell Phone Interview #1). Willie assiduously kept her pain level at a pain rating of three to four out of ten, while Mrs. L preferred to be in pain rather than be sedated by the prescribed dosage of her pain medication (Mrs. L, Cell Phone Interview #3; Willie, Cell Phone Interview #1). Mrs. L's pain was a significant part of her CCT experience; she discussed her pain in every cell phone interview in which she participated.

Katie had breast pain secondary to her cancer. She worked, cared for her sons, had massages, and, otherwise, continued her daily routine. She used oxycodone to control her pain. Except, she could not take her opiate pain medication in the morning, since she drove to work each day (Katie, Cell Phone Interview #4). The oxycodone made her too drowsy to feel safe driving. Although, there were times when the pain prompted her to take the opiate medication at work:

Now, there's been time I taken it at work, because hoping—like if I take it when I get to work, hoping that I, I'll be okay by the time I drive home. Which I, I was, but I don't know. I just felt a little iffy about that. (Katie, Cell Phone Interview #4).

So, she was able to relieve her pain despite putting herself at risk, when she drove home in the evening. The pain severity was enough for her to risk taking the oxycodone at work.

In addition to pain caused by their disease, patient-participants related the occurrence of pain resulting from treatment, procedures, or evaluations secondary to the CCT. Mrs. L reported feeling incredible pain while she was positioned for a MRI. Ellie had a portacath, or a central line in her chest which had to be accessed by inserting a

needle into its barrel. Because the portacath laid under the skin, accessing it necessarily entailed piercing the skin overlying it. The process of piercing the skin was painful for Ellie. She had endured the pain until a home infusion nurse recommended that Ellie get a prescription for topical lidocaine from her oncologist. Bob developed a pleural effusion in one of his lungs which compromised his ability to breathe effectively and without discomfort. A thoracentesis¹⁵ was performed three times, before a pleur-x-catheter was inserted into the pleural effusion (Bob, Cell Phone Interview #3). Bob's husband was trained in the use of a pleur-x-catheter by a home care nurse. The pleur-x-catheter allowed frequent draining of excess pleural fluid as it accumulated around Bob's lung, thereby permitting Bob to breathe effectively and without discomfort. In addition, it could be performed by his husband in their home, as needed. Subsequent to drainage of the pleural effusion, Bob would experience pain in his lung for approximately an hour (Bob, Cell Phone Interview #3). Eventually, he and his husband learned to stop draining the pleural effusion as soon as Bob felt the slightest discomfort.

Shortness of breath (*shortness of breath*) was mentioned by only three of the participants in their cell phone interviews (Bob, Cell Phone Interview #3; Diane, Cell Phone Interview #3; Mrs. Washington, Cell Phone Interview #4). Mrs. Washington mentioned it for the first time in her last cell phone interview. Bob mentioned it in relation to the pleur-x-catheter inserted secondary to his pleural effusions. He had reported to his oncologist that he had experienced, "Um, extreme *shortness of breath*, just

¹⁵ A thoracentesis is the insertion of a needle, or small tube, into a pleural effusion with the intent to drain the excess fluid. It is performed in inpatient and outpatient hospital settings.

from very little activity” (Bob, Cell Phone Interview #3). Bob’s shortness of breath resolved with more frequent removal of pleural fluid at home with the pleur-x-catheter (Bob, Cell Phone Interview #3). By contrast, Diane’s shortness of breath was debilitating and affected every aspect of her life. It resulted from the disease in her lungs, abdominal ascites, and an abdominal tumor pressing up on her lungs (Diane, Cell Phone Interview #3; Diane, Cell Phone Interview #4). She had to do everything slower (e.g., personal hygiene, walking, dressing), eventually could not drive, and had difficulty working her entire eight-hour shift (Diane, Cell Phone Interview #3; Cell Phone Interview #4).

Peripheral neuropathy (*neuropathy*) affected several members of the sample. For Ellie, peripheral neuropathy was the CCT symptom which bothered her the most, “Uh, just that with—what bothers me—I think what bothers me the most is dealing with *neuropathy*. Mm-hmm. It really—it-it just bothers—seems to bother me the most” (Ellie, Cell Phone interview #3). It was caused by medications administered as part of the CCT. Peripheral neuropathy for Katie, Kit, and Mrs. Washington (all of whom who had breast cancer) was expressed as numbness and occasional pain in their hands and fingers (Katie, Cell Phone Interview #3; Kit, Cell Phone Interview #1; Mrs. Washington, Cell Phone Interview #3). During their cell phone interviews, neither Kit, Katie, nor Mrs. Washington mentioned any situations when the peripheral neuropathy affected their daily activities. They were not given medication. However, Katie’s oncologist did lower the dosage of the medication causing her peripheral neuropathy (Katie, Cell Phone Interview #4).

Mrs. L and Ellie had severe peripheral neuropathy that impeded their daily activities. If Ellie touched objects with her hands during an exacerbation, her skin felt like it had been burned (Ellie, Cell Phone Interview #3). She could not pick up objects, open containers, or button her clothes (Ellie, Cell Phone Interview #4). She attempted to cope with the sensory impairment by wearing gloves. Her oncologist prescribed Neurontin; however, "...it took about four weeks for it to really kick in like it's supposed to" (Ellie, Cell Phone Interview #4). Eventually, the medication causing the peripheral neuropathy was discontinued by the oncologist. Mrs. L's tactile sensory impairment from peripheral neuropathy resulted in her feeling like she was "being electrocuted" (Mrs. L, Cell Phone Interview #1). Like Ellie, she learned to use gloves, or oven mitts, to touch objects in her kitchen. She could not touch or ingest anything cold (Mrs. L, Cell Phone Interview #1). All food and drink had to be room temperature, or she would experience a very unpleasant sensation in her throat, which was "indescribable" (Mrs. L, Cell Phone Interview #1). Unlike Ellie, Mrs. L was not given any medication for her peripheral neuropathy.

Table 4-10: *Who I Am*

<u>Theme</u>	<u>Who I Am</u>		
Category	I Didn't Want to Be Different Than Who I Was	Cancer Has Changed My Life	Getting the Word Out
<i>Code</i>	<i>"I don't let it consume my whole day" "balance" "faith"</i>	<i>"you gotta do whatever you have to do" "next thing that has to be worked on" "insurance companies" "work"</i>	<i>"I am very open" "they've been through it" "a dialogue" "sharing your story"</i>

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Who I am. Throughout their CCT treatment, patient-participants expressed a desire to remain “who they were” before their CCT participation (**I Didn’t Want to Be Different Than Who I Was**). They struggled to maintain a sense of who they were and what was important in their lives by continuing to live despite the presence of their cancer in their lives (*I don’t let it consume my whole day*), keeping a sense of balance in their lives (*balance*), and acknowledging and sustaining their spiritual beliefs (*faith*). Ultimately, the participants did acknowledge that their cancer diagnosis and their participation in the CCT had changed their lives (**Cancer Has Changed My Life**). At various times during their cellphone interviews, patient-participants spoke candidly of finding ways to adjust to their new lives with cancer and CCT participation (*you gotta do whatever you have to do*). They discussed their interactions with insurance companies (*insurance companies*), acknowledged the effect of CCT participation on their work lives (*my job*), and learned to manage new medical conditions which developed secondary to CCT participation (*next thing that has to be worked on*). Finally, one common characteristic of many of the patient-participants was the strong desire to bring knowledge of cancer and CCTs to their family members and into the Black community (**Getting the Word Out**). Patient-participants spoke of how and with whom they had shared information regarding their cancer diagnosis and their CCT participation (*I talk openly*). Some were fortunate to have other individuals share their cancer and CCT

experiences before or during the patient-participants' CCT participation (*they've been through it*)—in turn, this sharing prompted the participants to do their own sharing about their cancer and their CCT experiences (*sharing my experience*) in their church and in the Black community (*opening the dialogue*).

I didn't want to be different than who I was. During the face-to-face interviews, patient-participants expressed the affirmation that they were alive, present, and surviving their cancer and CCT treatment. They typified this affirmation during their cell phone interviews. A large part of this affirmation were their efforts to balance the demands of CCT treatment with the demands of their home life, work life, and/or school life (Kit was a doctoral student) (*balance*) by making a concerted decision to fit the CCT into their daily schedule, instead of allowing it to become the central focus of their lives. Kit stuck to a strict schedule to maintain normalcy in her three children's lives, "I generally stick to the schedule because I have to maintain a *balance*" (Kit, Cell Phone Interview #1). Although maintaining normalcy in family life was mentioned by some of the patient-participants, maintaining a work life balance was mentioned by more patient-participants—especially by participants who continued to work during CCT enrollment.

Patient-participants balanced work and CCT treatment in various ways. Ro integrated yoga into his work as a school administrator, by offering yoga as a part of the summer program at his school in order to calm and de-stress students with behavioral differences (Ro, Cell Phone Interview #1). Katie was strategic in scheduling her CCT appointments as close to the late afternoon as possible, in order to preserve her sick time (Katie, Cell Phone Interview #4). Diane attempted to schedule as many appointments as

possible on the same day (Diane, Cell Phone Interview #1). Despite these efforts, participants with progressive disease began to find that CCT appointments began to consume more and more time out of their day (Diane, Cell Phone Interview #1). Kit was the only patient-participant who was faced with integrating her work life, family life, and school life with her CCT enrollment. Kit was a doctoral student, as well as a single mother and a full-time school administrator, who was in the midst of taking her comprehensive examinations and writing her dissertation proposal. She balanced her CCT enrollment, work, school, and family by compartmentalizing every facet of her life:

I have three children. So, um, whatever I do at work is at work. And whatever I do at home is home. And my schoolwork. But other than that, I don't – I don't do work at home. So, I generally want time so I can make sure I get home and be there for my own children. Cook dinner... I still have time for everything. I make time for everything. Um, and it helps to ignore how you feel anyway. It kinda makes it go away. So, um, yeah I don't – I don't let the cancer impede on my life. (Kit, Cell Phone Interview #1).

Many of the patient-participants were anchored by their belief in God, or the significant presence of God in their daily life (*faith*). Katie's faith allowed her to disclose her cancer diagnosis and CCT participation to her children:

These are my children. I can't believe they have to deal with this. And I wasn't. I was just open, and candid, and okay with just talking to them, and, you know, in the midst of this here just holding them, but talking to them, but I wasn't crying or anything. And I told him if I didn't have that firm belief in that *faith* that I wouldn't even be able to do that. I probably would've been a mess. (Katie, Cell Phone Interview #1).

Their faith sustained them, when there were indications of disease progression:

So, you know, I was—I was a little concerned and, you know, just a little depressed, but I was like, you know what? If God worked all the rest of that out, he's gonna work this out too. One way or the other, if it's, you know, if it's—I-I can't do anything about this. You know, I'm part of the study and he has total control. I mean I take medication and do whatever, but he has total

control. (Gina, Cell Phone Interview #2).

Faith enabled the patient-participants to move each day against all odds, and to believe that they were “not always going to be this way, feel this way, act this way” (Gina, Cell Phone Interview #1). It kept them involved in activities at their church. RR was a member of the trustee board at his church (RR, Cell Phone Interview #2). Diane was a member of a cancer support group and was spearheading a cancer prevention/CCT informational session at her church—even as she endured disease progression and increasing symptom burden (Diane, Cell Phone Interview #2). Gina was a member of a telephone prayer group that met every morning at 6:30 a.m. (Gina, Cell Phone Interview, #2). Katie participated in a clothing donation program at her church (Katie, Cell Phone Interview #1). Also, when the time came, faith enabled Katie to step away temporarily from her church activities and still know that God was with her, even though she could no longer be active in her church:

And I just remember at the end [of a conversation with a friend] he said, you know, he was talking about you know praying and being faithful and whatever. He said, ‘But we as church members have to know how to take a break.’ And it was just so weird, and that just resonated in my head, you know, and I always say, you know, do I hear this, and I’m running this, and I’m doing this. (Katie, Cell Phone Interview #4).

When she appreciated the enormity of her belief in God and His integral role in her life, she could put aside her church involvement, for a time.

Cancer has changed my life. Despite attempts to manage the various aspects of their lives, invariably there were certain aspects of the patient-participants’ lives that were altered by their cancer diagnosis and CCT participation (*Cancer Has Changed My Life*). Living with their cancer and CCT enrollment presented challenges to the

participants. However, many of the patient-participants reconciled themselves to surmounting these challenges (*you gotta do whatever you have to do*), as voiced by Ro, "You gotta do what you gotta—if you wanna survive, if you wanna beat this, *you gotta do whatever you have to do*" (Ro, Cell Phone Interview #3). One of the earliest challenges was willingness to talk about their cancer diagnoses. Some participants still had difficulty talking about their cancer with others. Katie acknowledged that being interviewed as part of this dissertation study made her feel that it was okay to talk about her cancer, "And then just with you talking to me, asking me questions, just reaffirms that, you know, it's okay to talk about it. It's okay to, you know—you know, share. You know?" (Katie, Cell Phone Interview #1).

Her ability to talk about her cancer changed over the course of her cell phone interviews. She made tentative, then repeated, efforts to talk to her sister, mother, and sons about her cancer, thereby assisting them in adjusting to her cancer and the ensuing side effects of the CCT medication (Katie, Cell Phone Interview #1, Katie, Cell Phone Interview #2; Katie, Cell Phone Interview #3; Katie, Cell Phone Interview #4). By her fourth cell phone interview, Katie was talking freely about her changed life.

Significantly, she had accepted her hair loss and her mother's inability to accept her cancer diagnosis:

I'm so used to it now I just come in, like I wear a wig. I just come in the house and take it off, and I have no hair. But I do this. Like, she will just stare at me. I don't say anything. Used to say, like, ask questions, but I don't say anything—I just let it go. That's how she deal, deals with it. I just leave it alone. (Katie, Cell Phone Interview #4).

Initially, Jay had a more difficult time contending with his cancer diagnosis, since he used a mini-infuser strapped to his body to deliver chemotherapy over several days. He abhorred the stares and comments of others. Jay sensed, whether correctly or incorrectly, that other individuals viewed him as a pariah to be avoided, because he was “sick” or “contagious” (Jay, Cell Phone Interview #1). Their perceived reactions angered him (Jay, Cell Phone Interview #1). The oral formulation of his CCT chemotherapeutic medication made it easier for Jay to accept his diagnosis and treatment:

They look at you like, you know, they see somebody with a bottle, and right away they think that, ‘Oh, he’s sick. He’s contagious. Stay away from him.’ I’m, like, ‘Y’all are [inaudible 05:40]. Y’all don’t know what I’m going through,’ you know. They shouldn’t be talking... Yeah, so I’d—like, I really didn’t like it, you know, that’s—gotta wake up with a bottle, go to bed with a bottle, you gotta make sure you don’t sleep on the bottle and all that. Make sure you don’t pop the IV [inaudible 06:03] like it says. **Interviewer:** Right. **Interviewee:** But with the pill, I gotta take my little pills [inaudible 06:08] take it with me and I’m good to go. (Jay, Cell Phone Interview #1).

Preexisting caregiving relationships were changed by cancer and CCT participation. Some patient-participants’ family members willingly assumed caregiving roles, such as Bob’s spouse, Ellie’s spouse and daughter, and Diane’s spouse. Patient-participants’ with established caregiving roles for family members instituted changes to these relationships, as a result of CCT appointments. Pursuant to her interviews, Kit appeared to be successful in compartmentalizing her work, home, and school lives (Kit, Cell Phone Interview #1). Mrs. L managed by being home with her daughter and making her CCT appointments contemporaneous with her daughter’s appointments (Mrs. L, Cell Phone Interview #3). Katie wanted always to be present for her sons, despite juggling work and CCT appointments. As a result, her sons had to accept a modicum of

responsibility and acknowledge the necessity for a precise schedule, from the moment they awakened in the morning until Katie had completed helping them with their homework in the evening (Katie, Cell Phone Interview #3).

Gina had a more demanding situation. She was the sole caregiver for her mother who had dementia. Because of lack of support and financial resources, she could only afford to have a neighbor “look in” on her mother periodically during the day instead of a full-time caregiver while Gina worked (Gina, Cell Phone Interview #1). Despite coming home as late as 7PM or 8PM, she began her caregiving activities as usual: cooked dinner for her and her mother, washed the dishes, washed/bathed her mother, put her mother to bed, and prepared herself for the next day (Gina, Cell Phone Interview #2; Gina, Cell Phone Interview #2). Gina was relieved of this responsibility proximate to the second cell phone interview. She had to place her mother in a nursing home, after her mother developed bilateral deep vein thromboses and would require lifelong anticoagulation.

Many of the patient-participants realized they had to adopt healthier lifestyles in order maintain their functional status during their CCT participation, such as Diane who increased your walking despite having shortness of breath,

And I walked more than I have in a long time last night from the-the distance that they have me walking in this hospital. I started, uh, I started to go back and get in the car, but I went on and I pursued it and I walked all the way back. And I said, now that’s huffing and puffing and deep breathing probably do a lot of that stuff out of me, which I hope it did. (Diane, Cell Phone Interview #1).

They increased their fluid intake of water and other liquids to combat dehydration and cramping secondary to electrolyte imbalances:

And I find that when I drink more fluids that I don’t have that—the muscle spasms and the cramps and stuff that I was having. Especially now since it’s so

hot, you know, I definitely have to stay hydrated. And I realize that the more that I drink fluids that, um, the better it is for me, and I'm not—I'm—I'm not cramping and, you know, that kinda thing. (Gina, Cell Phone interview #2).

Other patient-participants meditated to promote mental and psychological health, while the men in the Yoga CCT performed yoga for physical and mental wellness independent of scheduled sessions (RR, Cell Phone Interview #2; Ro, Cell Phone Interview #1; Steed, Cell Phone Interview # 3).

The lives of some of the patient-participants were changed by the development of additional comorbidities. They were tasked with managing not only their prior conditions, but also learning to manage their new comorbidities (*next thing that has to be worked on*), as noted by Kit regarding her new diabetes diagnosis. Kit was aware of her borderline diabetic status, prior to her participation in I-SPY II:

And I found out I have diabetes yesterday now. But, uh, other than that, you know, it's good. So, now I'm just addin' that to the *next thing that has to be worked on* I was borderline before, but now because of the steroids it's pushed it over. So, I was close but I never made it to actually havin' it. So, now I'm fully there. (Kit, Cell Phone Interview #1).

Kit managed her diabetes methodically, as she did every aspect of her life. Ellie's life was complicated when she developed a pulmonary embolus (blood clot in her lungs) towards the end of the cell phone interviews (Cell Phone Interview #4). She adapted to the new medical condition and learned to self-inject lovenox (an anticoagulant) with the assistance of her family (Ellie, Cell Phone Interview #4).

All the participants had to interact with the insurance companies responsible for covering (or not covering) the costs of their CCT participation and the usual and customary care related to the CCT treatment (*insurance companies*). The cost of CCT

participation was borne, often uneasily. All the participants had some type of insurance coverage and appreciated the availability of insurance coverage (Bob, Cell Phone Interview #3; Mrs. L, Cell Phone Interview #3). Having insurance also meant keeping insurance and managing all of the paperwork. When asked regarding recent challenges, Bob mentioned, “[D]ealin’ with these, you know, *insurance companies*” (Bob, Cell Phone Interview #4). Bob nearly lost his health insurance coverage, when his employer failed to pay the premiums and the insurance company failed to notify Bob of the nonpayment for two months (Bob, Cell Phone Interview #3):

Something just clicked in my mind [chuckles] one day, so I called to find out. And she was like, ‘Well, yes, um, you know, your benefits haven't been paid—‘ I think it was since May. At the time, that was May 16th that my payroll stopped paying for, you know, my benefits. But then they let it go. She said, ‘They don’t contact you until the bill reaches—the past-due bill would reach \$100’-- which mine, I think, at that time had only reached, like, \$24. (Bob, Cell Phone Interview #3).

Insurance coverage for services performed frequently was an issue. Diane faced this insurance reality. Diane made a practice of requesting that her physician, radiographic, and other CCT-related appointments be grouped on one day, in order to avoid the \$20 per visit copay (Diane Cell Phone Interview #1). Before she made the request, she had two to three appointments a week, two to three times a month (Diane, Cell Phone Interview, #1). Response assessments required frequent radiography studies. However, insurance companies did not always pay for every response assessment radiography study required by CCTs. So, often, the PET scans were not done:

And [I] was askin' about the PET scan also, and they were, like, ‘Well, you know, we don’t even request PET scans anymore because the insurance companies they just, you know, deny, deny, deny, deny. They don’t accept—after you already had one they figure that’s enough. (Bob, Cell Phone Interview #4).

If the PET scan was performed, the patient-participant would have to pay for it.

Several of the participants discussed the impact of CCT participation on their employment (*work*):

Well, um, people at *work*, you know, have been really, really, um, cooperative, you know, because I'm showing up—it's not like you're going and you're trying to take advantage of anything. You know, they know what I'm going through. So I really, you know, I've—I-I don't put any pressure on myself at work and they seem to be working with me, so I'm very happy about that. (Diane, Cell Phone Interview #3).

Diane was placed in an untenable position. She had to ascertain how to retain her job, in order to keep the insurance enabling her continued CCT participation—in turn, the increasing symptom burden and time spent at CCT appointments were resulting in her impending job loss:

...I'm still having my manager and a couple other people have been noticing that they know that I'm short of breath. So I'm—I'm thinking in terms of now that there's something that I might have to lookin' forward to is them puttin' me out. (Diane, Cell Phone Interview #4).

Her position was extremely precarious during the fourth cell phone interview. Her new oncologist was proposing major abdominal surgery for temporary relief of her respiratory distress, which would require her to recuperate at home for several weeks. She had worked too few hours to qualify for leave time under the Family Medical Leave Act, had no vacation time left, and had 13 hours of sick time left (Diane, Cell Phone Interview #4). Diane chose the surgery.

Getting the word out. As is evident from the interviews, the Black cancer patient-participants had varying experiences derived from their symptom burden, the measure of support they received from their families and CCT teams, and the manner in which they

managed their cancer. However, many were similar in their desire to share their cancer diagnoses and CCT experiences. Many patient-participants, such as Kit, were willing to discuss candidly with others their cancer diagnosis and cancer treatment (*I am very open*), “*I’m very open*, so I share whatever. I feel like people should learn what’s happenin’ to me” (Kit, Cell Phone Interview #1). The patient-participants were open in sharing information regarding their cancer diagnoses and CCT participation with church members, their other healthcare providers, and abject strangers:

Um, there were some people that walked into me yesterday and I had the IV in my hand because when I left MRI and I went—okay, I had to—I didn’t have any money. I had to come back and talk with the—the credit union and then come back out, and a few of them say, ‘Oh, are you okay?’ And I just—I just wanted to run ahead and [inaudible] and I was like, ‘I’m okay.’” She was like, ‘You’ve got an IV in your hand. Something’s going on.’ And I said, ‘You know what? I have breast cancer.’ She said, ‘Oh my God.’ I said, ‘It’s okay. I’m okay. I’m [mumbling voice 26:27]. I’m here for my treatment. I’m good.’ (Katie, Cell Phone Interview #1).

Some patient-participants were motivated to share experiences, because someone had shared their on-going, and/or past, experiences with them (*they’ve been through it*).

Mrs. Washington shared her on-going conversations with her co-workers:

...seems like most of the ladies where I work from has started finding lumps in they breasts. So they—that has, uh, uh, and *they’ve been through it*. So we have each other's phone numbers. And, you know, like, they'll call me up. I'll call them up. (Mrs. Washington, Cell Phone Interview #4).

Some patient-participants simply listened to the stories of cancer survivors who were patients at the Cancer Center, church members, or neighbors who lived across the street (Diane, Cell Phone Interview #2; Katie, Cell Phone Interview #4; Ro, Cell Phone Interview, #3; Steed, Cell Phone Interview #1). Ellie spoke with a church member who had experienced severe peripheral neuropathy secondary to continued use of

oxaliplatin—the chemotherapy drug that had caused Ellie’s peripheral neuropathy and that had been stopped by Ellie’s oncologist (Ellie, Cell Phone Interview #4):

I know there’s a woman at my church who did that, and she’s so sorry because things didn’t go-go well with her. She, uh, she-she developed some other problems because of the neuropathy. Uh-huh. She developed some other-other problems...I mean, I can’t remember what all she said. But I do remember that she said neuropathy was driving her crazy, so. (Ellie, Cell Phone Interview #3).

This discussion affirmed Ellie’s trust in her oncologist’s individualizing her chemotherapy plan, rather than continuing with treatment consistent with the chemotherapy regimen. Mrs. Washington’s cancer diagnosis resulted in an outpouring of expressions of support from the wives of her husband’s co-workers and from her coworkers, who were cancer survivors, or who were “going through it” at the same time as she (Mrs. Washington, Cell Phone Interview #4). Male members of Steed’s church congregation reached out to him, when he disclosed his prostate cancer diagnosis—men, who heretofore, had never revealed their cancer history to Steed (Steed, Cell Phone Interview #1). A few, or many, words expressing support buoyed the spirits, as well as the resolve of several participants to continue their CCT treatment (Kit, Cell Phone Interview, #1; Ro, Cell Phone Interview #3).

The patient-participants shared their cancer and CCT experiences (*share your story*) with members of their church, members of their community, and other individuals with and without cancer, as a means of opening up the discussion about cancer, cancer prevention, cancer treatment, and cancer clinical trials (*a dialogue*). A few patient-participants did not discuss sharing their cancer and CCT experiences with others. Bob stated frankly that he had not talked about his pancreatic cancer and CCT with people,

other than his family members or individuals involved in his care (Bob, Cell Phone Interview, #2). Some participants, such as Katie, spoke prospectively of what they would share with other individuals. She addressed many of the issues she discussed during her cell phone interview. However, paramount among her concerns was the necessity to listen, as well as talk, so as not to overshadow their experiences (Katie, Cell Phone Interview #4). Katie stated that she would try to explain clinical trials and the reasons why they are done (Katie, Cell Phone Interview #4). She sought to impart hope and encouragement that there is a CCT team and physicians who can provide care for them (Katie, Cell Phone Interview #4):

Interviewee: Uh, I would be supportive, but in a way that, you know, like, if whatever they needed from me, I would give them. I wouldn't like, I wouldn't like push on like or continue—I, I would talk about uh my experience, my journey, but not in a way that, you know, it overshadows what, what they're going through. **Interviewer:** Okay. **Interviewee:** Um, but do let them know that, you know, there, there's always hope, the light at the end of the tunnel. Um, and even though they may not see it yet, you know, I, I feel that you know there is. And just try to just, encourage them and, you know, let them know that you know, I guess all depends on if they're diagnosed and where they are with it, but you know, just let them know that um, there is, there, there, there's, there's a team out there. There's some doctors out there who can you know, take care of them. (Katie, Cell Phone Interview #4).

Several participants shared their knowledge and experience with individuals they did not know. Ellie recounted one day, when she stopped at an infusion room (on her way to her infusion room to receive chemotherapy) and began talking to the woman inside, because she appeared sad (Ellie, Cell Phone Interview #4). As they began talking, Ellie discovered that the woman knew nothing about her cancer and her treatment. Drawing from her experience, Ellie stated:

I said, ‘Well, you go home, and you said you can find it [information regarding the cancer clinical trial].’ She said, ‘I don’t even know where it is.’ I said, ‘If you can find it, you read it because there are—there’s information in there that you need to know. So that-so that when the doctor’s treating you, you can ask questions about what they’re doing.’ (Ellie, Cell Phone Interview #4).

The woman thanked Ellie, who never saw her again. Patient-participants spoke to individuals in their community and churches (*a dialogue*):

Um, about three deacons came to me and they were telling me about, um, their experience. So they came to me and they spoke to me about it, but I don’t think that there is *a dialogue* in the churches, the churches of ethnicity, about that type of thing. And I do think that’s where the informed pastors, that’s how I’ll put it—these informed pastors, I think that that’s *a dialogue* that they want to go on in these churches. (Steed, Cell Phone Interview #1).

Patient-participants spoke in their church at the pulpit and among their fellow congregants. Encouraged by his pastor, Steed spoke candidly at the pulpit about his cancer experience and his CCT participation. Steed’s sharing affected the men and the women in the congregation who had listened so intently:

He said that he wanted me to set up at the pulpit and talk about it. And I was surprised that a whole lot of other people were surprised, you could hear a pin drop on the church floor. You know, in the sanctuary, you could hear a pin drop anyway. But, you know, it was noticeable, because all of the men—I had their attention. All of them, all of the men.

And what was surprising was that it was the women, after I finished my piece at the pulpit, I came down. And it was during offering time when people are putting their offerings in the basket, and it was the women—the men discussed it. But it was the women that came to me. They came to me for their brother, for their nephew, for their fathers... (Steed, Cell Phone Interview #1),

After church, congregants approached him with questions—however, “[m]ost of them, they were the women that had questions for the men who they loved” (Steed, Cell Phone Interview 1). His words had opened the dialogue among the women in the congregation. Ro felt strongly about dialoguing with men in his church and the community. He stated,

matter-of-factly, “...you gotta *share your story* because so many guys out here—us black guys, and I’m sorry, us black guys, we procrastinate” (Ro, Cell Phone Interview #4). It became his personal mission to share his story and reach out to as many Black men as possible:

[s]ome are older than me, some are younger than me, some are much younger than me, some are friends, and for me, just to be with them and let them know to see that I went through it, that it’s nothin’ to be afraid of. If you need to, and if you ever come up to me and say, “Yo, Ro. Last week I went to the doctor. I got ‘em to do my PSAs. I got ‘em to do this.” That makes me feel good. (Ro, Cell Phone Interview #4).

Ro stated frankly that he did not consider himself a “role model,” but rather he felt good knowing that he was assisting other Black men to take the necessary steps to safeguard their health and to not be afraid of CCTs (Ro, Cell Phone Interview #4). Like Ro, patient-participants felt an intense need to share their experiences. Mrs. Washington revealed that it made her feel strong (Mrs. Washington, Cell Phone Interview #4). Ellie was motivated by the sadness she saw in a stranger’s eyes. Steed was motivated by a young pastor who recognized the silence among Black men about prostate cancer and wanted the silence to end with Steed broaching the issue in the pulpit (Steed, Cell Phone Interview #1). Katie felt empowered to share because of her participation in this dissertation study; more specifically, after the semi-structured interview. She had permitted her mother to be present. She took the first of many steps to share her experience with her mother, then others subsequently:

I felt good, like, getting it out and just, um, feeling like she—she heard me because she did kind of...well, since she came home with me last night, uh, and she stayed over, and um, she was just like sitting there quiet, and um, I just felt like she was listening and she heard what I was saying, because we did, you

know, have a talk, like open and candidly about some of the things that I, you know, said during the interview with you. (Katie, Cell Phone Interview #1).

Katie attempted to open the dialogue with her mother about her cancer and her CCT participation repeatedly throughout the dissertation study. Despite her lack of success with her mother, her sharing enabled her to accept her changing body image and be at peace with her breast cancer diagnosis (Katie, Cell Phone Interview #3). She and the other members of the sample disclosed their cancer and CCT experiences to family members, friends, church members, neighbors, co-workers, employers, members of the CCT team, and people they did not know. They shared what brought them to The Cancer Center, how and why they enrolled in their CCT, how and the manner in which they were treated in their CCT, their relationships with their CCT teams, the support they received from their family members and friends, their symptom burden, and expressions of who they were and what was important in their lives. They shared themselves and their experiences in their CCTs.

Summary

The two specific aims for this study were addressed through quantitative data from the Socio-demographic Form and the MSAS-SF, as well as the qualitative responses from 66 face-to-face and cell phone interviews. The patient-participants openly and candidly described the factors influencing their decisions to participate and to remain in a CCT, as well as their experiences during their respective CCTs.

Patient-participants described why they sought treatment at the Cancer Center, why and how they decided on CCT participation and what ultimately led them to enroll on their CCT. Many family members were staunch advocates for the participants,

caregivers as the need arose, and unflagging support at home and at the Cancer Center and wherever they were needed. They were present when no one else could be present. Patient-participants described how oncologists and the CCT team influenced CCT enrollment and retention. Also, patient-participants shared their experiences as they progressed through their CCTs. The patient-participants were eloquent, poignant, and sincere in their depictions of their lives and the individuals with whom they daily interacted. They described the details of their appointments, the symptom burdens they endured, their struggle to maintain balance and stability in their lives, and their efforts to disseminate information about cancer, cancer prevention, and CCTs.

CHAPTER V: DISCUSSION

The purposes of this study were to understand the factors that influence Black cancer patients to enroll and to remain in CCTs, as well as to understand the daily experiences of Black cancer patients during the CCT process. This was the first study to seek the perspectives of Black cancer patients in determining the decisional factors influencing their CCT enrollment and retention, as well as to explicate their experiences during the CCT process. A multimethod approach was used and included a qualitative descriptive design with semi-structured face-to-face and cell phone interviews with 21 Black cancer patients involved in CCTs and a descriptive statistical analysis of the sample's sociodemographics and a quantitative measure of symptom burden (the Memorial Symptom Assessment Scale-Short Form). The findings for the deductive qualitative aim suggests that all of the factors of Albrecht's Model are important to patient participants in their decisions to enroll and to remain in CCTs in varying degrees. Albrecht's model includes the following four factors that are important for treatment decisions: patient, family member, physician and protocol. Moreover, the data provided some delineation of the four factors which the Albrecht Model had left relatively undefined. There were several **Patient Factors** that motivated patient-participants to enroll and to remain in CCTs at the Cancer Center. **Family Member Factors** were mentioned minimally in the data as it pertained to influences on initial CCT participation. By contrast, the data persuasively reflected the meaningful impact that **Family Member Factors** had on the patient-participants remaining in their CCTs. **Physician Factors** contributed to both patient-participant enrollment and retention. A few patient-

participants mentioned the importance of **Protocol Factors** in influencing their enrollment in CCTs. However, there was no mention of the role **Protocol Factors** played in CCT retention.

Elements of real-time data capture were also used to facilitate collection of four semi-structured cell phone participant interviews over a 2 month period, in order to understand patient-participants' everyday experiences in CCTs. Patient-participants' experiences centered around three areas: (1) interactions with the CCT Team during their CCT participation (**The Cancer Clinical Trial Team**), (2) experiences at patient-participants CCT appointments and symptom burden (**I'm Going Through It**), and (3) struggles to maintain integral aspects of their lives and to share their cancer and CCT experiences (**Who I Am**). This chapter begins with a discussion of the research findings as they relate to the two specific aims. Next, implications for theory, practice and health equity are presented. Limitations are discussed and, finally, considerations for future research and inquiry are outlined.

Discussion of Findings

Specific Aim One

Patient factors. The patient-participants in this study articulated three broad categories of **Patient Factors** that contributed to their decision to enroll and to remain in CCTs at the Cancer Center. First, there was a willingness to seek additional information about their cancer diagnosis and treatment options (*unhappy where I was; go somewhere else*). This willingness to obtain additional information and to understand the information received regarding one's cancer and cancer treatment options is associated

significantly with consenting to participate in CCTs (Brandberg, Johansson, & Bergenmar, 2016; Miller et al., 2013). Second, altruism motivated patient-participants to enroll in CCTs (*To Help Others*). Several researchers have cited altruism as a motive for CCT participation (Harrop et al., 2016; Jenkins & Fallowfield, 2014; Ulrich et al., 2012). Although patient-participants offered altruistic reasons for CCT enrollment, the desire to help themselves was also paramount (Kaplan et al., 2015). This finding was consistent with three of the four factors articulated by the Black and White cancer patients in Bryne et al. (2014): (1) the CCT offered optimum treatment for their cancer (*give myself the best possible chance*), (2) the CCT offered more information (*learn more about my condition*), and (3) the CCT was the sole treatment option (*if one trial doesn't work*). As commented by Ro, it was vital that the choice to participate in a CCT was deliberate and personal (*go to the study for you*). These findings of personal benefit were consistent with work by Ulrich and colleagues (2012) who reported that cancer patients participated in research based on the personal benefits they might achieve. For example, the sense of helping oneself was typified by patient-participants who were diagnosed with stage four cancer ($N=8$, 40%), and/or had participated in prior CCTs ($N=3$; 15%). To some degree, participation in CCTs were a means of extending participants' lives. In fact, several patient-participants continued to seek, or had family members who continued to seek, available CCTs during their present CCT (*if one trial doesn't work*).

Family member factors. The data indicated that family members, although important, had minimal effect on patient-participants' CCT enrollment decisions. A small number of patient-participants admitted to relying on family members in their

decision to enroll in their CCT. This finding is contrary to Brown et al. (2013), where family members had a significant impact on CCT enrollment decision-making. Only two patient-participants in this study mentioned the involvement of family members (*he talked to all my children; my family heard*). By contrast, patient-participants spoke expansively of the ways in which their family members supported them *during* CCT participation. Contrary to their role in CCT enrollment, family members were integral in CCT retention and positively affected the daily lives of the patient-participants (**Family and Friends Support Me**). Patient-participants spoke of the close familial ties that sustained them (*my family is close; we support each other*), the individuals who were their stalwart supports (*my rock*), and the many ways their family members supported them (*we support each other; friends that support me; we're like sisters; they're in my world*). However, most significantly, the findings show that family member factors were central to patient-participants *remaining* in clinical research (**Family and Friends Support**). This data supported the reconfigured Albrecht Model, wherein the physician-patient-family member triad was visualized as influencing cancer treatment (Albrecht et al. 2009).

Family members functioned as caregivers¹⁶ for the patient-participants in this study. Fifty-five percent (N=11) of the sample acknowledged that their caregivers were very important or extremely important to them during their CCT enrollment. The four top caregiver types by percentage were Child (35%), Spouse (30%), Sibling (20%), and Friend/Parent (Friend and Parent were tied at 10% each). Family members often

¹⁶ A caregiver is a person who assists in the daily care of an individual, by satisfying medical and non-medical needs (Cooper, Powe, & Smith, 2013).

provided informational, instrumental, emotional, and spiritual support consistent with other research (Cooper, Powe, & Smith, 2013; Molina et al., 2016; Williams & Jeanetta, 2015).

Family members provided ample informational support (communication of information to the patient-participant) as demonstrated by their attempts to seek CCT information for patient-participants, offering referrals to oncologists, and information regarding family cancer history (Molina et al., 2016). Also, they questioned the oncologist and the CCT team, which engendered information sharing with the patient-participants (Cooper, Powe & Smith, 2013; Molina et al., 2016). Instrumental support (provision of material, financial, and household assistance) was exemplified by transportation to the Cancer Center and management of household tasks. Emotional support (comprised of the conveying of love, affection and concern for the patient-participant) was typified by being present at appointments and acting as steadfast advocates for patient participants (Cooper, Powe & Smith, 2013; Molina et al., 2016). Last, spiritual support was provided by family members who enabled patient-participants to remain grounded in their faith and belief in God by engaging in prayer and other activities with them (Cooper, Powe & Smith, 2013). The presence of these integral supports enabled patient-participants to continue CCT participation and contributed to **Family Member Factors** being an important consideration on patient-participants' decisions to remain in their CCTs (Cooper, Powe & Smith, 2013; Molina et al., 2016; Williams & Jeanetta, 2015).

Physician factors. The **Physician Factors** underlying patient-participants' decisions to enroll and to remain in their CCTs run counter to existent literature and are representative of the uniqueness of this sample (Albrecht et al., 2003; Corbie-Smith, Thomas, & St. George, 2002; Ford et al., 2013; Penberthy et al., 2012; Schmotzer, 2012; Sheppard et al., 2011; Simon et al., 2004; Torke, Corbie-Smith, & Branch, 2004). Patient-participants' exercise of their judgment to choose the qualities they deemed important in their oncologists and CCT enrollment gave relevance to the **Physician Factors**. Findings suggest that patient-participants were not passively being acted upon, ignored, or awaiting communication from oncologists. The decision to enroll in a CCT was made by all, except one participant. The study sample were interacting actively with their oncologists and the CCT Team, voicing their concerns, and seeking other avenues of treatment, if they perceived that the CCT was not meeting their needs. Similarly, patient-participants remained at the Cancer Center, because they chose to remain. One individual voiced distrust of medical research—until, he interacted and chose a racially concordant oncologist. Racial discordance has been cited as the basis for lack of trust between Black cancer patients and their White oncologists (Gordon, Street, Scharf, Kelly, & Soucek 2006). For these reasons, **Physician Factors** were important, yet not primary reasons that the study sample enrolled and remained in their CCTs.

Protocol factors. The Face-to-Face and Cell Phone Interviews indicated that **Protocol Factors** had minimal bearing on CCT retention. By contrast, **Protocol Factors** influenced some of the patient-participants, who were knowledgeable of their features and were interested in the benefits they offered, to enroll in CCTs. Research literature

suggests that Blacks possess poor knowledge of CCT protocols and have little interest in participating in CCTs (Brown et al., 2013; Langford, Resnicow, & An., 2010; Meropol et al., 2007; Owen, Jackson, Thomas, Friedman, & Hebert, 2013). However, for studies involving predominantly White cancer patients, knowledge of, and interest in, CCTs, were associated with CCT enrollment (Agarwal et al., 2006; Brandberg, Johansson, & Bergenmar, 2016; Lara et al., 2005). A small number patient-participants in this study were focused on CCT features that they perceived enhanced the likelihood of optimum treatment (i.e., targeted treatment, additional diagnostic tests, and randomization to experimental treatment).

Most of the patient-participants' in this dissertation study were deliberate consumers of oncology care, who had firm expectations of what they desired in the facility where they were treated, the oncologist with whom they would interact, the manner in which they would be treated, and, for a few, the type of CCT in which they would enroll. The only factor over which they had limited control was the family members who supported them, advocated for them, and were present for them. For this reason, as with **Physician Factors**, **Protocol Factors** were not as influential in CCT enrollment for the patient-participants in this dissertation study.

Specific Aim Two

The second aim of this dissertation chronicled the everyday experiences of the study sample during their CCT participation through the use cell phone interviews to ascertain real-time information. Their experiences centered around three areas: (1) interactions with the CCT Team during patient-participants CCT participation (**The**

Cancer Clinical Trial Team), (2) experiences at CCT appointments and symptom burden issues (**I'm Going Through It**), and (3) struggles to maintain integral aspects of participants' lives and to share their cancer and CCT experiences (**Who I Am**).

The cancer clinical trial team. The cancer clinical trial team was a constant reminder of the collaborative nature of cancer clinical research. Its members included the oncologist, nurse practitioner, clinical research nurse, and clinical trial coordinator (*My Team*). This configuration existed at the Cancer Center—however, Bethelmie-Bryan et al. (2013) have suggested expansion of the CCT Team to include a social worker, data manager, investigational drug pharmacist, regulatory associate, and physician assistant. Functioning as a coordinated unit, the members of the CCT Team at the Cancer Center supported and supplemented the tasks and responsibilities of the oncologist. Oncologists were supported, and assisted in the care of the patient-participants, by the constituents of the CCT Team. The clinical research coordinators, nurse practitioners, and clinical research nurses, individually and together, performed tasks typically performed by oncologists at the CCT appointments (*What They Do for Me*). They introduced CCTs to patient-participants, acquired informed consent, entered laboratory and radiology orders, assessed the health status of patient-participants, provided detailed information about the CCT protocol, maintained contact with the study participants, and emergently admitted patient-participants to hospitals.

The role of the clinical research coordinator (*coordinator*) was mentioned only by patient-participants who participated in one particular clinical trial sampled in this dissertation study. The clinical research coordinator actively recruited subjects for this

particular study (as well as other studies for which he recruited subjects), administered questionnaires, acted as point of contact for participants, and maintained study data. During this dissertation study, the clinical coordinator for this particular clinical trial functioned as a variant of a gatekeeper by facilitating access to prospective participants.¹⁷ The gatekeeper role can have both benefits and burdens for researchers. This role is often typified by the gatekeeper presenting the researcher's proposed study to prospective participants. Much like a clinician gatekeeper, the clinical research coordinator can potentially affect the ability of patient-participants to make research decisions autonomously (Sharkey, Savulescu, Aranda, & Schofield, 2010).

The patient-participants' discussion of the CCT Team presented an invaluable opportunity to understand the expanding role of the nurse practitioner and the developing role of the clinical research nurse (Grady & Edgerly, 2009; Ulrich et al., 2013). In this dissertation study, patient-participants had effective communication with their nurse practitioners. Forty percent (N= 8) and 35% (N=7) of patient-participants rated their communication with the nurse practitioner as "Excellent" and "Very Good," respectively. Nurse practitioners addressed clinically-emergent issues and provided advanced nursing care that enabled patient-participants to continue enrollment in their respective CCT. As examples of their clinical activities, they admitted participants to the hospital for serious adverse events, ordered intravenous fluids and electrolyte repletions for acute

¹⁷ Sharkey, Savulescu, Aranda, & Schofield (2012) define gatekeepers as healthcare providers who prevent access to subjects for research, who are otherwise eligible for research enrollment secondary to "factors such as age, gender, the type and stage of disease and previous treatment history or scheduled treatment (p. 363)."

dehydration, and performed detailed and focused physical assessments to evaluate symptom burden.

From the perspective of the participants, the clinical trial research nurse oversaw several aspects of the CCT. She assessed the participant's responses to the research protocol, scheduled radiologic and laboratory orders, and evaluated and documented adverse responses to CCT medication. However, unlike the nurse practitioner and the oncologist who would often alternate in seeing patients, the clinical trial research nurse was present at all CCT research visits and was expected by the participants to be knowledgeable of the CCT protocol.

Through their coordinated efforts, the CCT Team offered continuity of care in tandem, and in the absence, of oncologists. Salman, Nguyen, Lee, and Cooksey-James (2016) have posited that the presence of ethnic minority nurses and clinical trial coordinators as members of CCT Teams could facilitate communication, and assist in diminishing mistrust between majority researchers and the diverse populations they seek to recruit in their CCTs. Arguably, the success of such an endeavor does not rest wholly on the ethnic and/or minority status of a CCT Team member. The cohesiveness of the members of the respective CCT Team, as well as inter-staff communication and staff-patient communication equally are important (Bethelmie-Bryan et al., 2013). All of these qualities appeared to exist among the CCT Teams described by the patient-participants in this dissertation work.

I'm going through it. The focal point of the patient-participants' CCT experience was their clinical appointment (**At My Appointment**). The patient-

participants valued the exchange of information at their CCT appointments. Eighty-five percent (N=17) of the sample felt that receipt of information regarding cancer diagnosis and treatment was extremely important. Sixty-five percent (N=13) considered it extremely important to be informed of their CCT treatment. At CCT appointments, health and disease status were assessed, the effectiveness and adverse effects of the CCT treatment were evaluated, and information regarding partial/complete response to CCT treatment and disease progression were shared.

The spectre of job loss and job insecurity secondary to CCT treatment, is a burden borne by CCT participants (Ulrich et al., 2012). Fifty percent of the sample in this dissertation continued to work during their CCT enrollment. The difficulty of arranging work schedules around appointments with oncologists and the CCT Team posed innumerable challenges to patient-participants (*using some time*). Patient-participants in this dissertation study attempted to offset time lost at appointments by forging alliances with fellow employees and supervisors, negotiating flexible work hour arrangements, and judicious use of paid time off (vacation and/or sick time). Some were successful, while others struggled. Time lost at appointments was matched by transportation time and the inherent costs of travelling back and forth between work, the Cancer Center, and home (*getting back and forth*). Additional time was lost waiting to be seen by the oncologist or the nurse practitioner or for CCT infusions or radiation (*nice little wait*). Breakdown in operational processes, overbooking, and mechanical failure of diagnostic equipment contributed to the occurrence waits of one to three hours. The patient-participants described these periods as the most frustrating aspects of their CCT participation.

News of disease progression and eventual withdrawal from a CCT (*no longer involved in that last trial*) occurred for 30% ($N=6$) of the patient-participants before completion of their four cell phone interviews. CCT enrollment did accord the patient-participants a short-term survival advantage (Unger et al., 2014). None of these patient-participants enrolled in another CCT, either because of unavailability of a suitable trial or because of disease progression which prevented CCT enrollment. Some returned to standard treatment options, while others did not receive any further treatment. All of these patient-participants had stage 4 disease. Research has indicated that Black cancer patients appear with later stage disease (stages III/IV), which has been associated with lower cancer survival rates among Blacks (DeSantis et al., 2016; Elfird et al., 2014; Parikh, Robinson, Zayfudim, Penson, & Whiteside, 2014; Phatak et al. 2013; Warner et al., 2012). Six of these patient-participants with stage 4 disease died within one year of CCT withdrawal. More work is needed to understand the specific needs of those patients who are diagnosed with stage 4 disease and the palliative measures that might also be warranted.

Despite the high levels of perceived communication between patient-participants and their CCT Team, fatigue, pain, and peripheral neuropathy were symptoms experienced more often by the largest number of patient-participants as reported in the MSAS-SF—80%, 60%, and 55% of the patient-participants reported distress from these symptoms, respectively. These symptoms were described also by many participants in their e semi-structured cell phone interviews. Moreover, patient-participants described

feelings of fear and anger. Feelings of worry, nervousness, and irritability were reported in the MSAS-SF by 40%, 45%, and 50% of the sample, respectively. These symptoms and emotional responses were consistent with those reported by cancer patients in research studies who had described the negative effects of chemotherapeutic symptoms on their daily tasks and responsibilities, as well as their continued participation in CCTs (Laugsand et al., 2010; Ulrich et al., 2012; Wootten et al. 2011). However, these symptoms and emotional responses could have been managed with the assistance of supportive care specialists such as palliative care practitioners, social workers, physical therapists, and occupational therapists.

Supportive care specialists provide services that can improve quality of life and survival outcomes (John, Kawachi, Lathan, & Ayanian, 2014; Temel et al., 2010; Wagner et al., 2010). Only two patient-participants reported referral to healthcare providers who provided supportive care specialists: Mrs. Washington (referred to a physical therapist for her increasing fatigue and deteriorating functional status) and RR (referred to a dietitian for his chronic constipation). The remainder of the patient-participants failed to mention in their interviews being sent for consultations with supportive care specialists by the oncologists or nurse practitioners for their unmet symptom burden needs, despite being sent for consultations with other medical professionals during CCT participation. However, lack of referral to supportive care services and failure to satisfy unmet symptom needs among Black cancer patients is consistent with existent literature (John, Kawachi, Lathan, & Ayanian, 2014; Reyes-Gibby et al., 2012; Walling et al. 2016). Walling et al. (2016) found a significant relationship between poor physician

communication and unmet symptom burden needs. The possibility of poor communication runs counter to the findings in this study whereas the majority of patient-participants perceived communication as very good or excellent. A possible explanation could be that the oncologists and nurse practitioners chose to manage, albeit inadequately, certain symptoms by prescribing medication and/or by reducing or eliminating CCT chemotherapeutic agents which caused the symptoms to manifest.

Who I am. A finding of this dissertation study was the importance of participants' self-image in CCTs. In her work on CCT patients and self-image, Ulrich (2013) posited that cancer patients struggle to retain their self-image and identity, which become defined by their cancer diagnoses. In navigating the changed landscapes of their lives, cancer patients are buffeted by the reality of their cancer diagnoses, the demands of their CCT procedures and requirements, and changes in social roles (Ulrich, 2013). Ulrich (2013) advanced that research participation could give meaning back to patient-participants' lives by contributing to the greater good, and benefiting future patients and their families.

The patient-participants in this dissertation study were clear that they participated in cancer research as a way to help others and themselves. However, their desire to help themselves was also paramount as previously indicated (Kaplan et al., 2015; Truong et al., 2011). For this reason, the patient-participants valued the importance of receiving information pertaining to their cancer diagnosis and CCT treatment. Eighty-five percent of the sample felt it was extremely important to receive information about their cancer diagnosis, while 65% believed it was extremely important for them to receive

information regarding their CCT treatment. In this data, patient-participants sought means to maintain their self-identity and what was important in their lives, by endeavoring to manage and to sustain their personal, family, work, school, and spiritual lives—separate and apart from their cancer diagnoses and CCT participation (*I don't let it consume my whole day; balance; faith*). Patient-participants were strategic in accepting their cancer diagnoses and moving on with their lives, instead of being overwhelmed by the enormity of their cancer diagnosis and realities of CCT participation. In seeking balance in their lives, they compartmentalized cancer as a necessary activity of their ongoing lives. Spirituality was a major component of the lives of 70% of the patient-participants, who reported that spiritual or religious beliefs were very important or extremely important in their lives. Their reliance on their spirituality supported them through disclosing their cancer status to their family members, accepting the reality of disease progression, and knowing they would not always be a person with cancer. Moreover, they were assisted in their efforts to retain the vestiges of their self-identity by their family members, especially when family members assumed supportive caregiving roles. Children (35%), spouses (30%), and siblings (20%) were the primary caregivers for the patient-participants and ably supported them when the patient-participants developed medical conditions secondary to their cancer diagnosis and/or CCT participation. This was consistent with Helgeson and Cohen (1996) who suggested that emotional, informational, and instrumental support from family members reduce feelings of inadequacy, loss of control, and vulnerability experienced by cancer patients.

Molina et al. (2016) expanded on the power of family member support by positing that emotional, instrumental, informational, and appraisal support contribute to greater self-advocacy and community/interpersonal advocacy among Black women with breast cancer (*I am very open; sharing your story; a dialogue*).¹⁸ Much like the sample in the Molina et al. (2016), the study sample in this dissertation began as recipients of support from their family members. The patient-participants transitioned from advocating for themselves (*unhappy where I was; going somewhere else*) to becoming resources for others, as well as advocates for CCTs. Therefore, family member support was considerable in patient-participants' willingness and desire to share their cancer and CCT experiences with others (**Getting the Word Out**) (Molina et al., 2016). They described being candid with others about their cancer diagnosis (*I am very open*), their desire to educate and to assist other individuals (*share your story*), and their efforts to motivate other Blacks to participate in CCTs and to engage in cancer prevention activities (*a dialogue*).

Implications for Theory

The data from this dissertation study supports the presence of the four factors in Albrecht's model as important to one's decision to participate in a CCT. However, from this point, it diverges. Albrecht's Model presents a physician-centered approach and posits that physician communication is a key mediating factor on an individual's treatment decision-making regarding research participation. In fact, physicians are

¹⁸ The addition of appraisal support represented efforts by family members to encourage the cancer patient to rely on her information-seeking facility to gather information for use in making cancer treatment-related decisions (Molina et al., 2016).

considered integral in CCT decision-making and in providing informed consent (Albrecht et al. 1999; Albrecht et al. 2008). Further, Albrecht et al. (2003) does not give explicit definitions for the four factors that are outlined in the model. The qualitative findings from this dissertation work can begin to define components of these factors and other concepts and items that might be relevant for future qualitative and quantitative work.

This dissertation study does not include communication as a factor that was explored in the deductive qualitative analysis. Its absence prevents a thoughtful, detailed consideration of the manner in which communication, specifically, motivated the patient-participants' interactions with their oncologists, CCT Teams, and family members. Even though communication was not directly examined, communication clearly was important to the study sample—as indicated, previously, by the high percentage of the patient-participants who valued the importance of receiving cancer diagnosis and CCT information. Moreover, as stated previously, 75% of the participants rated their communication with their nurse practitioners and oncologists very good to excellent. Those seeking second opinions at the Cancer Center desired discussion of additional treatment options and a larger role in treatment decision-making, both of which they did not receive from their initial oncologists possibly due to poor communication. Ro and RR described relationships with previous oncologists who failed to communicate treatment options. The question remains to be answered whether full testing of Albrecht's Model with communication as a mediating factor would be helpful. Further quantitative work to test Albrecht's Model would be instructive.

Use of Albrecht's Model posed unanticipated challenges that will necessitate a secondary analysis of the semi-structured interviews. Framing the findings of Specific Aim One with Albrecht's Model compelled use of deductive content analysis, that by definition required the key concepts (patient, family member, physician, and protocol factors) to be used as initial coding categories/themes (Hsieh & Shannon, 2005). This removed from consideration as organizing themes data that did not fit into the initial coding categories/themes, as they pertained to CCT participation and retention and that were not discussed in the semi-structured cell phone interviews. For example, each patient-participant invariably began the semi-structured face-to-face interview with a discussion of the circumstances surrounding their cancer diagnosis, i.e., their cancer story. The rich cancer stories of the patient-participants had no bearing on their decisions to enroll, or to remain, in their respective CCTs. However, it was a story each patient-participant wanted to tell, because it held a special meaning for them. Cancer secrecy, or the failure and/or refusal of family members to share information regarding cancer incidence among consanguineous relatives, emerged as a theme among several of the participants only during the initial semi-structured face-to-face interview. Again, cancer secrecy did inform, or influence, CCT participation or retention in relation to the four key concepts. Finally, as worded, Specific Aim One related to patient, family member, physician, and protocol factors which influenced CCT participation and retention. Negative aspects of CCT participation that emerged frequently in the semi-structured face-to-face interviews, and were not repeated in the cell phone interviews, were precluded from analysis. These negative aspects included lack of family support,

perceived discrimination, and the stress of hospitalization secondary to CCT symptom burden.

Last, the CCT environment at the Cancer Center has enabled the opportunity to observe collaborative practice in action. Additional research and theory-building is sorely needed on the expanding clinical and research roles of the CCT Team and its constituent nursing members, as well as their impact on CCT enrollment and retention. Exploring models that include interdisciplinary teams and the role of teams in improving communication regarding CCT participation and retention of patient-participants is now needed.

Implications for Practice, Ethics, and Health Equity

Implications for Practice

The findings from this dissertation study suggest several practice implications related to enrollment and retention of Black cancer patients in CCTs. First, the contributions of the CCT Team highlight the expanding need for collaborative nursing practice in clinical research. Within the realm of CCT research, expansion of nurses fulfilling nurse practitioner and clinical research nurse roles are sorely needed. The nurse practitioner and clinical research nurse fulfill differing, yet complementary, roles that directly affect Black cancer patients in CCT research—the nurse practitioner oversees the clinical care of the CCT participant, while the clinical research nurse evaluates the CCT participant for the occurrence of physical and psychological adverse events resulting from CCT interventions (Hastings, Fisher & McCabe, 2012; Grady & Edgerly, 2009). Despite these role differences, both nurses are charged with insuring CCT participants’

safety and advocating for CCT participants' rights and welfare during their enrollment in clinical research (Hastings, Fisher & McCabe, 2012; Grady & Edgerly, 2009).

Moreover, nurse practitioners and clinical research nurses are tasked with maintaining close communication and relationships with each other and with the clinical and research teams interacting with the CCT participants (Grady & Edgerly, 2009). In this way, nurse practitioners and clinical research nurses provide a continuity of care in the clinical and research realms that support CCT participation and influence patient health outcomes incident to CCT participation. An examination of the complementary roles of nurse practitioners and clinical research nurses also open new avenues for research. Little is known of the contribution of nurse practitioners and clinical research nurses to patient health outcomes, the role of nurse practitioners and clinical research nurses perform in ameliorating or contributing to disparate communication between oncologists and CCT subjects, or the ethical dilemmas faced by nurse practitioners and clinical research nurses as they seek to maintain the integrity of clinical research while safeguarding the rights and welfares of CCT participants.

Second, many of the oncologists administering the CCTs to which the patient-participants' were recruited exhibited a willingness to share information which was valued by and generated trust among the patient-participants. In describing their reasons for choosing the oncologists who would ultimately enroll them in CCTs, patient-participants shared how they valued the oncologists' evaluative meticulousness and willingness to provide information regarding their cancer and CCT. These characteristics were dependent upon effective communication and engendered trust. The trust the

oncologists created was contrary to much of the literature concerning Blacks and cancer clinical research, wherein distrust of clinical research and of physicians colored the participation decision-making of Blacks (Corbie-Smith, Thomas, & St. George, 2002; Ford et al., 2013; Schmotzer, 2012; Torke, Corbie-Smith, & Branch, 2004). However, the oncologists exhibited all of the characteristics deemed necessary to build trust: competence, honesty, caring, and effective communication (Hillen et al., 2014). This same competence of the oncologists resulted in their successful referral of the patient-participants to other healthcare providers, when necessary.

Penner et al. (2013) indicates that the time spent by the oncologists providing information may have engendered the trust felt by the patient-participants. In Penner et al. (2013), researchers found that greater trust was created between Black cancer patients and their White oncologists at an oncology clinic encounter, when the White oncologists answered the Black cancer patient questions as completely as possible, made certain that the Black cancer patients understood the content of the discussion, and listened carefully to the Black cancer patient. The willingness and thoroughness of the oncologists to discuss cancer diagnosis and CCT information ran counter to the existent literature, where investigators stated that oncologists spent less time and had less effective communication with Black cancer patients during discussion of CCTs (Eggle, Barton, Winckles, Penner & Albrecht, 2013; Kehl et al., 2014). This manner of information-sharing was not evident among all of the oncologists encountered by the patient-participants; however, it should be incorporated into the research practice of oncologists recruiting Black cancer patients into CCTs. However, much could be learned with

further research into the communication patterns that evoked trust in the patient-participants and ran counter to the disparate communication shared between Black cancer patients and their oncologists in the existing literature.

Last, there was a difference in symptom burden, as measured by the MSAS-SF and as reported by the patient-participants during the face-to-face and cell phone interviews. The MSAS-SF means for the sample for psychological and physical distress ranged from no symptom distress to mild symptom distress, respectively. The mean psychological and physical symptom burden values at baseline do not reflect the intense, life-altering symptom burden experienced by some of the patient-participants as they progressed through their trials. More importantly, the mean symptom burden scores self-reported by patient-participants in the MSAS-SF did not accurately reflect the range and severity of symptom burden experienced by the patient-participants. The members of the sample with the youngest mean age and the highest mean PHYS distress value were the Breast cancer group. Three of its members also were single parents who had school-age children. The patient-participants with the oldest mean age and the highest PHYS distress value were the Colo-rectal group who reported pain and peripheral neuropathy frequently during their cell phone semi-structured interviews.

As reported, the mean global distress index was 1.09. The median, range, minimum, and maximum for the global distress index were 1.06, 2.90, 0.00, and 2.90, respectively. For the PHYS scale, the mean value was 1.09; the median, range, minimum, and maximum were 1.07, 2.93, 0.00, and 2.93 respectively. Finally, for the PSYCH scale, the mean value was .77; the median, range, minimum, and maximum were

0.67, 2.43, 0.00, and 2.43. For all of the MSAS-SF distress sub-scales, the maximum distress values (all of which were higher than 2.40) were indicative of high moderate symptom distress and were offset by minimum distress values of 0.00. The cancer group with the highest PSYCH distress value was Breast with a maximum of 2.43 (and a mean of 1.15), whose members had a mean age of 47 years. The cancer group with the highest PHYS distress value was Colo-rectal with a maximum value of 2.93 (and a mean of 1.52), whose members had a mean age of 62.8.

The difference in the mean quantitative measure and the qualitative self-reported values may reflect unmet symptom burden needs that should be addressed by the CCT Team. Failure of the CCT Team to capture these unmet needs endangers the scientific integrity of the respective CCTs, if the symptom profile and adverse event data are deficient and incomplete. Moreover, patient-participants' quality of life during the CCT is adversely impacted. Explanations may include the ineffectiveness of written instruments to capture the degree and the intensity of the patient-participants' symptom experience over a particular point in time (Stone et al., 2007). There is the possibility that patient-participants minimized the extent of their symptom burden in order to continue to receive the perceived benefit of CCT enrollment and also be perceived by the CCT Team as a "good patient" (Joseph & Dohan, 2009). It is not known whether this was the case in the dissertation study. Understating symptom burden permits continued CCT participation, barring occurrence of disease progression. Incorporating elements of real-time data capture of symptom burden, via telephonic interview or text messaging, may enable a more complete capture of the symptom and toxicity profiles of

investigational agents. Moreover, it provides valuable data necessary for the CCT Team to evaluate cancer patients' true symptom burden needs. This may lead to more timely treatment, or referral to appropriate support services. The moderate to severe symptom burden self-reported by participants in the cell phone interviews also suggests the need for expansion of the CCT Team to include a palliative specialist, such as a palliative care nurse. Palliative care seeks to improve the quality of life of individuals with life-threatening disease, such as cancer, through relief and prevention of psychological and physical suffering (Bauman & Temel, 2014). Introduction of palliative care services early in CCT participation permits identification of potentially debilitating symptoms which can diminish a CCT participant's quality of life and avert unnecessary suffering (Bauman & Temel, 2014). The need for early referral is especially true for CCT participants with late stage cancer, since 40% ($N = 8$) of the patient-participants in the dissertation study were diagnosed with stage four cancer. Early integration of palliative care with late stage cancer patients maximizes their quality of life, increases their satisfaction with their clinical care and CCT treatment, and lessens symptom burden (Bakitas et al., 2009; Zimmerman et al., 2014).

Implications for Ethics

There are several ethical implications which can be drawn from the data. First, a therapeutic misconception can occur in research when participants mistakenly believe that they will receive medical benefit from their research participation. Often there is a failure to understand that the true purpose of CCTs is to produce generalizable knowledge (Appelbaum, Lidz, & Grssio, 2004; Pentz et al., 2012). CCTs are not

intended for curative purposes, although remission could occur as a result of the use of investigational medication and it might also provide participants with time to discuss their goals and preferences. The majority of patient-participants in this dissertation work perceived their CCTs to be medical care for their cancer; hence, their use of the term “my treatment” to refer to the CCT intervention. There were also a few patient-participants who actively sought CCTs to prolong their life. The potential for a therapeutic misconception was potentially high in this study sample, although questions surrounding this issue were not directly asked of participants. This could have been facilitated by several factors. All the patient-participants were enrolled in their CCTs by oncologists, who were both the principal investigators of the CCTs and the primary oncologists of the patient-participants. In addition, many of the patient-participants ($N = 11$; 52%) received their initial cancer treatment via CCTs—so it was possible that patient-participants could confuse the clinical trials with medical treatment. This confusion was typified by Bob’s belief that randomization in a CCT meant that he was receiving better treatment, and Kit’s decision to enroll in I-SPY II—more diagnostic testing meant better treatment for her breast cancer.

Two recommendations can be made. Oncologists who administer CCTs as initial treatment for cancer should state clearly the experimental nature of the CCT. Although there was not a question that directly asked the purpose of CCTs, the only patient-participants who understood that CCTs were for research purposes were those who had enrolled in prior CCTs (Diane, Gina, Niecy) and those who understood the life-limiting nature of their cancer (Bob and Reecy). An argument can be made that, perhaps,

oncologists who administer CCTs should relinquish primary “ownership” of their patients who are enrolled on their CCTs to other oncologists. Otherwise, there is a blurring of the line between clinical care and medical care. Also, oncologists should explain thoroughly the purpose of CCTs, especially when CCTs serve as front-line cancer treatment along with recognized standard treatment.

Second, there is also the possibility of unrealistic optimism in CCT participation. Unrealistic optimism is the belief held by a research participant that he is more likely to receive a benefit from a clinical trial than a similarly-situated person (Crites & Kodish, 2013). For example, a participant may not make a reasoned assessment of the risks and benefits of CCT participation, since he unrealistically believes that the CCT will impart a positive outcome. The possibility of attributing unrealistic optimism to any of the patient-participants flows from the blurred distinction between it and the strong spirituality characterizing many of the patient-participants. However, none expressed the tenets of unrealistic optimism as a basis for participating in their respective CCT. But, a formal question on optimism was not asked of participants. During the course of their enrollment, many discussed a belief that a spiritual force would assist them through the rigors of the CCT. More research on the role of spirituality and optimism is needed.

Third, medical paternalism is the failure of physicians to provide understandable information regarding a medical procedure or intervention and to allow sufficient time for a patient to make a reasoned decision. The inherent peril of medical paternalism is its stripping away of patients’, or CCT participants’, ability to act autonomously. Medical paternalism drove some of the patient-participants to leave their initial oncologists and

seek second opinions at the Cancer Center (Stirrat & Gill, 2005). Examples of imposition of such medical paternalism on the patient-participants included RR's oncologist who insisted on robotic prostate surgery and Ro's oncologist who did not discuss treatment options. However, a potential measure of medical paternalism resulted in Mrs. S's and Mrs. L's eventual CCT enrollments. It could be argued that their CCT participation was colored by the absence of self-determination—especially, Mrs. L who was given a CCT Informed Consent to sign without being given proper time to make a reasoned decision. Yet, the vast majority of the patient-participants exercised autonomy in the choice of their oncologists, the CCTs in which they ultimately enrolled, the management of their symptom burden, and the choice to withdraw from CCTs—as was done by Niecy and Diane. However, the troubling implication is that medical paternalism continues to occur and prompted two patient-participants to make a choice that potentially limited their autonomy. This study did not ask whether these particular participants perceived their autonomy to be affected in any way.

Implications for Health Equity

Despite possessing the attributes of high educational attainment and 100% insured status, the patient-participants in this dissertation were members of a racial/ethnic group with documented cancer health disparity and exhibited some of the characteristics indicative of cancer health disparity (Flowers et al., 2007; Halpern & Holden, 2012; Howerton et al., 2007; Kauh, Brawley, & Berger, 2007). The presence of discrimination was shared by a few of the patient-participants in terms of feeling that they were *being treated differently* because of race. Research has indicated that perceived discrimination

in healthcare is experienced most commonly among Blacks and affects the quality of life of Black cancer patients (Benjamins, 2012; Merluzzi, Philip, Zhang, & Sullivan 2015). Researchers have found that perceived discrimination is experienced when individuals are subject to curt responses, dismissive behavior, and limited eye contact (Tajeu et al., 2015). Cuevas, O'Brien, and Saha (2016) identified perceived discrimination when Black patients encountered discourteous and disrespectful treatment by office staff and physicians, failures by physicians to communicate concern or acknowledge symptoms and health issues, and feelings of being treated unfairly because of their racial background. Discussion of discrimination by the patient-participants was not stimulated by any one question of any of the face-to-face and cell phone interviews. The issue arose independently from the individuals based upon their healthcare experiences at the Cancer Center. The three patient-participants, who mentioned discrimination in their cell phone interviews sounded hesitant to address the topic.¹⁹ None of them stated that they had experienced any difference in treatment. Moreover, all of them in other portions of their cell phone and face-to-face interviews had espoused trust and satisfaction with their oncologists and/or CCT Team. It is unclear from the patient-participants' statements whether they perceived, or witnessed, discrimination at the Cancer Center, who exhibited the discriminatory behavior, and what behavior or actions were deemed discriminatory. These participants did not elaborate on their experiences or perceptions.

¹⁹ Interestingly, the issues of racial bias and discrimination in healthcare arose more frequently in the face-to-face interviews, where the patient participants explained in detail their experiences at the Cancer Center, in other healthcare venues, and during visits from health professionals to their homes. However, because the dictates of Specific Aim Two limit data only to cell phone interviews, a discussion regarding the patient-participants' experience of perceived racial bias and discrimination during their CCT participation cannot be addressed here.

Cancer health disparity among Blacks also has been characterized by initial presentation for oncology care with late stage disease, increased cancer mortality, and inability to access healthcare (DeSantis et al., 2016; Elfird et al., 2014). Forty percent (N = 8) of the patient-participants presented for treatment with late stage cancer—stage four cancer. Lack of access to health care pursuant to lack of insurance was not an issue for the members of this sample. One hundred percent of the patient-participants had insurance coverage. Insurance status did not insulate the patient-participants from additional costs related to CCT participation. However, the financial toxicity of conventional and CCT cancer care is not relegated only to Black cancer patients (Nipp et al., 2016; Zafar et al., 2013). It is a burden borne by countless cancer patients who, in their efforts to assuage the financial burden of cancer care, adopt strategies to reduce out-of-pocket costs such as selling personal possessions, missing appointments to avoid expenditures on co-payments, or partially filling (or not filling at all) medication prescriptions (Zafar et al., 2013).

Despite participating in a CCT at a NCI-Designated comprehensive cancer center, the patient-participants lacked access to resources that could have assisted them in managing the myriad of out-of-pocket expenses related to their CCT participation, i.e., cost of supportive medication related to CCT interventions (e.g., anti-emetics and opioids), co-pays for clinic visits and CCT medications, and co-pays and/or out-of-pocket expenses for imaging. Unlike the cancer patients in Zafar et al. (2013) who benefitted from a non-profit organization providing financial assistance for payment of cancer care-related costs, the oppressive burden of financial toxicity was identified by several

participants who lacked access to resources that could reliably have relieved the financial burden of cancer care. It was felt by Jill who could not pay her Medicare co-pays, by Mrs. L who relied on a sponsored taxicab service to take her to her appointments until the service stopped operating, and by Diane who attempted to arrange all of her CCT-related appointments on one day in order to avoid paying multiple insurance co-pays.

DeSantis et al. (2016) reported that, since the 1990s, cancer death rates have been decreasing for Black cancer patients. However, Black cancer patients continue to have lower survival rates than White cancer patients for most cancers at all cancer stages. Except for lung cancer in Black women, Black men and women have lower relative five-year survival rates than White men and women for the cancer types recruited for this dissertation study (DeSantis et al., 2016). The low survival rates are attributed to such factors as presentation to treatment with late stage disease (which has limited treatment options) and socioeconomic factors—both of which are related to concerns for health equity. DeSantis proposed that, if Black cancer patients receive cancer treatment similar to White cancer patients, they would likely have similar survival outcomes to White cancer patients. However, as has been stated, cancer disparity has claimed the lives of nearly one-half (10 of the 21) of the patient-participants since this dissertation study began in 2013, due to disease progression or related morbidity. Only one of the patient-participants had lived with cancer for more than four years.

Limitations and Methodological Considerations

There are limitations to this dissertation study. Every attempt was made to recruit new patient-participants in order to achieve 30 completed quantitative measures of

symptom burden. However, saturation was achieved with the data that was obtained and provided rich findings from which to address future research needs to understand the perspectives of Blacks enrolled in CCTs. The small sample size of this dissertation does, however, limit applicability to other Black cancer patients.

The choice of the Cancer Center (a NCI-Designated comprehensive cancer center in a large, northeastern city) introduced some level of sample selection bias. Choice of a comprehensive cancer center increased the likelihood of recruiting a sample of Black cancer patients willing to participate in CCTs. NCI-Designated comprehensive cancer centers are recognized for providing innovative cancer interventional, clinical, laboratory, and population-based research, as well being a central situs for cancer-related resources and programs, translational research, and public education and outreach programs (“NCI-Designated Cancer Centers,” n.d.). As a result, it was not surprising that the patient-participants shared similar sociodemographic characteristics, such as high levels of educational attainment (75% of the study sample attended at least some college and 35% of the study sample had completed college) and insured status. All of the patient-participants had insurance coverage (and some had more than one type of insurance). High educational attainment significantly correlates with enrollment in CCTs (Unger et al., 2013).²⁰ Moreover, lack of insurance is a barrier to CCT participation (Byrne et al., 2014; Du et al., 2005). The patient-participants’ educational attainment and insurance status heightened access to informational resources and to healthcare. However, these

²⁰ In a survey of 5499 cancer patients from 2007 to 2011 via an internet survey, Unger et al. (2013) used income and education as components of socioeconomic status and found that cancer patients with lower education ($p = .02$) were less likely to participate in CCTs.

attributes did not decrease the likelihood of their experiencing cancer disparity. The attributes did not improve their survival outcomes²¹, their ability to pay cancer-related costs, or their symptom burden.

Methodologically, the choice to limit analysis to cell phone interviews for the second aim of this dissertation study highlights the differences between real-time collection of symptom burden and symptom burden data collected via questionnaire and grounds the patient-participants' cancer experiential data in the moment of the interview. Communication was not included as a factor for deductive analysis in this dissertation study, given the extensive research on physician and patient communication by Albrecht and her research team with Black cancer patients (Albrecht et al., 2003; Albrecht et al., 2008; Albrecht, Penner, & Cline, 2009; Cline et al., 2007; Eggly et al., 2006; Penner et al., 2013). By contrast, Albrecht and her research team have done little in substantively defining the patient, family member, physician, and protocol factors that potentially influence CCT participation. The role of communication was, however, evident in all of the interviews. In the future, understanding the types of communication that are important to patient-participants and their families would be important to explore. Using cell phone interviews as a means to address real-time data capture of was limited by concerns for reducing respondent burden (i.e., the patient-participants' perception of physical, psychological, and economic privations experienced as a result of research participation) (Ulrich, Wallen, Fiester, & Grady, 2005). By limiting calls to 24-48 hours

²¹ DeSantis et al. (2016) found that the relative survival rates for Blacks continued to be lower than Whites for most cancer at every stage of cancer diagnosis. Of the ten patient-participants who died during the period October 2013 to November 2015, only one had had cancer for more than four years.

proximate to patient-participants' clinic appointments, it was hoped that patient-participants would not be unduly fatigued. Sometimes, however, it was difficult to contact some participants in the 24-48 designated period. Cell phone calls were made beyond the 24 to 48 hour period in order to reach some participants. There was also some concern about the spontaneous and authentic nature of the real-time responses because patient-participants came to expect calls from the doctoral candidate. Despite this limitation and the other limitations discussed as well as the methodological considerations, the information gathered from this dissertation study remains useful for subsequent study and hypothesis generation.

Last, despite the steps taken by the doctoral candidate to ensure trustworthiness, there was always the possibility that she may have misconstrued or misinterpreted the patient-participants' meaning and intent they wished to convey during analysis of the cell phone interviews. The absence of close physical proximity negated consideration of such physical nuances as facial expression, gestures, and posture, all of which could have resulted in differing interpretations of the data. Further, as with all quantitative and qualitative research, the doctoral candidate acknowledges that interjection of researcher bias was a possibility in such areas as the choice of research site, selection of participants, and analysis of the data (especially, here, where the doctoral candidate principally was responsible for collection and analysis of the data).

Benefits and Challenges of Using a Multimethod Approach

This dissertation study used a multimethod approach to describe the experiences of a sample of 21 Black cancer patients as they participated in CCTs. It was comprised

of differing types of qualitative analyses (inductive and deductive) used in independent aims as well as a quantitative measure. By using different data collection methods, it added descriptive richness and detail to the overall research question on why Black patient-participants' enroll and remain in their CCTs (Cheek, Lipschitz, Abrams, Vago, & Nakamura, 2015; Morse & Cheek, 2014).

Albrecht's Model provided the theoretical base to begin exploring and explicating the various elements of patient-participants' experiences (Morse & Cheek, 2014). A disadvantage of this deductive approach, however, was the necessity to solely focus on the model and its four factors. Thus, negative experiences such as perceived discrimination, cancer secrecy, conflict with the CCT Team, and instances where there was a lack of family member support were not included in the analysis for the first aim. Moreover, if these experiences did not emerge from the cell phone interviews, they were not included in the analysis for the second aim. Nevertheless, the use of inductive content analysis for the second aim provided several distinct advantages.

The cell phone interviews elucidated how symptom burden was a central aspect of patient-participants' CCT participation experiences. Patient-participants discussed the physical and emotional aspects of their symptom experiences on nearly every part of their lives (*How I Feel; It's Knocking Me Down*). A significant finding of this dissertation study was the differences in symptom burden experience as described by the qualitative cell phones interviews and reported by the self-report quantitative measure of the MSAS-SF. The cell phone interviews portrayed symptom burden experiences which were more

frequent and more intense than the mild to moderate physical and psychological symptom burden scores reported in the initial MSAS-SF completed by 20 study participants.

Despite being a reliable and valid symptom burden measure, there are always limitations with self-report questionnaires. Consistent with its instructions, the MSAS-SF measured the frequency and severity of a finite list of symptoms experienced by each patient-participant during the last seven days. Participants in this study recalled aggregated experiences and events that had occurred within the seven days preceding the moment the MSAS-SF was completed (Palmier-Claus et al., 2010; Shiffman, Stone & Hufford, 2008; Stone et al., 2007). EMA literature suggests that recall data are likely biased, imperfect, and outside the situational and environmental contexts of patient-participants' lives (Shiffman, Stone, & Hufford, 2008; Stone et al., 2007). More significantly, discrete moments of symptom burden could not be collected, nor described by the patient-participants. Using a multimethod approach with four cell phone interviews over a period of time showcased the advantages of real-time collection of patient-participants' experiences. They captured the richly textured features of the symptom burden experience at different time points in the study sample. With this method, patient-participants described more fully in their own words their attitudes, feelings, and impressions of their symptom burden experience. Ellie was able to share more fully the physical sensation of her peripheral neuropathy and her frustration with experiencing peripheral neuropathy as outlined below:

I go to pick up something, and I forget to put my gloves on. And then I end up feeling a slight—I don't know if you've ever had your hands in dry ice, but I remember as a kid one time—I didn't know what it was. And I put my hand in dry [ice], and it kind of, like, burned my skin. And-and that's the way it feels....

I think what bothers me the most is dealing with...neuropathy. Mm-hmm. It really—it-it just bothers—seems to bother me the most... it. (Ellie, Cell Phone Interview #3).

Her description and frustration were clear and concrete. It was easily understandable, why she felt enduring peripheral neuropathy was worse than managing her colostomy, the fatigue she felt during the first few days following her CCT chemotherapy, and the pain she experienced when her portacath was accessed. Completing the quantitative items on the MSAS-SF would not have provided the richness of information collected during this cell phone interview. The cell phone interviews suggested the existence of unmet symptom burden needs, despite the exemplary communication between the patient-participants and their oncologist and nurse practitioner. Seventy-five percent of patient-participants rated their communication with the oncologist as well as the nurse practitioner as “Very Good” or “Excellent.” More work is now needed on the use of real-time data capture and understanding the benefits and challenges of using this method with seriously ill populations with different types of data collection, such as text messaging or other approaches.

Future Research

In line with the findings of this dissertation and by the totality of the data gleaned from the face-to-face and cell phone interviews, several recommendations for future research are proposed. Qualitative and mixed-method research on larger samples of Black cancer patients enrolling in CCTs in NCI-designated comprehensive cancer centers, safety-net hospitals, and community settings is needed to determine differences in CCT experiences and perceived symptom burden. It would be helpful to know whether this

dissertation's study participants were indicative of all Black cancer patients, or Black cancer patients who sought cancer treatment at a NCI-designated comprehensive cancer center. Because this study did not study Black individuals who decided not to participate in CCTs, it is not known whether there would be a difference in perceptions and experiences between those who participate and those who do not. Future research should examine this inquiry. Because there were differences in the degree of symptom burden experienced by patient-participants, particularly when measured by a quantitative symptom burden tool (the MSAS-SF) and also by qualitative cell phone interviews, a larger mixed methods study comparing quantitative and qualitative assessments of symptom burden is now needed. More qualitative research on the role and influence of the CCT Team on the participation and retention of Black cancer patient in CCTs would also be instructive

The face-to-face semi-structured interviews for the first aim of this dissertation were analyzed deductively with a focus on Albrecht's model. Data that did not describe the specified factors within this model were not a focus of this dissertation. For this reason, a secondary data analysis is now warranted to identify the themes and categories that did not fit the constraints of Albrecht's model (e.g., communication, cancer secrecy, and perceived discrimination), but may add to a more expansive understanding of the factors influencing CCT participation and retention.

Last, this dissertation study was concerned with the patient, family member, physician, and protocol factors that were considered important to CCT participation. However, only a small percentage of Black cancer patients participate in therapeutic

CCTs. It would be interesting to expand the focus of inquiry to include Black cancer patients enrolled in various other types of clinical trials, including supportive care trials as well as those who are receiving outpatient conventional clinical treatment at a designated Cancer Center. We don't know whether the four factors that are considered in CCT participation based on Albrecht's Model would be the same for those who seek conventional clinical treatment. Nor do we know whether there are differences in symptom burden for those in conventional cancer treatment versus those participating in research.

Conclusion

Enrollment and retention continue to be issues of concern for the cancer research community. This study sought to understand the day-to-day experiences of Black cancer patients participating in CCTs and the patient, family member, physician, and protocol factors that contribute to Black cancer patient CCT enrollment and retention. Notably, the study data indicates that patient and physician factors were both important in enrollment and retention of patient-participants in their CCTs. Patient-participants had definite expectations of the characteristics they desired in their oncologists, how they wanted to be approached by healthcare providers, and how they wanted to manage cancer treatment. When their expectations were not met, they addressed the problem at hand and considered other available courses of action. Moreover, the patient-participants in this dissertation study were not passively being acted upon, ignored, or awaiting communication from oncologists. Many participants exercised their judgment and chose the qualities they deemed important in their oncologists and CCT enrollment. Arguably,

these actions gave relevance to the physician factors. Although protocol factors attracted some patient-participants to their CCTs, family member support kept them in their CCTs. Examination of family member factors revealed the informational, instrumental, emotional, and spiritual support which enabled the patient-participants to endure symptom burden, persevere through the uncertainties of their cancer diagnosis and CCT regimens, and become advocates for cancer prevention and CCT participation.

The study data indicates that, during their CCT enrollment, the patient-participants experienced physical and emotional stresses, work and financial challenges, and threats to their self-identity. Several patient-participants struggled with symptom burden throughout their participation in the trial. The physical changes in their bodies, as well as the rigors of CCT participation and their initial cancer diagnoses, drove them to attempt to retain some vestiges of themselves. They compartmentalized their daily lives so that their CCT and CCT-related appointments did not overwhelm them. Insurance and work issues were constant reminders of the economic toll of cancer and CCT participation.

Many of the patient-participants did not consider themselves “guinea pigs.” They were pioneers and trailblazers who sought to benefit themselves, other Black cancer patients, their churches, and their communities. They were consumers of cancer clinical research, who actively scoured the Internet seeking CCT opportunities—alone and with the assistance of their family members. Far from laboring under the paternalistic control of oncologists, the patient-participants sought second opinions, addressed symptom burden issues, and personally withdrew (Diane and Niecy) from CCTs which they felt

were not benefitting them. In sum, the study data contributed to nursing knowledge by revealing the heterogeneity of Black cancer patients beyond the narrow confines of existing research inquiry. The question which must be answered by additional research is whether the heterogeneity of this sample reflects Black cancer patients who seek cancer care at the Cancer Center, or Black cancer patients whose personal perspectives are not represented in the research literature. For these reasons, it is critical to test the generalizability of this study's findings on a larger sample, as a first step to developing interventions targeted at reducing the crippling cancer disparities affecting Black cancer patients.

APPENDIX A

Semi-Structured Face-to-Face Interview Guide

Type of Clinical Trial _____ (i.e., prostate, breast, lung, or colo-rectal)
Clinical Trial Phase <input type="checkbox"/> Phase I <input type="checkbox"/> Phase II <input type="checkbox"/> Phase III
Interviewee ID: _____
Interview Subject Pseudonym: _____
Audiotaped: Yes____ No____
Date Administered: ____/____/____

Interview with Participants

"Good morning/afternoon/evening. I am _____ (introduce self). I have received funding from the National Institutes of Nursing Research to better understand the cancer clinical trial experiences of Black adults with cancer enrolled in cancer clinical trials. I have received permission from the Cancer Center to call you to discuss your interest in talking about these issues. I am not part of your specific cancer clinical trial nor do I have any relationship with any cancer clinical trial research team at the Cancer Center. Everything you share with me will be kept confidential and will not be shared with any member of the cancer clinical trial team. So, it will be very important that you contact and share the following information with the nurse/physician on the cancer clinical trial team: (1) any symptom information that you describe to me, and (2) any issues or concerns about your experiences during the cancer clinical trial. All information you provide will be grouped together with other interviewees' information and analyzed together as a group. No one will be able to identify your individual information.

This interview is being done to determine your individual perceptions, feelings, and opinions of being involved in a cancer clinical trial. I will be asking you to describe to me your feelings and perceptions about participating in a cancer clinical, the factors in your decision to participate in a cancer clinical trial, and the symptoms you may be experiencing as part of participation in a cancer clinical trial. I am very interested in learning more about the experience of Black patients and their views on cancer clinical trials.

Discuss prior acquisition of Informed Consent with subject (purpose, risks/benefits, confidentiality, audio taping of information, aggregate of data, and other essential elements).

"If it is okay with you, I will be tape recording our conversation. By recording our conversation, I can get all the details of our discussion and concentrate on your thoughts on this subject. All your comments will remain confidential and no results will reference any specific individual. My proceeding with this interview indicates your agreement to this interview and to the tape-recording."

INDIVIDUAL-RELATED FACTORS

1. "Can you share with me some of your personal reasons for wanting to participate in your clinical trial?"
2. "What are your expectations for the clinical trial?" (Probes: What do you want to happen? What has happened so far?)
3. "In your own words, describe for me how things in your everyday life affected your decision to enroll in the clinical trial? (Probes: Does the clinical trial affect your ability to work? Does participation in the clinical trial take away time from time spent with your family or friends? Time for hobbies? Postponement of vacation?)

FAMILY/CAREGIVER SUPPORT FACTORS

1. "Can you share with me your support, if any?" (Probes: Do you have someone who takes care of you, runs errands for you, provides childcare, takes care of you when you are sick, etc.)
 - If so, who are they (relationally)? Probe: How would you describe them? (brother? sister? friend? son? daughter? church member? spouse?)
 - What do they do for you?
 - How often do they help you or provide care for you?
2. "Can you describe in your own words how having cancer has affected the people who help you?"
3. "Describe how you feel about the help you receive?"
4. "How do members of your family feel about your participation in a cancer clinical trial?"

SYMPTOM MANAGEMENT/SUPPORTIVE CARE

1. “In your own words, can you describe your health right now? How would you describe your health before you joined the clinical trial?”
2. “Have you told anyone at your oncologist’s (cancer doctor) office about how you are feeling?” If so, whom? If not, why not?
3. “Can you share with me if you are receiving any treatment for any symptoms?” (Please describe the symptoms and the treatment that you are receiving.)
 - Can you describe the symptoms that you feel are being treated well?
 - Can you describe symptoms that you feel are not being treated well?
 - Can you describe any symptoms that you feel are not being treated at all?”
4. “Can you describe any symptoms that you are having that you did not have before starting the cancer clinical trial?” (Probes: Are any of them worse than others? How long have you had the symptoms?)

HEALTHCARE PROVIDER FACTORS

1. Describe in your own words what the research team has meant to you as part of participating in the cancer clinical trial.
2. Can you share with me your thoughts about the contributions of the oncologist (cancer doctor) and other members of the clinical trial team such as the clinical research nurse and the nurse practitioner to your experience in the clinical trial?
 - How have they been helpful or not so helpful to you?
 - When you have questions about the clinical trial, who is most helpful to you? (Probes: Who gives you information about “what comes next” in the clinical trial and your cancer care and treatment?) Can you share with me your experiences or give an example?

PROTOCOL-RELATED FACTORS

1. “In your own words, can you tell me about your cancer clinical trial?” (Probes: How often per month do you visit the Cancer Center for appointments? How often do you receive chemo? How often do you go to the Cancer Center to have blood drawn or to have blood products? Can you describe for me what they are studying in your specific cancer clinical trial?)
2. Can you share with me anything that might make you drop out of the trial? (Probe: Side effects? Symptom burden? Financial concerns?)

3. “Can you describe anything that you do not or did not understand about the cancer clinical trial?”

- “If there is anything that you do not understand, have you shared that with any member of the cancer clinical trial team?”

4. Can you share with me your travel arrangements and appointment scheduling? (I ask this question because some patients report that it is difficult to come to the Cancer Center) (Probes: How easy is it for you to get to the Cancer Center? Has it interrupted your work schedule or child care needs in any way (if needed)? Has it interrupted your ability to provide care for an adult?)

5. Have you experienced any financial concerns related to participating in the clinical trial? If so, would you be willing to share this information with me or give me examples?

Is there anything you could share with me from your perspective as a Black adult with cancer who is participating in cancer research? I ask this question because very few Black adults with cancer participate in clinical trials, but they often suffer from higher rates of cancer. So, I would be interested in your thoughts and what you think might help other Black adults with and without cancer understand about participation in a cancer clinical trial.

Thank you.

APPENDIX B

Semi-structured Cell Phone Interview Guide

Type of Clinical Trial _____ (i.e., prostate, breast, lung, or colo-rectal)
Clinical Trial Phase <input type="checkbox"/> Phase I <input type="checkbox"/> Phase II <input type="checkbox"/> Phase III
Interviewee ID: _____
Interview Subject Pseudonym: _____
Audiotaped: Yes____ No____
Date Administered: ____/____/____

Cell Phone Interview with Participants

"Good morning/afternoon/evening. I am _____ (introduce self). I am a doctoral nursing student at the University of Pennsylvania School of Nursing. I have received funding from the National Institutes of Nursing Research to better understand the cancer clinical trial experiences of Black adults with cancer enrolled in cancer clinical trials. I have received permission from the Cancer Center to call you to discuss your interest in talking about these issues. I am not part of your specific cancer clinical trial nor do I have any relationship with any cancer clinical trial research team at the Cancer Center.

This cell phone interview is being done to gather your real-time life issues associated with your participation in a cancer clinical trial. I will be asking you to answer questions from your perspective as a Black adult living with cancer. These questions will concern your participation and experiences in the cancer clinical trial and any challenges that you are facing currently.

Everything you share with me will be kept confidential. All information you provide will be grouped together with other interviewees' information and analyzed together as a group. No one will be able to identify your individual information. I want to remind you that I am not involved with the cancer clinical trial team and will not be sharing this information with the cancer clinical trial team. So, it is very important that you contact and share the following information with the nurse/physician on the cancer clinical trial team: (1) any symptom information that you describe to me, and (2) any issues or concerns about your experiences during the cancer clinical trial.

This short interview will be audio-recorded. My continuing with this interview indicates your agreement to this interview and to the audio-recording.”

ASSESSMENT OF PRIVACY AND SAFETY

Let me begin by asking you a few short questions about you and your surroundings:

1. “Right now, do you feel safe and secure where you are located.”
2. “Where are you located right now? Is there another telephone nearby that would allow me to contact you (e.g., if your cell phone lost power or stopped working, and I was unable to continue our interview using your cell phone)?”
3. “Are you comfortable talking to me at this point?” (Probes: Are you by yourself or are there other individuals present? Is this okay with you? Would you like me to call you back at another time to protect your privacy?)
4. “Do you feel comfortable discussing the cancer clinical trial, right now?” (Probes: “Is someone close enough to you to hear your conversation with me? If someone is close enough to hear our conversation, are you comfortable with that person listening to our conversation? If no, would you like to move to a place where you can answer my questions without anyone listening nearby? Would you like me to call back at another time.”?)
5. “If you experience any severe symptoms during your interview,
 - Do you have any medications or equipment nearby?
 - Is there someone nearby who you know will help you? Who I can call?
 - In case you have a medical emergency and are unable to talk to me during your interview, can I call 911 for you?”

BRIEF TELEPHONE INTERVIEW QUESTIONS FOR REAL-TIME DATA CAPTURE

- 1.” How are you today? Can you briefly describe how you are doing today? How long have you been in the trial at this point?”
2. “Would you briefly describe (in your own words) ONE EXPERIENCE today that stands out in your mind related to your participation in the cancer clinical trial? The experience you describe can be positive, negative, or neutral.”
3. “In your own words, briefly describe your most recent experience with the cancer clinical trial research team. What has been helpful or not so helpful in your care and treatment?”
4. “Can you share and describe any symptoms that you have been experiencing. This can be of any type that is important to you. ” (Prompt: Remind subject that any symptom

information described should be shared also with nurse/physician of cancer clinical trial team)

5. “What are the challenges that you have been facing as you continue to participate in the cancer clinical trial? Can you share a few of these that are most important to you?”

Thank you.

APPENDIX C

Telephone Recruitment Script

Type of Clinical Trial _____ (i.e., prostate, breast, lung, or colo-rectal)
Clinical Trial Phase <input type="checkbox"/> Phase I <input type="checkbox"/> Phase II <input type="checkbox"/> Phase III
Subject Assent: _____
Date Available for Informed Consent/HIPAA Authorization: _____
Date Administered: ___/___/___

Telephone Recruitment Script

"Good morning/afternoon/evening. I am _____ (introduce self). I am a Black doctoral nursing student at the University of Pennsylvania School of Nursing. I have received funding from the National Institutes of Nursing Research to better understand the cancer clinical trial experiences of Black adults with cancer enrolled in cancer clinical trials. I have received permission from the Cancer Center to call you to discuss your interest in talking about these issues.

I am not part of your specific cancer clinical trial nor do I have any relationship with any cancer clinical trial research team at the Cancer Center. Everything you share with me will be kept confidential. I am not involved with the cancer clinical trial team and will not be sharing this information with any member of the cancer clinical trial team. So, it will be very important that you contact and share the following information with the nurse/physician on the cancer clinical trial team: (1) any symptom information that you describe to me, and (2) any issues or concerns about your experiences during the cancer clinical trial. All information you provide will be grouped together with other interviewees' information and analyzed together as a group. No one will be able to identify your individual information. At no time will your information be able to be connected to you.

I have permission from your oncologist, Dr. _____, to call you. I am very interested in learning more about the experience of Black patients and their views on cancer clinical trials. I am calling you to see if you would be interested in sharing with me your feelings, opinions, and experiences about participating in a cancer clinical trial. I will be asking you to describe to me your feelings and perceptions about participating in

a cancer clinical trial, the factors in your decision to participate in a cancer clinical trial, and any symptoms you may be experiencing as part of participation in a cancer clinical trial. Your total time commitment will be about four hours spread over three months. As a token of my appreciation for your participation, you will be reimbursed a total of \$35.00 for your time.

Are you interested? Would you be willing to meet me at the Perelman Center and talk about it further?"

(a) Yes: "Thank you very much. Before I go any further, I want to explain very briefly what you will be doing. The study has three parts:

- First, I want to meet with you for about one and one-half hours during one of the days that you have an appointment with your oncologist at the Perelman Center. During this appointment, you will fill out four forms. Two of the forms provide more information about what you will be doing and the information you will be providing. Next, you will complete a form which provides information about you and another form asks you to describe any of the symptoms you may be experiencing during the cancer clinical trial in which you are participating. Last, I would like to interview you about your experiences and feelings as a Black cancer patient involved in a cancer clinical trial. The interview should take about one hour. We can also do the interview over the telephone.
- You will be asked to complete four (4), 20-30 minute cell phone interviews over the course of two months; during these interviews you will be asked questions about your experiences and perceptions about participating in a cancer clinical trial and any symptoms you may be experiencing;
- At a final meeting, you will be asked to complete a form which describes some of the symptoms you may be experiencing during the course of the cancer clinical trial in which you are participating and review a few of your interviews to make sure the statements you made express how you felt.

Do you have any questions? (Arrange first meeting). If at any time you have any questions, please feel free to call me at _____. Thank you for your time."

(b) No: "Thank you for your time. If you change your mind and decide that you want to participate please do not hesitate to contact me at _____."

APPENDIX D

SOCIO-DEMOGRAPHIC INFORMATION FORM

1. What is your race or ethnic background?

- | | |
|---|---|
| <input type="checkbox"/> Black/African | <input type="checkbox"/> Black/Biracial |
| <input type="checkbox"/> Black/African American | <input type="checkbox"/> Black/Multi-racial |
| <input type="checkbox"/> Black/Caribbean American | <input type="checkbox"/> Black/Other |

2. Are you Hispanic or Latino?

- Yes
 No

3. What is your gender:

- | | |
|---------------------------------|---------------------------------------|
| <input type="checkbox"/> Female | <input type="checkbox"/> Other: _____ |
| <input type="checkbox"/> Male | |

4. What is your age? _____

5. Check the highest level of education completed?

- | | |
|--|--|
| <input type="checkbox"/> 8 th Grade or Less | <input type="checkbox"/> Some College |
| <input type="checkbox"/> Some High School | <input type="checkbox"/> College Graduate |
| <input type="checkbox"/> High School Graduate | <input type="checkbox"/> Graduate/Postgraduate |

6. What is your marital status?

- | | |
|--|------------------------------------|
| <input type="checkbox"/> Never Married | <input type="checkbox"/> Separated |
| <input type="checkbox"/> Married | <input type="checkbox"/> Widowed |
| <input type="checkbox"/> Divorced | <input type="checkbox"/> Partnered |

7. What type of cancer do you have?

- | | |
|-----------------------------------|--|
| <input type="checkbox"/> Breast | <input type="checkbox"/> Uterine |
| <input type="checkbox"/> Lung | <input type="checkbox"/> Cervical |
| <input type="checkbox"/> Prostate | <input type="checkbox"/> Stomach (Gastric) |

_____ Colo-rectal

_____ Pancreatic

_____ Leukemia

_____ Head & Neck

_____ Multiple Myeloma

_____ Liver

8. How long have you had cancer?

_____ 0-1 Years

_____ 11-15 Years

_____ 2-5 Years

_____ 16-20 Years

_____ 6-10 Years

_____ More than 20 Years

9. What medical treatment are you receiving for your cancer (check all that apply)?

_____ None

_____ Immunotherapy

_____ Chemotherapy

_____ Surgery

_____ Radiation

10. Do you know what stage of cancer that you have?

_____ Don't Know

_____ Stage 3

_____ Stage 1

_____ Stage 4

_____ Stage 2

11. Do you have any other type of health problem (for example: high blood pressure, diabetes, high cholesterol, etc.)?

_____ Yes

_____ No

12. If you have another type of health problem, please write it below:

13. How would you describe the area where you live?

_____ Urban

_____ Suburban

_____ Rural

14. Do you have insurance?

Yes

No

15. If you have insurance, what type of insurance do you have?

Private health insurance (Aetna, Blue Cross, etc.)

Out-of-pocket/Self Pay

Medicare

Medicaid

Veterans Benefits

Other (please specify: _____)

16. How important are your spiritual and/or religious beliefs?

Not Important

Important

A Little Important

Very Important

Somewhat Important

Extremely Important

17. Are you currently employed?

Yes

No

18. If employed, what are your hours?

Full-time

Part-time

19. If not employed, what below applies to you:

Unemployed

Student

Retired

Stay-at-home parent

Disabled

Other (please specify: _____)

20. Do you have a caregiver (someone who takes care of you, runs errands for you, provides childcare, takes care of you when you are sick, etc.)?

Yes

No

21. If you have a caregiver, how important is having a caregiver to you?

Not Important

Important

A Little Important

Very Important

Somewhat Important

Extremely Important

22. If you have a caregiver, who is your caregiver (check all that apply)?

Spouse (husband or wife)

Parent

Partner

Child

Sibling (sister or brother)

Friend

Grandparent

23. How important is it for you to get information about your cancer diagnosis and treatment?

Not Important

Important

A little Important

Very Important

Somewhat Important

Extremely Important

24. How would you rate your ability to get information about your cancer diagnosis and treatment from your oncologist?

Poor

Very Good

Fair

Excellent

Good

25. How would you rate your communication with your oncologist?

Poor

Very Good

Fair

Excellent

Good

26. How would you rate your communication with your oncology nurse practitioner (if you have one)?

_____ Poor

_____ Very Good

_____ Fair

_____ Excellent

_____ Good

27. How important is it for you to get information about your clinical trial treatment?

_____ Not Important

_____ Important

_____ A little Important

_____ Very Important

_____ Somewhat Important

_____ Extremely Important

APPENDIX E

Memorial Symptom Assessment Scale-Short Form

Patient's Name _____ Date ___/___/___ ID # _____

MEMORIAL SYMPTOM ASSESSMENT SCALE – Short Form [MSAS-SF]

I. **INSTRUCTIONS:** Below is a list of symptoms. If you had the symptom **DURING THE PAST WEEK**, please check Yes. If you did have the symptom, please check the box that tells us how much the symptom **DISTRESSED** or **BOTHERED** you.

Check <u>all</u> the symptoms you have had during the PAST WEEK.	IF YES: How much did it DISTRESS or BOTHER you?					
	Yes [X]	Not at All [0]	A little Bit [1]	Some-what [2]	Quite a Bit [3]	Very Much [4]
Difficulty concentrating						
Pain						
Lack of energy						
Cough						
Changes in skin						
Dry mouth						
Nausea						
Feeling drowsy						
Numbness/tingling in hands and feet						
Difficulty sleeping						
Feeling bloated						
Problems with urination						
Vomiting						
Shortness of breath						
Diarrhea						
Sweats						
Mouth sores						
Problems with sexual interest or activity						
Itching						
Lack of appetite						
Dizziness						
Difficulty swallowing						
Change in the way food tastes						
Weight loss						

MEMORIAL SYMPTOM ASSESSMENT SCALE – Short Form [MSAS-SF]

I. INSTRUCTIONS: Below is a list of symptoms. If you had the symptom **DURING THE PAST WEEK**, please check Yes. If you did have the symptom, please check the box that tells us how much the symptom **DISTRESSED** or **BOTHERED** you.

Check <i>all</i> the symptoms you have had during the PAST WEEK.	<u>IF YES:</u> How much did it DISTRESS or BOTHER you?					
	Yes [X]	Not at All [0]	A little Bit [1]	Some-what [2]	Quite a Bit [3]	Very Much [4]
Hair loss						
Constipation						
Swelling of arms or legs						
“I don’t look like myself”						
If you had <u>any other symptoms</u> during the PAST WEEK, please list them below, and indicate how much the symptom DISTRESSED or BOTHERED you.						
1. _____						
2. _____						

II. Below are other commonly listed symptoms. Please indicate if you have had the symptom **DURING THE PAST WEEK**, and if so, how **OFTEN** it occurred.

Check <i>all</i> the symptoms you have had during the PAST WEEK	<u>IF YES,</u> How OFTEN did it occur?				
	Yes [X]	Rarely [1]	Occasionally [2]	Frequently [3]	Almost Constantly [4]
Feeling sad					
Worrying					
Feeling irritable					
Feeling nervous					

APPENDIX F

University of Pennsylvania Institutional Review Board Approval

University of Pennsylvania
Office of Regulatory Affairs
3624 Market St., Suite 301 S
Philadelphia, PA 19104-6006
Ph: 215-573-2540/ Fax: 215-573-9438
INSTITUTIONAL REVIEW BOARD
(Federalwide Assurance # 00004028)

13-Aug-2013

Connie M Ulrich
culrich@nursing.upenn.edu
Attn: Terease Waite
Waite@Nursing.Upenn.Edu

PRINCIPAL INVESTIGATOR : Connie M Ulrich
TITLE : Real-time Data Capture of the Experiences of Blacks in Cancer Clinical Trials
SPONSORING AGENCY : National Institute of Nursing Research/NIH/DHHS
PROTOCOL # : 818152
REVIEW BOARD : IRB #8

Dear Connie Ulrich:

The above referenced protocol and was reviewed and approved by the Executive Chair (or her authorized designee) using the expedited procedure set forth in 45 CFR 46.110, category 6,7, on 09-Aug-2013. This study will be due for continuing review on or before 08-Aug-2014.

Approval by the IRB does not necessarily constitute authorization to initiate the conduct of a human subject research study. Principal investigators are responsible for assuring final approval from other applicable school, department, center or institute review committee(s) or boards has been obtained. This includes, but is not limited to, the University of Pennsylvania Cancer Center Clinical Trials Scientific Review and Monitoring Committee (CTSRMC), Clinical and Translational Research Center (CTRC) review committee, CAMRIS committee, Institutional Biosafety Committee (IBC), Environmental Health and Radiation Safety Committee (EHRS), and Standing Conflict of Interest (COI) Committee. Principal investigators are also responsible for assuring final approval has been obtained from the FDA as applicable, and a valid contract has been signed between the sponsor and the Trustees of the University of Pennsylvania. If any of these committees require changes to the IRB-approved protocol and informed consent/assent document(s), the changes must be submitted to and approved by the IRB prior to beginning the research study.

If this protocol involves cancer research with human subjects, biospecimens, or data, you may not begin the research until you have obtained approval or proof of exemption from the Cancer Center's Clinical Trials Review and Monitoring Committee.

The following documents were included with this submission:

- HS-ERA IRB Application, (Confirmation Code : bdbddhid), submitted 08/06/2013
- Telephone Recruitment Script, Version dated August 6, 2013
- Cover Letter, dated July 18, 2013 Re: Response to IRB
- Email Correspondence, dated July 19, 2013
- Cover Letter, dated August 6, 2013
- HIPAA Authorization Form, dated August 6, 2013
- Informed Consent Form, dated August 5, 2013
- Socio-Demographic Information Form, uploaded 08/06/2013
- Cell Phone Interview Guide, dated August 6, 2013
- Semi-Structured Interview Guide, dated August 6, 2013
- NIH Notice of Grant Award- Grant Number: 1F31NR013847-01A1, Issue Date: 01/08/2013
- Memorial Symptom Assessment Scale- Short Form [MSAS-SF], uploaded 05/21/2013
- References List, uploaded 05/21/2013
- Cover Letter, dated May 21, 2013
- NIH Grant Application, uploaded 05/29/2013
- NRSA Grant Proposal, dated August 6, 2012
- CTSRMC Letter of Approval, uploaded 06/04/2013
- Cover Letter, dated June 4, 2013 Re: Response to IRB
- Letter from Landmark Associates, uploaded 06/04/2013 Re: PHI Policy
- Letter from Landmark Associates, uploaded 06/04/2013 Re: Security/Confidentiality Measure
- CITI Training Initiative- Human Research Curriculum Completion Report for Connie Ulrich, Stage 2 Refresher Course Passed on 05/19/2013
- Recruitment Algorithm, uploaded 07/01/2013
- Cover Letter, dated July 1, 2013 Re: Response to IRB
- CTSRMC Approval letter, dated June 27, 2013
- Letter from DSMC, dated June 27, 2013

When enrolling subjects at a site covered by the University of Pennsylvania's IRB, a copy of the IRB approved informed consent form with the IRB approved from/to stamp must be used unless a waiver of written documentation of consent has been granted.

If you have any questions about the information in this letter, please contact the IRB administrative staff. Contact information is available at our website: <http://www.upenn.edu/regulatoryaffairs>.

Thank you for your cooperation.

Sincerely,

Melissa Eng

Digitally signed by Melissa Eng
DN: cn=Melissa Eng, o=IRB, ou=IRB, email=engm@upenn.edu,
c=US
Reason: I attest to the accuracy and integrity of this document
Date: 2013.08.13 16:15:32 -0400

IRB Administrator

APPENDIX G

Clinical Trials Scientific Review and Monitoring Committee



Clinical Trials Scientific Review Monitoring Committee

June 27, 2013

Connie Ulrich, PhD, RN
Claire Fagin Hall: Rm. 418

RE: UPCC 11913: Real Time Data Capture of the Experiences of Blacks in Cancer Clinical Trials

Dear Connie:

The Cancer Center's Clinical Trials Scientific Review and Monitoring Committee reviewed the above study utilizing expedited mechanism. This protocol was granted full approval on June 27, 2013.

CTSRMC Approval may be withdrawn if the following on-going requirements are not met:

1. **Amendments:** Any modifications to the protocol, consent(s) or other study related documents must be submitted electronically to Jane Daly jane@mail.med.upenn.edu. Revisions cannot be initiated until CTSRMC approval has been given.
2. **Accrual Monitoring:** The CTSRMC is mandated by NCI to assess the scientific progress of your study. This is accomplished through monitoring enrollment onto your study every three months from the date your protocol opens to enrollment and evaluation of your annual Continuing Review. Late or inaccurate accrual data prevents the CTSRMC from meeting our obligations to NCI. **As you accrue patients to this study, you must update your accrual information in Velos.** <https://velos.uphs.upenn.edu:5443>
3. **Exceptions/Deviations:** Any variation from the approved protocol must be acted upon appropriately. The IRB and ACC Data and Safety Monitoring Committee have specific documentation and reporting requirements. Please visit their websites to familiarize yourself with their expectations. DSMC requirements can be reviewed at www.ctsrc.org
4. **Completion of Study:** Please notify the CTSRMC in a timely manner when the status of your study changes (e.g. closes, terminates, suspended, withdrawn). Inaccurate data prevents the CTSRMC from meeting our obligations to NCI. **You are required to keep your study status current in Velos.** <https://velos.uphs.upenn.edu:5443>

Regards,

Vicki Sallée, MS, RD
Administrative Director, Clinical Trials Scientific Review and Monitoring Committee

cc: IRB



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UNIVERSITY OF PENNSYLVANIA HEALTH SYSTEM

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