



HHS Public Access

Author manuscript

AJOB Empir Bioeth. Author manuscript; available in PMC 2021 December 08.

Published in final edited form as:

AJOB Empir Bioeth. 2019 ; 10(3): 190–200. doi:10.1080/23294515.2019.1618417.

Cancer clinical trial patient-participants' perceptions about provider communication and dropout intentions

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Abstract

Objective: To study the relationship between cancer patient/research participants' perceptions of communication with their research nurse and doctor and 1) participants' thoughts of dropping out from their cancer clinical trials (CCTs), 2) how informed they felt before and during their clinical trial participation, and 3) trust in their researchers.

Methods: We surveyed 110 adult cancer patients who were enrolled in cancer clinical trials by using 15 modified items from the Medical Communication Competence Scale measuring information exchange and relational communication. Retention was measured by two items: ever thought about dropping out (yes/no) and likelihood of remaining enrolled in the clinical trial (5-point Likert item). We asked how well informed about the trial participants felt at enrollment, at the date they filled out the survey, and about changes in the trial.

Results: Patient-participants with thoughts of dropping out from their CCTs rated their communication with research doctors lower than those who did not have thoughts of dropping out (4.14 versus 4.46, $t=2.22$, $p=0.03$). Patient-participants' intention to remain enrolled was

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AUTHOR CONTRIBUTIONS:

Qiuping Zhou, Sarah J. Ratcliffe, and Tianhao Wang have made substantial contributions to the conception and design of the work, data analysis, and interpretation of data for the work; and, drafted the work for important intellectual content.

Christine Grady and Jun J. Mao have made substantial contributions to the conception of the work; and, revised it critically for important intellectual content.

Connie M. Ulrich has made substantial contributions to the conception and design of the work; and the acquisition, analysis, or interpretation of data for the work and drafted and revised the work for important intellectual content.

CONFLICTS OF INTEREST: None disclosed.

ETHICAL APPROVAL: This study was approved by the institutional review board(s) at the University of Pennsylvania and the Abramson Cancer Center.

The opinions are the views of the authors and do not reflect the official policies or positions of the Department of Health and Human Services, NIH, or the Public Health Service.

correlated with more favorable scores on relational communication (such as contributing to a trusting relationship and showing compassion) with research doctors ($r=0.20$, $p=0.04$) and nurses ($r=0.25$, $p=0.01$). Communication with doctors was also associated with how informed patient-participants felt during their clinical trials.

Conclusions: Relational communication with research doctors and nurses was significantly related to thoughts about remaining enrolled or dropping out of a clinical trial among adult participants in cancer treatment clinical trials.

Practice Implications: Relational skills with cancer patients advances communication in research.

Keywords

Cancer Clinical Trials; retention; Communication with research doctor; communication with research nurse

Introduction

Cancer clinical trials (CCTs) are essential for finding life-preserving treatments for cancer patients and testing the safety and effectiveness of potential treatments. CCTs offer opportunities to access novel, but unproven investigational therapies that are not available outside CCTs. For CCTs to be successful and produce best evidence, they need to successfully recruit and retain participants from all backgrounds. However, studies have shown that only 2–7% of adult cancer patients ever enroll in a CCT (Murthy, Krumholz, and Gross 2004) and an estimated 22% to 38% of CCTs sponsored by the National Cancer Institute do not achieve sufficient accrual rates (Cheng, Dietrich, and Dilts 2010; Korn et al. 2010). Low enrollments increase type II error and reduce the power of the study, thus reducing the ability to successfully assess the safety and effectiveness of experimental interventions in CCTs. Moreover, the low accrual of participants across all sociodemographic indicators affects the ability to develop generalizable knowledge that is essential to equitable, ethical, and quality care. Emanuel, Wendler, and Grady (2000) point to several requirements that support the ethical conduct of clinical research, including the social and scientific validity of the research questions being asked, the methods that are used, and the informed consent of participants. Adequate enrollment and retention in CCTs and well-informed participants are essential to generating knowledge that advances cancer care.

In addition to low recruitment, dropout from CCTs is a significant problem. Dropout or attrition reduces statistical power and can cause selection bias, posing an internal validity threat. It also limits the generalizability of study results. Estimates vary on attrition in CCTs. Hui et al. (2013), for example, reported high attrition rates in palliative oncology clinical trials (25% for the primary endpoint and 44% for the end of the study); the high rates were associated with characteristics such as participant burden, hospitalization, personal preference, and death. Multiple factors are important to the success of participant recruitment and retention. Mathibe (2007) noted that side effects, management issues

related to the protocol, poor communication, and patient sociodemographic characteristics all influence cancer patients' withdrawal from longitudinal clinical trials.

In 2013, after synthesizing the qualitative literature regarding trial participation decisions, McCann, Campbell, and Entwistle (2013) developed a conceptual model delineating a person's decision about taking part in a trial. They proposed that personal circumstances, such as facing an urgent and life-threatening health condition like cancer, affected patients' assessment of personal implications of trial interventions and processes. The authors also found that patients' communication with and relationship with trial recruiters was important, as were the personal altruistic benefits expressed by patient-participants as "giving back" or "helping others." Indeed, as stated by the National Institutes of Health, "key to encouraging public support for and participation in clinical research is trust, and researchers must take the time and make the effort to build that trust" (Department of Health and Human Services 2016). To build and maintain this trust, communication by research personnel with trial participants is essential, not only when patients join the study, but also during the time when they are enrolled, and after the completion of the trial. In qualitative work, Ulrich et al. (2012) reported that trust was an important factor in how participants in CCTs weighed the benefits and burdens of research participation; the authors recognized the central role of physicians in patients' decision-making process. Although this study did not specifically examine trust by race or ethnicity, other researchers have reported that African Americans have less trust in physicians than their white counterparts do, believing that physician investigators might expose them to unnecessary risks and not fully explain information pertinent to research participation (Corbie-Smith, Thomas, and St George 2002).

In a proposed multilevel model to reduce barriers to CCT participation, particularly for racial and ethnic minorities, Hamel and associates posited that training professionals in communication skills could lead to interpersonal-level team building, thus leading to high-quality communication with potential participants about CCTs that ultimately increases participation rates (Hamel et al. 2016). Several authors have also identified the importance of communication associated with recruitment efforts (Bower et al. 2014; Kirkby 2012; Morgan et al. 2016); yet very few studies have evaluated the aspects or components of communication that are related to participants' thoughts of dropping out when they are actively enrolled in CCTs or on how well informed they feel about the trial. For the purpose of our study, we adapted Albrecht et al.'s (2003) model of physician-patient communication because the model identifies communication as a key process in patients' CCT treatment decisions and hypothesizes that several independent factors (i.e., patient, family, physician, and protocol) affect decision making. Albrecht et al. identified communication as a mediator between these factors and treatment decisions. The purpose of our study was to examine the relationship between adult CCT participants' perceptions of communication with their research doctor and research nurse and 1) participants' thoughts of dropping out from their CCTs; 2) how informed they felt before and during their CCT participation; and 3) trust in their researchers.

Methods

Study procedures and sample

This study was a subanalysis of primary data collected in a cross-sectional survey between 2010 and 2011 examining adult CCT participants' perceived benefits and burdens of research participation and related factors. Following approval by the Institutional Review Board at the University of Pennsylvania and the participating cancer site Abramson Cancer Center, we recruited a convenience sample of adult cancer patients who were enrolled in CCTs at one university cancer center. Eligible participants included all English-speaking patients age 18 and older who had a diagnosis of cancer, and were enrolled in therapeutic treatment CCTs for at least 60 days, including those enrolled in Phase I, II, and III trials and those who might have participated in other types of clinical treatment trials (e.g., compassionate use of a drug for advanced disease, pilot/feasibility institutional studies for refractory cancer diagnoses, and acute myeloid leukemia studies). A research assistant or the principal investigator (CU) obtained either verbal or written consent from 149 patient-participants, and the survey questionnaire was distributed either face-to-face or via mail to these consented patients depending on their preference. Six patients became ineligible due to death or hospitalization, leaving 143 patients. A total of 110 patient-participants completed the survey, for an adjusted 77% response rate (as reported in Ulrich et al. 2016).

We performed a statistical power analysis for the primary purpose of determining the appropriate sample size for the survey. With alpha of 0.05, this sample size of 110 gave us 80% power to detect a moderate effect size for two-tailed hypotheses.

Measurements

Measures included in this analysis are: 1) perceptions of communication with the research doctor and the research nurse, using subscales of the Medical Communication Competence Scale, 2) responses to questions about thoughts of dropping out and intention to complete the clinical trial, 3) responses to questions about how informed participants felt, 4) responses about trust in researchers, and 5) sociodemographic characteristics.

Communication was measured using an adapted version of the Medical Communication Competence Scale (MCCS) (Cegala, Coleman, and Turner 1998). Using parallel items with slight variations in language, Cegala and colleagues designed the MCCS to measure both providers' and patients' perceptions of self- and other-communication competence in a clinical interaction. The provider version of the MCCS includes 37 items and the patient version 40 items (16 self-competence and 24 other-competence). In this study, to focus on patient-participants' perspectives on communication with their research doctors and nurses, we used only 15 of the 24 "other-competence" communication items; these items measured information seeking (i.e., using questions to seek information), information verifying (i.e., using repetition to assess understanding), and relational development (i.e., expressing care and concern). Because the other items regarding information giving were for a treatment context rather than a CCT context, they were less relevant to our study and thus we did not include them. We modified the MCCS by changing "doctor" to "research doctor" or "research nurse" and asked patient-participants to complete the scale for both types

of providers separately. Each item was measured on a 5-point Likert scale ranging from strongly disagree to strongly agree, with higher scores indicating better communication. The shortened scale had acceptable reliability and validity (as indicated below).

Expected retention was measured by two items: “Have you ever thought about dropping out of the study?” (yes/no) and “How likely is it that you will remain enrolled in this clinical trial?” (5-point Likert item). Perception of feeling informed was measured by three questions asking, “How well informed did you feel when you enrolled in the clinical trial/research study?”; “How well informed do you feel at this point of your research participation?”; and “How well were you informed about any changes in the study, including side effects or study procedures?”. Participants were asked to rate each question using 5 points ranging from “not at all” to “fully informed.”

Trust in researchers was measured in two ways: 1) a single item from a larger benefit scale (Ulrich et al. 2018), “I trust my researcher knows what is best for me” using a 5-point scale ranging from strongly disagree to strongly agree; and 2) a distrust index, created using the sum of seven questionnaire items as suggested by Corbie-Smith, Thomas, and St. George (2002), which created a score that ranged from 0 for the most trusting to 7 for the most distrusting. Scores on the first trust measure (i.e., the single item with responses on a 5-point scale) were dichotomized into “not trust” (strongly disagree, disagree, or neither agree nor disagree) and “trust” (agree or strongly agree).

Sociodemographic data were collected from the questionnaire, including gender, age, racial background (Caucasian vs. others), education (college vs. less than college), occupation (employed/retired vs. unemployed/homemaker/disabled/student), marital status (married vs. not married), and health insurance status (government medical benefits such as Medicare/Medicaid/veteran benefits vs. self-supported such as private health insurance/out of pocket). Categorical demographic variables were coded dichotomously to boost statistical power (subcategories had a limited number of cases). We also included questions on the importance of patient-participants’ spiritual-religious beliefs (not important/a little important/ somewhat important vs. important/very important), and whether they enrolled in any research studies prior to their current participation (yes/no).

Data analysis

We used SPSS 24 (IBM Corporation 2016) to analyze the data. All data were screened for outliers, and a random 10% of entries was checked for errors. Exploratory factor analyses, with varimax rotations, were used to examine the structure of the modified MCSS specific to our analysis. Internal consistency of the subscales and total scale was evaluated using Cronbach’s alpha. Missing data only occurred in eight (7%) subjects. For scale scores, personal mean scores were used to impute any missing items; missing data were <50% for any single participant. Sensitivity analyses using complete cases only gave similar results.

The association between communication with the research doctor and research nurse and the outcomes of thoughts of dropping out (yes/no) and perception of being informed (informed/ fully informed vs. not at all to not sure) were first assessed using Student’s t-tests. The relationships with intent to remain in the trial were assessed using Pearson r or Spearman

correlations, as appropriate. Multivariate regression was then used to check for potential modification/confounding effects of demographic variables on the relationships between communication and retention. Logistic regression was used for the outcome of “thoughts about dropping out” and linear regression analyses for the 5-point dependent variable “likelihood to remain enrolled in the clinical trial.” For ease of exposition, we considered only the total communication score of research doctors and nurses in the models. Only demographic variables significant at the 0.1 level in the fully adjusted model were retained in the final multivariate model. For all analyses, alpha was set at 0.05. Results were not adjusted for multiple comparisons.

Results

Participants

Patients’ mean age was 58.7 years, ranging from 23 to 86 years; 46 (45.1%) were younger than 60. Approximately half the 110 participants were male (n=57, 52.3%), 89.9% were white (n=98), and 54.1% (n=59) had less than a college education. More than two-thirds of participants (68.5%; n=74) were employed or retired, 81.8% (n = 90) were married at the beginning of the trial, 30.6% (n=33) received medical benefits from the government, 91.7% (n=99) had at least part of their medical expenses covered by private insurance or by themselves, 57.8% (n = 63) thought spiritual and/or religious beliefs were important or very important to them, and 23.2% (n=25) had been enrolled in one or more research studies prior to the one in which they were currently participating. The types of cancer included 24 hematologic, 17 breast/gynecological/perineal, 15 multiple myelomas, 12 melanomas, 4 prostate, 4 urology/urothelial, 3 lung, 3 digestive, 1 liver, and 7 other types; data for the rest were missing (n=20). Eighty-nine participants reported the phases of their clinical trials, including 50 (56.2%) in a phase 2 trial, 20 (22.5%) in phase 3, and 19 (21.3%) in phase 1–2 trials.

Communication Measurements

For communication with research doctors, 80.9% (n = 89) of the participants had an overall mean communication score greater than or equal to 4 (maximum 5), and the mean score of all participants was 4.41 (sd = 0.55). Exploratory factor analysis identified two factors accounting for 80.43% of the variance. The first factor, consisting of items 1 through 9 with factor loadings ranging from 0.75 to 0.88, measured patients’ perceptions about information exchange. The second factor, consisting of items 10 through 15 with factor loadings ranging from 0.81 to 0.85, measured socioemotional communication (or relational communication). In this study, question 9, “The research doctor did a good job using language I could understand,” clustered with information exchange rather than relational communication. The internal consistency for the two factors were both 0.96, and it was 0.97 for the entire scale (factor loadings available upon request).

For communication with research nurses, 79.1% (n = 87) of the participants had an overall mean communication score higher than 4 (maximum 5), and the mean score for all participants was 4.43 (sd = 0.60). The same two-factor structure was identified for communication with the research nurses. These two factors accounted for 86.57% of the

variance. The loadings for the information exchange and relational communication factors ranged from 0.76 to 0.88 and from 0.83 to 0.91, respectively. The Cronbach's alpha was 0.97 for information exchange, 0.98 for relational communication, and 0.98 for the total scale (factor loadings available upon request).

Relationship between Communication and Retention Intention

In this study, 17 participants (16.3%) reported that they had thought about dropping out of their CCT. When asked about the likelihood for them to remain enrolled, 51 participants (48.6%) indicated that they would complete their trial, 31 (29.5%) reported that it was very likely that they would complete their trial, 9 (8.6%) were unsure, and 14 (13.4%) said they might not complete the trial or that they were not at all likely to remain enrolled. The bivariate associations between perceived communication with the research doctor and research nurse and 1) thoughts of dropping out and 2) intention to remain enrolled are summarized in Table 1. Patient-participants with thoughts of dropping out rated their communication with research doctors slightly, but significantly, lower than those who did not have thoughts of dropping out ($t=2.22$, $p=0.029$). The information exchange that patient-participants had with their research doctors was not significantly related to their intention to remain enrolled ($r=0.12$, $p=0.21$); however, perceived relational communication (such as contributing to a trusting relationship and showing compassion) was related to intention to remain enrolled ($r=0.20$, $p=0.037$).

For perceived communication with the research nurse, neither information exchange nor relational communication were related to patients' thoughts of dropping out, although relational communication with the research nurse was positively correlated with participants' reported intention to remain enrolled ($r=0.25$, $p=0.01$). When asked about importance of communication with the research nurse during research participation, most (85.2%) participants responded that it was very important (72, 66.7%) or important (20, 18%), while 9 participants (8.3%) responded not important or a little important, and 7 (6.5%) responded somewhat important.

In the multivariate regression analyses, none of the demographic variables were found to significantly modify the relationship between research doctor communication and retention. For the thoughts of dropping out outcome, better perceived research doctor communication (modified MCSS) was associated with lower likelihoods of dropout thoughts, even after controlling for demographic variables ($OR = .10$, $p = .006$). Nurse communication was not a significantly related to thoughts of dropping out ($OR = 1.09$, $p = .843$).

In adjusted regression analyses for the outcome of likelihood of remaining enrolled in the clinical trial, better perceived research doctor communication (modified MCSS) was associated with a higher likelihood of remaining enrolled (coef. = .48, $p = .049$), as was insurance status (coef. = 1.081, $p = .023$). Research nurse communication was not significantly associated with likelihood of remaining enrolled.

Relationship between Communication and Perception of Feeling Well Informed

We asked three questions about how well informed participants felt: at enrollment, at the point they filled out the survey, and about changes in their clinical trial. We compared

communication scores between participants who felt they were informed or fully informed versus those who said they felt not at all informed or were unsure. The results are summarized in Table 2 and Table 3.

As shown in Table 2, research physician communications were significantly related to how well patient-participants felt informed at enrollment, at the point of the survey, and about changes in the study. The information exchange scores all registered medium to large effect sizes. The effect sizes for relational communication and being informed were small and not significant.

As shown in Table 3, communication with research nurses was not significantly related to how well informed participants felt at enrollment; however, it was significantly associated with how well informed participants felt at the time of the survey ($t = -2.11, p = 0.038$). Information exchange showed similar patterns and was significantly correlated with how well informed participants felt at the point of the survey ($t = -2.34, p = 0.021$). Examination showed small to medium effect sizes for total communication (d range 0.36–0.62) and for information exchange (0.39–0.70). In contrast, relational communication was not significantly related to how well informed participants felt, even though the difference for feeling informed at the time of the survey showed close to a medium effect size.

We examined the relationship between feeling informed and thoughts of dropout. We found that the less informed participants felt about changes in the study, the more likely they were to have thoughts of dropping out ($z = 2.07, p = 0.039$). However, feeling informed at enrollment and at the time of the survey were not significantly related to patients' thoughts of dropping out ($p = 0.16$ and $p = 0.81$, respectively).

Relationship between Communication and Trust

Over 70% of the sample ($n = 79, 71.8\%$) agreed or strongly agreed with the statement “I trust my researcher knows what is best for me.” For the distrust index, 50.9% ($n = 56$) had zero distrust, and 96.3% ($n = 105$) scored 2 or less on the distrust index. Table 4 presents the results of the bivariate correlations between trust and communication. The single-item trust measure was significantly correlated with all communication measurements for both doctors and nurses. But the distrust index measured in our study was not correlated with any of the communication measurements, or even with the single-item trust measure.

Discussion

Communication is an important component in the CCT participant-researcher relationship. It is important not only during the initial recruitment phase of a CCT but also as the trial progresses and retention of patient-participants becomes critical to meeting study goals. We found that CCT participants rated their overall communication with their research doctors and nurses as positive based on the high scores they reported. We also found that participants' perceptions of communication were related to thoughts of dropping out, how well informed they felt, and the degree of trust they had in their researcher. Different types of communication also had significant associations.

Relational communication with both the research doctor and research nurse was more closely related than was informational communication to patients' intention to remain enrolled in their trial. In fact, patient-participants with thoughts of dropping out rated their communication with research doctors slightly, but significantly, lower than those who did not have thoughts of dropping out ($t=2.22$, $p=0.029$). Patient-participants were more likely to intend to remain in the trial if they had positive perceptions of the relational communication of both their research doctor and research nurse, including being open and honest, showing compassion, and helping patient-participants feel relaxed and comfortable.

The significant correlation between relational communication with the research nurse (or those implementing CCT protocol/procedures or affiliated with the CCT on behalf of the principal investigator) and intention to remain enrolled supports the observation that most participants considered communicating with the research nurse important or very important for their CCT participation. Indeed, registered nurses are critical to research, serving in a variety of roles ranging from principal investigator to caring for research participants at the bedside. Nurses remain one of the most trusted professional groups in the United States, and clinical research nurses are integral to many aspects of CCT protocols, including recruitment, retention, informed consent, implementation of study procedures, study and patient advocacy, and the overall ethical care of patient-participants (Grady and Edgerly 2009). Even though the overall nurse communication score was not significantly related in the logistic regression analysis to thoughts of dropping out, better relational communication with the research nurse reduced the probability of thoughts of dropping out. This finding warrants further investigation in studies designed to test these associations.

Although communication with the research doctor is very important at enrollment, once enrolled, patients may spend more time interacting with the research nurse than with the research physician-investigator. For instance, if the patient-participant is enrolled in a chemotherapy trial, the research nurse is the one who administers the treatment and collects the outcome data. Moreover, the research nurse often is the point person to follow up on patients during the trial, addressing any concerns related to adverse effects, symptom burden, or other issues.

Feeling informed about the clinical trial is an important aspect of the ethical requirement for informed consent. We assume that information exchange at the beginning of a CCT is crucial as all aspects of the research trial are outlined. However, current guidance and most research on communication focus on recruitment and enrollment; there is little research on communication patterns between and among research staff and patient-participants after people enter their trials. We found significant differences in reported communication with research doctors between patient-participants who reported feeling well informed and those who did not feel well informed. These differences were seen not only when patient-participants enrolled, but also at the time of our survey and when participants were asked about being informed of changes in the study protocol. There is some evidence to suggest that participants who withdraw from trials have difficulties with trial information (Eborall et al. 2011).

In a systematic review of interventions to improve informed consent, Nishimura and colleagues (2013) reported that while various mediums are important to improving informed consent and knowledge comprehension of participants, both enhanced informed consent documents and extended discussions seem to be the most effective ways of increasing patient-participants' understanding in the informed consent process. Gillies and Entwistle (2012) speculated that as participants' situations, beliefs, and expectations change during the course of the trial, supportive communication is needed to meet their specific needs. Our study provides support for these ideas and highlights the importance of keeping patients abreast of study changes so they can continue to assess the benefits and burdens of their participation.

As expected, we found significant relationships between trust and all communication measurements for both doctors and nurses. However, there was no significant correlations between the distrust index and communication. The lack of significance could be due to the selection bias that our patients were already enrolled in CCTs. Those who had high levels of distrust could have refused to participate in their CCTs at the beginning. It is interesting to note that the distrust index measured in our study was even not significantly correlated with the single-item trust measure. This is partially due to the fact that the distrust indices in our data were too concentrated in small values: only four participants had a measure of 3 or higher, which is the lowest threshold value for high levels of distrust considered in Corbie-Smith et al. (2002). Moreover, some authors argue that trust and distrust are separate concepts; at times, however, they are also linked (Lewicki 1998). For example, a participant's high trust in a researcher does not necessarily equate to low distrust.

Investigators often feel pressure to meet enrollment goals for the advancement of science. As stated by Albrecht et al. (2003), "For the provider, accruing patients to clinical trials is a communication task comprised of multiple and at times conflicting goals, including: providing the patient with the best care, enrolling patients in studies yet also maintaining a neutral position on the patient's decision for scientific and ethical reasons." (p. 40). Every patient, however, has the ethical right to refuse research participation at any point along the research continuum, and good provider communication skills can help patients assess and reassess their preferences and goals. Indeed, there may be times when participation or continuing participation in research is not the best option for the patient and alternative options should be discussed and offered. Wendler and Rackoff (2002) suggested that investigators should reaffirm study participants' willingness to continue research participation; this is a reflection of respect for persons and offers participants an opportunity to express their questions, concerns, or uncertainties to the research team.

Our findings also support Albrecht et al.'s model of communication in CCTs and the direct relationship between communication and treatment decisions. More research is needed to better understand how characteristics of the communicator as well as the recipient of the communication might affect overall retention in clinical research or other research outcomes. What are the affective qualities that are important to patient-participants and how are they ranked compared with informational knowledge exchange related to the trial? Does the quality and importance of communication exchange and relational aspects differ by the gender, race and ethnicity, or other demographic characteristics of the communicator as well

as the patient-participant? How do emotions and interpersonal attributes affect perceptions of benefits and risks of participating in research? Finally, we need to better understand how the role of complex and mixed emotions in CCTs (for example, a sense of trust of the research team with fear or uncertainty about cancer prognosis and whether the trial will be beneficial) combine to predict decision making related to research participation and retention and other treatment options (Lerner and Tiedens 2006). “Knowing whether a person is fearful, angry, sad, or disgusted (or some combination of these) in a medical context, and understanding judgment and decision-making implications for such emotion states, has tremendous potential to improve outcomes by allowing healthcare providers the potential to tailor discussions about health behaviors, screenings, or treatments based on patients’ emotional state” (Ferrer 2016).

Clinical Implications

Our study shows that CCT patient-participant perceptions of communication with research doctors and nurses during CCTs influence participants’ thoughts about remaining in a trial. We did not study or specifically address the content of those communications, and future research could shed light on the usefulness of communication skills training for research doctors and nurses that enhances their ability to deliver patient-centered communication that involves sharing information, explaining treatment options, and building a trusting relationship. Communication is important in all aspects of clinical trial participation, including recruitment and retention as well, as when patient-participants transition from the trial. Patient-participants and their families rely on clinicians to answer questions, show concern, and address risks and benefits of their trial participation as they make difficult decisions related to their overall cancer care and well-being. This reliance was evident in the relationship between communication and trust. Trust that the researcher knows what is best for the patient was significantly related to all types of communication (i.e., relational, informational, and total communication scores) that we studied. We often assume that seriously ill patient-participants rely on others because of the vulnerability associated with a cancer diagnosis and the decisions that need to be made. Trust is generally earned over time yet it is foundational to the patient-provider relationship. What we do not know from patient-participants, however, is why trust matters to them in their cancer decision-making processes, the important characteristics associated with trust in their research doctor or nurse, or the different types of trust that might be present in clinical research (e.g., informational or knowledge based).

Limitations and future research

Our study was limited by enrollment of participants from a single urban cancer center; therefore, we cannot generalize beyond the sample or geographic region. Future research should examine communication styles of research doctors and nurses in different geographical locations of the country as well as with diverse patient-participant groups. Further psychometric work is also needed on the modified M CCS. In developing the original survey, given the seriously ill population, we were cognizant of burden with the number of items on the scale. Additionally, we did not study physicians’ perceptions of their communication with patients or patients’ perceptions of their self-competence. How physicians and patients perceive they communicate with each other and their degree of

self-competence in doing so in medical or research settings are important areas to explore in future research. For example, do patients perceive that they do a good job of being open and honest with physicians and do physicians perceive that they do a good job of being open and honest with their patients? We did find, however, that with the smaller number of items that we focused on, the validity and reliability estimates remained acceptable for our population. We are currently in the process of further validating the MCCS with a larger sample of CCT patient-participants.

Given the strong correlations between the informational and relational subscales, future psychometric work is now needed to measure the different domains relevant for our population. In addition, we are examining how thoughts about the likelihood of remaining in a CCT influence actual dropout rates. We also need to know more from patients and families about what they perceive to be the “right mix” of interaction with research doctors and nurses, as well as aspects of the CCT that could potentially influence their thoughts about dropping out. This might include the effectiveness of the trial and adverse events, type of changes made to the protocol, and the nature, demands, and length of the trial. Although we specifically asked individual participants to identify their perceptions of communication with their research doctors and nurses, they may not have correctly identified the “research” doctor or nurse. Regardless, participants’ perceptions of the individual they chose to report on has implications for CCT participation. We also need to examine how communication and communication skills training might affect patient-participants’ trust or mistrust in researchers and participation in clinical trials. Our study participants were particularly trustful, as partially indicated by the fact that scores on the distrust index were concentrated in small values: only four participants had a measure as 3 or higher, which is the lowest threshold value for a high level of distrust considered in Corbie-Smith, Thomas, and St. George (2002). Finally, adjusting for any potential clustering within a provider group would be instructive, as it is possible that our findings represent a small group of providers who communicated well with patient-participants in their trials.

Conclusion

Participating in CCTs can create anxiety, stress, and uncertainty for patient-participants. Helping them understand all relevant aspects of the CCT can be challenging depending on the specific components of the CCT and its demands on participants. Showing a caring disposition and communicating with openness, honesty, and transparency are key to mitigating any distress that may ensue and to addressing changing aspects of the CCT that impact retention. Recognizing the influence of communication between patient-participants and investigators and research nurses, we concur with the following statement by Tulskey and colleagues (Tulskey et al. 2017) who proposed a research agenda for communication between health care clinicians and their seriously ill patients: “Improving communication between clinicians and patients living with serious illness can alleviate physical and psychological suffering. There is an urgent need to improve quality of communication in serious illness through a broad range of research that covers communication skills, tools, patient education, and models of care” (p. E5). Strategies that support and value interdisciplinary communication are critical to improving recruitment and retention in CCTs. Patient-participants in our study cited the importance of both informational and relational

patient-physician and patient-nurse communication as central to their trust in researchers and to their research participation. More work is now needed to better understand the importance of communication in CCTs and how different styles of communication affect participants' retention in these trials.

ACKNOWLEDGMENTS:

We thank the participants who were enrolled in CCTs and who thoughtfully gave of their time to help us better understand communication within CCTs.

FUNDING:

This study was supported by the National Institutes of Nursing Research, Grant # 1R21NR010259-01A1. Dr. Ulrich is supported in part by the National Cancer Institute, National Institutes of Health (R01CA196131). Dr. Mao is supported in part by the National Cancer Institute / National Institutes of Health (P30-CA008748).

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Table 1.

Relationship between communication and thought of dropping out and intention to complete the clinical trial

Communication Scores	Dropout thought			Intent to remain in trial till completion
	No (n=85) Mean (SD)	Yes (n=17) Mean (SD)	t statistics, p value	Pearson r, p value
MD Info exchange	4.38 (0.59)	4.04 (0.74)	2.12, p=0.036	0.123, p=0.215
MD relational communication	4.57 (0.52)	4.28 (0.66)	1.98, p=0.051	0.205, p=0.037
MD total communication	4.46 (0.52)	4.14 (0.68)	2.22, p=0.029	0.164, p=0.098
RN Info exchange	4.36 (0.64)	4.40 (0.51)	0.23, p=0.820	0.159, p=0.110
RN relational communication	4.49 (0.69)	4.48 (0.67)	0.04, p=0.970	0.253, p=0.011
RN total communication	4.41(0.63)	4.44 (0.52)	-0.20, p=0.845	0.192, p=0.052

Note: Significant results are bolded.

Table 2.

Communication with research doctor and perception of being informed

	Informed/fully informed Mean (SD)	Not at all to unsure Mean (SD)	t statistics, p value	Cohen's <i>d</i> (effect size)
Communication Total Score				
How well informed when enrolled in treatment clinical trials	4.45 (0.52) n=95	4.06 (0.70) n=11	-2.26, p=0.026	0.63
How well informed at this point of participation	4.45 (0.53) n=96	4.03 (0.62) n=10	-2.36, p=0.020	0.73
How well informed about changes in study	4.48 (0.53) n=82	4.15 (0.57) n=23	-2.55, p=0.012	0.60
Communication Information exchange				
How well informed when enrolled in treatment clinical trials	4.38 (0.58) n=95	3.86 (0.79) n=11	-2.73, p=0.007	0.75
How well informed at this point of participation	4.38 (0.58) n=96	3.77 (0.71) n=10	-3.14, p=0.002	0.94
How well informed about changes in study	4.42 (0.58) n=82	3.98 (0.65) n=23	-3.13, p=0.002	0.71
Relational Communication				
How well informed when enrolled in treatment clinical trials	4.55 (0.53) n=95	4.36 (0.66) n=11	-1.09, p=0.277	0.32
How well informed at this point of participation	4.55 (0.55) n=96	4.42 (0.58) n=10	-0.71, p=0.478	0.23
How well informed about changes in study	4.56 (0.54) n=82	4.41 (0.56) n=23	-1.16, p=0.249	0.27

Note: Cohen's *d* effect size: small=0.2, moderate=0.5, large=0.8

Table 3.

Communication with research nurse and perception of being informed

	Informed/fully informed Mean (SD)	Not at all to unsure Mean (SD)	t statistics, p value	Cohen's <i>d</i> (effect size)
Communication Total Score				
How well informed when enrolled in treatment clinical trials	4.45(0.60) n=95	4.20 (0.63) n=11	-1.34 p=0.183	0.42
How well informed at this point of participation	4.47(0.58) N=96	4.05 (0.74) n=10	-2.11 p=0.038	0.62
How well informed about changes in study	4.48 (0.61) n=82	4.28 (0.51) n=22	-1.44, p=0.154	0.36
Communication Information exchange				
How well informed when enrolled in treatment clinical trials	4.41 (0.60) n=94	4.07 (0.63) n=11	-1.77, p=0.079	0.55
How well informed at this point of participation	4.42 (0.60) n=94	3.96 (0.71) n=11	-2.34, p=0.021	0.70
How well informed about changes in study	4.44 (0.61) n=81	4.22 (0.52) n=22	-1.53, p=0.128	0.39
Relational Communication				
How well informed when enrolled in treatment clinical trials	4.52 (0.66) n=93	4.39 (0.80) n=11	-0.57, p=0.568	0.18
How well informed at this point of participation	4.54 (0.64) n=94	4.20 (0.92) n=10	-1.13, p=0.284	0.43
How well informed about changes in study	4.55 (0.67) n=80	4.38 (0.66) n=22	-1.10, p=0.276	0.26

Note: Cohen's *d* effect size: small=0.2, moderate=0.5, large=0.8

Table 4.

Relationship between communication and trust

	I trust researcher knows what is best for me			Distrust Index
	Strongly disagree to Neither agree nor disagree (n = 29) Mean (SD)	Agree or Strongly agree (n = 76) Mean (SD)	t statistics, p value	Pearson r, p value
MD information exchange	4.05 (0.72)	4.42 (0.55)	-2.86, p = 0.005	-0.098, p = 0.317
MD relational communication	4.18 (0.65)	4.65 (0.45)	-4.17, p < 0.001	0.006, p = 0.950
MD total communication	4.10 (0.64)	4.51 (0.47)	-3.59, p = 0.001	-0.063, p = 0.517
RN information exchange	4.17 (0.69)	4.45 (0.57)	-2.09, p = 0.039	-0.092, p = 0.349
RN relational communication	4.21 (0.91)	4.60 (0.54)	-2.64, p = 0.010	-0.105, p = 0.289
RN total communication	4.18 (0.73)	4.51 (0.53)	-2.58, p = 0.011	-0.092, p = 0.345
Distrust Index	0.66 (0.61)	0.67 (0.99)	-0.58, p = 0.954	

Note: Significant results are bolded.