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Attitudinal barriers to participation in oncology clinical trials: factor analysis and correlates of barriers

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Abstract

Patient participation in cancer clinical trials is low. Little is known about attitudinal barriers to participation, particularly among patients who may be offered a trial during an imminent initial oncology consult. The aims of the present study were to confirm the presence of proposed subscales of a recently developed cancer clinical trial attitudinal barriers measure, describe the most common cancer clinical trials attitudinal barriers, and evaluate socio-demographic, medical and financial factors associated with attitudinal barriers. A total of 1256 patients completed a survey assessing demographic factors, perceived financial burden, prior trial participation and attitudinal barriers to clinical trials participation. Results of a factor analysis did not confirm the presence of the proposed four attitudinal barriers subscale/factors. Rather, a single factor represented the best fit to the data. The most highly-rated barriers were fear of side-effects, worry about health insurance and efficacy concerns. Results suggested that less educated patients, patients with non-metastatic disease, patients with no previous oncology clinical trial participation, and patients reporting greater perceived financial burden from cancer care were associated with higher barriers. These patients may need extra attention in terms of decisional support. Overall, patients with fewer personal resources (education, financial issues) report more attitudinal barriers and should be targeted for additional decisional support.

Keywords

decision support; attitudinal barriers; oncology clinical trials

INTRODUCTION

Cancer is a leading cause of death in the USA, second only to heart disease (Centers for Disease Control and Prevention 2012). The efficacy of new treatments for cancer is typically

tested by conducting clinical trials to evaluate promising new therapies. Despite the fact that clinical guideline development and progress in the treatment of cancer is dependent on the completion of cancer clinical trials, less than half of patients who are offered these trials enrol (Lara *et al*. 2001; Simon *et al*. 2004) and a variety of studies suggest that overall accrual into these trials among all cancer patients in the USA is less than 5% (Murthy *et al*. 2004; Al-Refaie *et al*. 2011). Low accrual rates have a negative impact on the progress of new treatments because they can prolong the duration of trials, delaying the analysis of results, and may lead to early closure of studies.

A voluminous literature evaluates reasons why patients do not enrol in oncology clinical trials. Barriers consist of knowledge and awareness deficits, practical barriers/ protocol requirements, attitudinal factors on the part of patient and medical professionals, as well as institutional barriers (e.g. a lack of clinical trials offered). Physician barriers include time and economic constraints such as low reimbursement from the study sponsor (Kaplan *et al*. 2013), poor impression of the trial's scientific merit (Wright *et al*. 2002) and concern that the patient would not return to their practice if the study were discussed (Kaplan *et al*. 2013). Physicians' perceptions of their patients' barriers including the patient's insurance coverage and protocol non-adherence (Kaplan *et al*. 2013) are important, as well as the perception that the patient may not understand the concept of a clinical trial (Meropol *et al*. 2007).

In the present study, we focused on patient-related factors. A wide variety of patient factors have been identified in the literature (Mills *et al*. 2006; Ford *et al*. 2007). The most commonly cited patient-related barriers are individual characteristics such as cultural background (Wright *et al*. 2002), health literacy, race and ethnicity (Murthy *et al*. 2004), and age (Ford *et al*. 2007), practical barriers such as a lack of knowledge, insurance coverage, time constraints and patient ineligibility (Klabunde *et al*. 1999; Melisko *et al*. 2005). Attitudinal barriers include general factors such as discomfort with research (e.g. fears about randomisation; Comis *et al*. 2003; Meropol *et al*. 2007; Quinn *et al*. 2012) and trial-specific factors such as fear of side-effects (Lara *et al*. 2001; Melisko *et al*. 2005; Meropol *et al*. 2007), sense of personal benefits from the trial (Ellis *et al*. 2001), expectations about the efficacy of standard therapy (Meropol *et al*. 2003; Wright *et al*. 2004), impression of the side-effects (Ellis *et al*. 2001; Wright *et al*. 2004), support for enrollment (Ling *et al*. 2000; Wright *et al*. 2004) and feeling coerced (Fleissig *et al*. 2001).

Despite this extensive literature, attitudinal barriers have not been the primary focus of most studies. In addition, most studies do not use standardised measures and, if they do, they do not examine the psychometric properties of the measures. Most studies also do not evaluate their instrument in a large cohort of oncology patients who are assessed before an initial consultation at a cancer setting where they may be offered an oncology clinical trial. The advantage of assessing patients at this point in time is that the barriers are more likely to be perceived as relevant rather than hypothetical, because they may be offered a trial during the consultation. Finally, few studies have used health belief theories to guide measurement development.

We will briefly review the available barriers measures. Fallowfield *et al*. (1998) developed the Attitudes Towards Randomised Trials scale, which assesses willingness to participate

under different conditions: if the participant was randomised to a treatment arm, if the doctor did not know whether one treatment was better than the other, if plenty of information were provided, and if the participant could leave the study at any time. This measure has not been subject to psychometric evaluation. Sutherland *et al*. (1998) used the Theory of Reasoned Action to develop their behavioural beliefs measure, and the scale was administered to patients with varied forms of cancer who were not going to be approached for a clinical trial in the imminent future. Psychometric properties of the scale were not evaluated. Avis and colleagues (Avis *et al*. 2006) evaluated a measure that included benefits and barriers, but psychometric data were provided. Jacobsen *et al*. (2012) developed a 20-item attitudes scale for their study of a brief multimedia educational intervention for oncology patients who were not offered a clinical trial in the past. The instrument was administered before or after an oncology visit, which was an advantage of this study, and the sample size was relatively large. Psychometric properties of the measure were not reported.

In the present study, our goal was to extend the prior literature on attitudinal barriers to cancer clinical trials by examining an attitudinal barriers measure in a large cohort of patients presenting for an initial consultation at a cancer centre. The measure was partially based on a psychosocial model of health-related behaviour, the Cognitive-Social Health Information Processing Model (C-SHIP), which posits that patients react to health information on both a cognitive and an affective level, particularly when the information may be emotionally threatening and involve medical risks (Miller *et al*. 1996). The C-SHIP proposes that both cognitive (e.g. health values and goals) and affective (e.g. fears and worries) factors influence decision making about cancer treatments (Miller *et al*. 1991, 2005). We identified 48 cognitive and affective barriers as well as known practical barriers to participation in clinical trials based on interviews with patients and oncologists (Meropol *et al*. 2007). Based on this initial study and additional focus group feedback, we developed a shorter measure of attitudinal barriers which we piloted in a small sample of oncology patents (Eads *et al*. 2011). This 28-item attitudinal barriers measure was factor analysed in this pilot sample. The analysis indicated four subscales including an affective factor labelled Fears and Emotions, two cognitive factors labelled Knowledge/Finances and Logistical concerns, and one values factor labelled Mistrust of the medical system (Eads *et al*. 2011).

The present study had three aims. The first aim was to re-evaluate the presence of these four factors with a large sample of oncology patients attending an initial consultation at a cancer centre. We proposed that four factors would be validated in this larger cohort. The second aim was to characterise the most prevalent patient attitudinal barriers. The third aim was to examine demographic and medical factors contributing to attitudinal barriers. Little is known about what characteristics of the patient influence attitudinal barriers to enrolling in oncology clinical trials. Most research has focused on correlates of participation or interest in participation (Ellis *et al*. 2001; Meropol *et al*. 2003; Weinfurt *et al*. 2003; Murthy *et al*. 2004; Lara *et al*. 2005) rather than correlates of attitudinal barriers. Identifying which subgroups of patients report the most barriers or certain types of barriers is important so that these subgroups can be targeted for greater levels of decisional support. Prior studies have suggested that gender, education, race/ethnicity and income may influence perceived attitudinal barriers (Meropol *et al*. 2007; Eads *et al*. 2011). In the present study, we explored

factors not previously examined as correlates of attitudinal barriers, including age, marital status, employment status, hospital site, the perceived degree to which cancer care posed a financial burden, whether the patient had taken part in a prior clinical trial, and the patient's metastatic cancer status. We proposed that greater attitudinal barriers would be endorsed by participants perceiving a greater financial burden for the cancer care and fewer attitudinal barriers would be endorsed by patients who had metastatic disease or had participated in a prior oncology clinical trial.

METHODS

Procedures

The study population of baseline survey data collected from participants in a randomised study of a web-based educational intervention, PRE-ACT: Preparatory Education About Clinical Trials (Meropol *et al*. 2010; Meropol *et al*. 2013; note: the 2013 presentation is available from NM). Site research staff reviewed patient records to ascertain patients who met the eligibility criteria. Before patient contact, consent for patient contact was obtained from the scheduled physician. Eligibility criteria were: age >18 years, cancer diagnosis, scheduled for an initial medical oncologist visit at the study site, high speed (Digital Subscriber Line or cable) internet access at home or at the study site, and able to read English. Potential participants were contacted by telephone by site study personnel and offered participation. A phone script was used to ensure consistency in this process. Participants provided electronic consent before gaining access to the baseline survey to allow participants to complete the survey (thus, written consent was not used). Participants were provided with a toll-free phone number to answer any questions the participant had about the study. This study was approved by the Institutional Review Boards (IRBs) at each site where data were collected. It should be noted that participants were randomised to study condition at the time of providing electronic informed consent. However, participants were not informed of their study assignment until after they completed the baseline survey.

Research staff attempted to contact 6878 patients by telephone to offer study participation. Of these 6878 patients, 3859 patients were reached by phone and 3019 patients could not be reached. Of the 3859 patients who were spoken with on the phone, 1291 patients declined participation, and 2568 patients were interested in the study and provided access to the study's website (which contained the informed consent form). Of the 2568 patients provided access to the study's website, 1256 patients consented and completed the baseline survey. These 1256 participants formed the basis for the study analysis. Overall, the acceptance rate among the 3859 patients who were contacted about the research study was 32.5% (1256/3859).

A comparison of available data (age, site) from the 1256 study participants with the 1312 patients who were provided access to the website but did not provide consent to the study suggested that acceptance rates were significantly lower at two study sites (Cleveland Clinic and Northwestern, 26%) as compared with all other study sites (ranges 31% to 42%) [Chi-square (2) = 54.6, $P < 0.001$].

A comparison on available data from the 1256 study participants with the 1291 patients declining participation suggested that participants were significantly younger [$t(2530) = 12.7$, $M_{participants} = 59.0$ (SD = 11.8), $M_{refusers} = 65.1$ (SD = 12.3)], more likely to be Caucasian [84.3% of participants, 73.7% of refusers, Chi-square (2) = 38.0, $P < 0.001$], and more likely to be married [70.6% of participants, 56% of refusers, Chi-square (2) = 46.3, $P < 0.001$].

Measures

Demographics—Demographics included age, gender, ethnicity, race, education, marital status, employment status and site participant enrolled from.

Diagnosis and treatment history—This information was gathered from medical chart and participants and included cancer metastatic status (yes/ no), financial burden of cancer care (rated on a five-point scale; ratings were: Not a burden, Minor burden, Moderate burden, Major burden, Extreme burden) and previous participation in a clinical trial (yes/ no).

Barriers to participation in clinical trials—We used a 28-item scale based on our previous barriers research, using focus groups, state-wide surveys and literature review (Bevan *et al*. 1993; Daugherty *et al*. 1995; Ratain *et al*. 1997; McCaskill-Stevens *et al*. 1999; Ellis 2000; Crosson *et al*. 2001; Lara *et al*. 2001; Grunfeld *et al*. 2002; Comis *et al*. 2003). This scale has been used in our prior work (Eads *et al*. 2011). Items were rated on a five-point scale (Strongly agree, Agree somewhat, Neither agree nor disagree, Disagree somewhat, Strongly disagree). As noted previously, there were four subscales from the previous study: Knowledge and financial barriers, 5 items (‘I am afraid my health insurance won't pay for a clinical trial’), Logistical barriers, 4 items (‘I wouldn't be willing to travel extra distance to take part in a clinical trial’), Fear/ Emotional barriers, 15 items (e.g. ‘I am afraid of the side-effects I'll have on a clinical trial’), and Mistrust of the medical system and concerns about physician conflict of interest, 4 items (e.g. ‘I don't trust drug companies’).

RESULTS

Descriptive information about the sample

Characteristics of the sample are shown in Table 1. Overall, the sample was relatively well-educated and Caucasian, and approximately half of the sample was working full-time. Approximately 14% of the sample was non-white, 22.3% had less than or equal to a high school education and 13.7% were either not employed or unable to work. Forty-six per cent of the sample had metastatic disease. Approximately 54% of the sample perceived the financial burden of the cost of cancer care to be ‘moderate’ (rating of 3) to ‘extreme’ (rating of 5) (M = 2.6, SD = 1.2, range = 1–5).

Factor analyses of the attitudinal barriers measure

Descriptive information on the barriers measure is shown in Table 2. As a first step, we conducted a confirmatory factor analysis (CFA) using the four original scales as put forth by Eads *et al*. (2011). The CFA for this original solution resulted in very poor fit with $\chi^2(344) =$

3345.62, $P < 0.001$, root mean squared error of approximation (RMSEA) = 0.083, comparative fix index (CFI) = 0.793. Given that Hu and Bentler (1999) suggest that a RMSEA less than 0.06 and a CFI of 0.95 or greater indicates that the model provides a reasonable fit to the data, this CFA suggests that the original four-factor model is not a good fit to the data. Moreover, the correlations between scales in the CFA were very high, with correlations ranging from 0.49 to 0.73 with an average correlation of 0.62.

Based on these results, we conducted a second exploratory factor analysis to determine whether there was a better four-factor solution. An item was considered an indicator of a factor when its loading on that factor was higher than 0.4 and when the item had no other factor loadings higher than 0.4. Table 3 shows the items that loaded on each scale. The factors differed from the original subscales as put forth by Eads *et al*. (2011). The four factors were named General Concerns (11 items), Fears and Worries (9 items), Medical Mistrust (3 items) and Financial Concerns (2 items). Three items from the original 28-item measure did not load on any of the four new scales. We then used CFA to test the adequacy of this new model and unfortunately, the CFA for this new solution also resulted in very poor fit with $\chi^2(269) = 2259.95$, $P < 0.001$, RMSEA = 0.077, CFI = 0.855. Although these indices of model fit suggested that the new four-factor model was a better fit to the data, they were still substantially below accepted standards (Hu & Bentler 1999). In addition, the CFA indicated that four scales correlated strongly with one another with correlations ranging from 0.39 to 0.74 and an average correlation of 0.58. Examination of the scree plot and eigenvalues suggested the possibility of a two-factor solution. The first factor was identical to the General Concerns factor from the four factor solution, and the second factor included all of the items on the Fear and Worries factor along with the item ‘I don't trust the medical system’ and ‘I think clinical trials are best used for people with cancer that can't be treated any other way’. The CFA based on this factor solution yielded poor fit, $\chi^2(208) = 2008.36$, $P < 0.001$, RMSEA = 0.083, CFI = 0.848. These two factors were highly correlated, $r = 0.75$. An examination of the ratio of the first two eigenvalues, 9.144 and 1.436, suggested that the attitudinal barriers scale would be adequately described by a single factor. Therefore, these analyses support a one-factor solution best represents this measure, which we call the Cancer Clinical Trials Barriers Scale, and the factor coefficients for the single factor solution are presented in the final column of Table 3. The Cronbach's alpha for the full scale was 0.92 and the average inter-item correlation was 0.307.

Highest-rated attitudinal barriers

As can be seen in Table 2, the most highly rated barriers of the 28 items, as defined by the barriers for which endorsement scores were one standard deviation above average, were: ‘I'm afraid of the side-effects I'll have on a clinical trial’, ‘I'm afraid that my health insurance won't pay for a clinical trial’, ‘I'm worried that the treatment I'd receive on a clinical trial wouldn't work for me’, and ‘I'm afraid I'll get a sugar pill (placebo) instead of real medicine on a clinical trial’.

Demographic and medical correlates of the cancer clinical trials barriers scale

We evaluated whether there were differences in barriers as a function of the following demographic and medical variables, using univariate analysis: participant age, gender,

employment status, marital status, education, race, site participant enrolled from, the degree to which the patient perceived that cancer care posed a financial burden, whether the participant had taken part in a prior clinical trial, and metastatic cancer status. Results for categorical variables are shown in Table 4. Results for the two continuous variables (age and financial burden of cancer care) are described below. Patient characteristics were associated with attitudinal barriers. Men reported significantly fewer attitudinal barriers than women. Married patients endorsed fewer barriers than non-married patients. There was also an association between education and attitudinal barriers. Participants who had less than a high school education reported significantly greater attitudinal barriers than participants with a college degree or higher. Attitudinal barriers were lower as the education level increased. White participants reported significantly fewer attitudinal barriers than non-whites. Employment status had complex associations with attitudinal barriers. Specifically, patients employed for wages reported significantly more barriers than retired patients and more than patients who were self-employed. Finally, patients who were unable to work reported significantly more barriers than self-employed patients.

Patients who had taken part in a prior clinical trial or had metastatic cancer reported fewer attitudinal barriers. There was no significant association between attitudinal barriers and hospital site. In terms of continuous variables (age, financial burden), there was an association between age and attitudinal barriers. With regard to continuous variables (age and financial burden), older participants reported significantly greater attitudinal barriers ($r = -0.07$, $P < 0.05$), and participants who reported greater financial burdens from cancer care also reported more attitudinal barriers ($r = 0.17$, $P < 0.05$).

Next, the nine factors identified in the univariate analyses as significantly associated with attitudinal barriers (employment, gender, education, marital status, race, prior participation in a clinical trial, metastatic site, age and financial burden) were placed into a multivariate regression. Results are shown in Table 5. Among the nine factors evaluated, education, $b = -1.59$, $t(1086) = 2.89$, $P < 0.01$, metastatic status, $b = -1.28$, $t(1086) = 2.35$, $P = 0.019$, previous oncology clinical trial participation, $b = -4.86$, $t(1086) = 4.59$, $P < 0.001$, and perceived financial burdens from cancer care, $b = 2.33$, $t(1086) = 4.95$, $P < 0.001$, remained significant predictors of barriers. The coefficients suggest that, controlling for the other five variables in the model, patients with a college degree or higher had barriers scores 1.59 points lower than patients with less than a college degree, patients with metastatic cancer had barriers scores 1.28 points lower than those with nonmetastatic cancer, patients who had been in a previous cancer clinical trial had barriers scores 4.86 points lower than those who had not been in a clinical trial, and finally, for each one unit increase in perceived financial burdens from cancer, patients reported 2.33 points increase in barriers.

DISCUSSION

Notwithstanding the role of the physician and availability of trials, decisions about participating in oncology clinical trials are largely made based upon the patient's attitudes. These attitudes have been described in the literature. In a prior study, we developed an instrument to assess attitudinal barriers to enrolment in oncology clinical trials (Meropol *et al*. 2007) and identified four subscales to this measure in a second study (Eads *et al*. 2011).

In the present study, we extended this work to re-evaluate the presence of these scales in a large cohort of oncology patients on their initial consultation at a cancer centre. In contrast to our hypothesis, we were not able to confirm that these factors existed. Rather, all of the attitudinal items loaded on a single scale. Some studies have been able to confirm free-standing subscales for attitudinal barriers measures. For example, Ellis *et al*. (2001) identified four factors from a factor analysis. However, our finding is consistent with other recently developed measures of attitudinal barriers to cancer clinical trials that suggest a single factor (Jacobsen *et al*. 2012). When the attitudes we assessed were examined using sophisticated statistical techniques (model fit indices), patients considered barriers as a whole, rather than in separate categories. This finding is important, because personalised decision support aids must therefore be tailored to address specific barriers to clinical trial participation, rather than in categories of barriers such as ‘medical mistrust’. However, conclusions should be tempered by the fact that our sample was comprised primarily of well-educated, white and relatively young cancer patients. The homogeneous nature of the sample may have biased the results, because barriers such as medical mistrust and logistical concerns may have been less salient for this well-educated, white and relatively young sample. Future studies should evaluate a more heterogeneous sample to examine whether separate factors for barriers emerge.

Our second aim was to examine the most prevalent barriers. The most highly rated barriers, fear of side-effects, fears about insurance coverage, worry about efficacy of treatments offered, and fear of placebos are each commonly cited barriers in the literature. Similarly, Ellis *et al*. (2001) reported that treatment severity and worry about efficacy were the top-rated barriers. Avis and colleagues (Avis *et al*. 2006) found that fear of side-effects and worry about efficacy were the top two rated barriers in their sample of cancer patients, and we also identified fear of side-effects as the top-rated concern for cancer patients considering clinical trials in our prior work (Meropol *et al*. 2007; Eads *et al*. 2011). Because our measure did not contain the same barriers as other measures, it is difficult to make direct comparisons between measures. For example, we did not assess patient's barriers associated with perceptions of their relationship with their treating oncologist or perceptions that the physician should make the decision (Ellis *et al*. 1999), and we did not assess benefits such as altruistic reasons for joining clinical trials or the engenderment of hope for a cure (Meropol *et al*. 2007). Our work suggests that side-effects, perceived treatment efficacy, misconceptions about use of placebos and insurance concerns are important issues to be addressed by decision support interventions as well as by health-care professionals presenting oncology clinical trials to patients.

The third aim was to evaluate demographic and medical correlates of barriers. In univariate analyses, only hospital site was not associated with attitudinal barriers. We also confirmed our previous observation that race is associated with barriers in univariate, but not multivariate analyses (Eads *et al*. 2011). While this finding is consistent with the fact that minorities are under-represented in cancer clinical trials (Rivers *et al*. 2013), it also suggests that other factors associated with race, for example education or socio-economic status, are responsible for this relationship. The fact that older patients reported more barriers is consistent with some studies suggesting that older patients are less likely to enrol in clinical

trials (Kemeny *et al*. 2003). However, the factors contributing to lower enrolment among older patients are more complex and barriers ratings may reflect other known issues in older populations such as medical co-morbidities and physician concerns about using more aggressive or unproven therapies with older patients (Kemeny *et al*. 2003). It is interesting to note that patients who had metastatic disease reported significantly fewer attitudinal barriers than those with earlier stage disease. One likely explanation for this finding is that these patients have fewer standard treatment options available and thus may be more motivated to participate in experimental trials. Finally, the associations between employment status suggested that patients who were employed for wages reported more barriers than retired and self-employed persons. Time flexibility and therefore availability and convenience factors may be less among those patients who worked for wages, thus accounting for higher ratings on the barriers measure. The pattern of significant differences was not entirely consistent. In general, it is possible that employment status is a reflection of both time availability and financial barriers.

Perceived financial burden from the cost of cancer care contributed to greater perceived barriers, and insurance concerns were a highly rated barrier. The financial burdens of clinical trials and cancer care are little-studied but important factor in how patients perceive clinical trials (Virani *et al*. 2011). There may be a significant amount of uncertainty regarding out-of-pocket costs associated with clinical trial participation that is amenable to clarification before patients enrol. Furthermore, there is variability between insurance plans with regard to coverage of clinical trial costs. The Affordable Care Act contains a provision to address this latter concern by mandating the coverage of routine costs associated with clinical trials (Kircher *et al*. 2012). The relationships between employment status and barriers were complex and diffi-cult to interpret. It is possible that employment status was a proxy for both financial and insurance barriers, and should be explored in further research.

When we controlled for all other factors in a multivariate analysis, patients with a college degree or higher, patients with metastatic cancer, patients who had enrolled in prior clinical trials, and patients reporting greater concern about the possible financial burden from cancer care were associated with higher barriers. Thus, these four variables were the strongest correlates of oncology clinical trials barriers.

A key strength of this study was the very large sample of cancer patients studied as well as the fact that data were collected at a key time point for clinical trial decision making – an initial consultation at a cancer centre – making the results particularly relevant. However, the study has several limitations. The fact that the sample was comprised primarily of well-educated, white and relatively young patients may temper our conclusions. However, it should be noted that the sample had a relatively large number of non-white, less educated and un-employed patients, as well as a large number of patients who perceived that cancer care posed a significant financial burden for them. Thus, the sample was sufficiently heterogenous to evaluate demographic correlates of barriers. A second limitation is the cross-sectional design, which precludes conclusions regarding the directionality of effects. A third limitation is the 32.5% acceptance rate into the study, which is relatively low. Given that study participants were significantly younger, more likely to be Caucasian and more

likely to be married than refusers, results are less able to be generalised to older, minority and unmarried cancer patients.

Despite these weaknesses, our findings add to the literature on attitudinal barriers to enrolment in cancer clinical trials using instruments that are based on theory and evaluated in terms of their psychometric properties. Future studies should include a greater proportion of less educated, minority and older patients to determine whether our findings replicate and expand the evaluation of correlates to include other demographic information such as income and other possible medical correlates including time since diagnosis and type of cancer. In terms of clinical implications, our results indicate that patients with less than a college education, patients with nonmetastatic disease, patients with no prior exposure to clinical trials, and patients reporting greater concern about financial burden from cancer care might need extra attention in terms of decisional support. Overall, patients with less practical support (lower education, financial issues) report more attitudinal barriers and should be targeted for additional decisional support. The PRE-ACT study from which this sample is drawn (R01 CA127655; Meropol *et al*. 2013) is comparing educational videos tailored to individual patient barriers versus generic educational text about clinical trials. The results of this study will hopefully shed additional light on which demographic groups benefit most from different types of information delivery and also whether preferences for video or text are associated with specific patient characteristics.

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Table 1

Descriptive information on the study sample

Variable	M (SD)	*n* (%)
Age (years)	58 (11.8)	
Gender		
Female		736 (58.6)
Male		520 (41.4)
Education		
<High school		29 (2.3)
High school		262 (20.9)
Some college		409 (32.6)
College degree		534 (42.5)
Missing		22 (1.8)
Marital status		
Married		880 (70.1)
Divorced/separated		149 (11.9)
Widowed		59 (4.7)
Not married		146 (11.7)
Missing		22 (1.8)
Employment status		
Employed		553 (44.0)
Not employed		70 (5.5)
Homemaker		89 (7.1)
Student		6 (0.5)
Retired		398 (31.7)
Unable to work		116 (9.2)
Missing		24 (1.9)
Race		
Caucasian		1109 (88.3)
Black		116 (9.2)
Asian		17 (1.4)
Native Hawaiian/Pacific Islander		1 (0.1)
American Indian		1 (0.1)
Mixed race		8 (0.6)
Other		4 (1.0)
Metastatic status		
No		621 (49.4)
Yes		530 (42.2)
Missing		105 (8.4)

Table 2

Descriptive information on cancer clinical trials barriers measure using the original factors and 28 items

	M (SD)
Factor 1: Knowledge and Finances (5 items)	
I'm afraid that my health insurance won't pay for a clinical trial.	3.21 (1.2)
I don't know where to find a clinical trial for me.	2.94 (1.2)
I think that clinical trials are best used for people with cancer that can't be treated any other way.	2.83 (1.2)
I'm afraid I would not be able to afford the costs of treatment of treatment on a clinical trial.	2.82 (1.3)
I don't know what clinical trials are.	2.25 (1.2)
Factor 2: Fear and Emotions (14 items)	
I'm afraid of the side-effects I'll have on a clinical trial.	3.39 (1.1)
I'm worried that the treatment I'd receive on a clinical trial wouldn't work for me.	3.11 (1.2)
I'm afraid I'll get a sugar pill (placebo) instead of real medicine on a clinical trial.	3.04 (1.3)
I'm afraid that if I take part in a clinical trial my treatment will be selected at random by a computer rather than by my doctor.	2.87 (1.2)
I'm afraid that taking part in a clinical trial would make me sicker than I am now.	2.80 (1.0)
I don't like to try new treatments until they've been around for awhile.	2.75 (1.2)
I think that being on a clinical trial is dangerous.	2.55 (1.0)
I'm afraid I'll be used as a guinea pig if I'm in a clinical trial.	2.51 (1.2)
I'm worried I'd be treated like a number, not a person, on a clinical trial.	2.40 (1.1)
I'm worried that my family wouldn't want me to go on a clinical trial.	2.32 (1.2)
I'm worried that my medical care wont be as good if I join a clinical trial.	2.31 (1.0)
It would be too upsetting for me to be on a clinical trial.	2.08 (1.0)
I'm too upset now to think about taking part in a clinical trial.	1.96 (1.1)
I wouldn't be able to find transportation to get me to my clinical trial treatment centre.	
Factor 3: Logistics (4 items)	
I wouldn't be willing to travel extra distance to take part in a clinical trial.	2.87 (1.2)
I wouldn't be able to keep up with the clinical trial treatment schedule.	2.27 (1.1)
I wouldn't be able to find transportation to get me to my clinical trial treatment centre.	2.06 (1.1)
I don't have time to take part in a clinical trial.	2.04 (1.0)
Factor 4: Medical Mistrust (5 items)	
I wouldn't ask about clinical trials unless my doctor brought them up first.	2.85 (1.3)
I think clinical trials are best used for people with cancer that can't be treated any other way.	2.83 (1.2)
I don't trust drug companies.	2.68 (1.2)
I don't trust the medical system.	2.03 (1.1)
I don't trust doctors.	1.73 (.93)

Table 3

Pattern matrix coefficients for a revised four factor solution and for a single factor solution

	Four factor				Single factor
	1	2	3	4	
Factor 1: General Concerns (11 items)					
I wouldn't be willing to travel extra distance to take part in a clinical trial.	0.445				0.427
It would be too upsetting for me to be on a clinical trial.	0.572				0.731
I wouldn't be able to find transportation to get me to my clinical trial treatment centre.	0.659				0.530
I wouldn't be able to keep up with the clinical trial treatment schedule.	0.762				0.650
I'm too upset now to think about taking part in a clinical trial.	0.724				0.657
I don't have time to take part in a clinical trial.	0.851				0.654
I wouldn't ask about clinical trials unless my doctor brought them up first.	0.556				0.457
I'm worried that my family wouldn't want me to go on a clinical trial.	0.780				0.667
I'm worried that going on a clinical trial would burden my family.	0.683				0.675
I'm concerned that people other than my doctor would see my personal information if I was on a clinical trial.	0.517				0.597
I don't like to try new treatments until they've been around for a while.	0.543				0.597
Factor 2: Fears and Worries (9 items)					
I think that being on a clinical trial is dangerous.		0.555			0.512
I'm afraid of the side-effects I'll have on a clinical trial.		0.456			0.513
I'm afraid that if I take part in a clinical trial my treatment will be selected at random by a computer rather than by my doctor.		0.596			0.470
I'm afraid I'll get a sugar pill (placebo) instead of real medicine on a clinical trial.		0.706			0.503
I'm afraid that taking part in a clinical trial would make me sicker than I am now.		0.681			0.622
I'm worried that my medical care won't be as good if I join a clinical trial.		0.589			0.715
I'm worried I'd be treated like a number, not a person, on a clinical trial.		0.572			0.718
I'm afraid I'll be used as a guinea pig if I'm in a clinical trial.		0.578			0.745
I'm worried that the treatment I'd receive on a clinical trial wouldn't work for me.		0.570			0.612
Factor 3: Medical Mistrust (3 items)					
I don't trust drug companies.			0.518		0.508
I don't trust doctors.			0.776		0.425
I don't trust the medical system.			0.769		0.529
Factor 4: Financial Concerns (2 items)					
I'm afraid that my health insurance won't pay for a clinical trial.				0.616	0.439
I'm worried that I wouldn't be able to afford the costs of treatment on a clinical trial.				0.518	0.565
Items not included in the revised four-factor solution.					
I think clinical trials are best used for people with cancer that can't be treated any other way.					0.240
I don't know where to find a clinical trial for me.					0.325
I don't know what clinical trials are.					0.444

Table 4

Descriptive information for demographic and medical predictors of barriers

Barriers				
	n	**M (SD)**	***F*(df)**	***t*(df)**
Gender				
Male	499	69.86 (18.26)		$t(1208) = -2.17^{*}$
Female	711	72.18 (18.25)		
Marital status				
Married	861	70.28 (18.17)		$t(1207) = 2.76^{**}$
Not married	348	73.48 (18.33)		
Race				
White	1074	70.81 (18.12)		$t(1208) = 1.98^{*}$
Non-white	182	73.85 (19.09)		
Education status				
Not a high school graduate	27	73.73 (20.89)	$F(3,1205) = 3.78^{**}$	
High school graduate	254	73.71 (18.64)		
Some college/technology school	401	71.99 (17.87)		
College graduate	527	69.28 (18.11)		
Employment status				
Employed for wages	456	$72.97^{a,b}$ (19.24)	$F(7,1200) = 2.10^{*}$	
Self-employed	91	$66.91^{a,c}$ (18.10)		
Out of work >1 year	28	72.64 (17.94)		
Out of work <1 year	41	73.06 (18.02)		
Homemaker	85	71.96 (15.49)		
Student	6	71.67 (16.55)		
Retired	388	69.35^{b} (16.31)		
Unable to work	113	72.45^{c} (15.78)		
Metastatic status				
Yes	512	69.77 (17.17)		$t(1113) = 2.36^{*}$
No	603	72.34 (18.95)		
Prior clinical trial				
Yes	83	61.23 (16.35)		$t(1207) = 5.21^{**}$
No	1126	71.95 (18.21)		
Hospital site				
Fox Chase CC-Temple University	450	71.32 (16.87)	$F(4,1205) = 0.60$, n.s.	
Northwestern University-Lurie CC	17	67.53 (19.79)		
University Hospitals-Seidman CC	359	72.08 (19.69)		
Karmanos CC	194	70.03 (17.82)		
Cleveland Clinic	190	71.22 (18.28)		

Superscripts denote *post-hoc* tests revealed significant differences between the groups. Shared superscripts denote differences between the two groups sharing superscripts. Sample sizes differ from those in Table 1 because not all participants completed the Barriers measure.

CC, Cancer Center.

* $P < 0.05$

** $P < 0.01$.

Table 5

Multiple regression evaluating correlates of cancer clinical trials barriers

Predictor	df numerator	Mean square	*F*
Employment status	7	411.85	1.33
Gender	1	168.48	8.55
Education	1	2574.36	8.34**
Marital status	1	990.38	3.21
Race/ethnicity	1	76.58	0.25
Age	1	3.97	0.01
Previous oncology clinical trial	1	6506.22	21.07**
Metastatic status	1	1698.77	5.50*
Perceived financial burden	1	7554.86	24.47**

df denominator = 1086.

Employment status was categorical with eight categories; Gender code: 1 = men, –1 = women; Education status code: 1 = college graduate or higher, –1 = less than college degree; Marital status code: Married = 1, not married = –1; Race/ethnicity code: White, non-Hispanic = 1, All others = –1; Previous clinical trial participation code: 1 = yes; –1 = no; Metastatic status code: 1 = yes, –1 = no. Higher scores indicate older age and greater financial burden of cancer.

* $P < 0.05$

** $P < 0.01$.