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# Feasibility, acceptability, and effectiveness of a decision aid versus an informational website to promote clinical trial decision-making among cancer patients: A pilot randomized controlled trial

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ABSTRACT

*Objective:* To assess intervention feasibility and acceptability, and compare the effectiveness of the CHOICES Decision Aid (DA) versus the National Cancer Institute (NCI) Cancer Clinical Trials (CCT) website to improve knowledge about CCTs and preparedness to make an informed decision.
*Methods:* Oncology patients ($n$ = 101) with a scheduled clinic visit were enrolled and randomized. Decision-making variables were collected at two timepoints. Post-intervention scores were examined via paired $t$-tests and multivariate regression analyses. Predictors of the magnitudes of the change in scores were examined in multivariable regression analyses.
*Results:* The interventions were feasible to implement and acceptable to participants. Both interventions increased objective and subjective knowledge, improved clarity of opinions, and reduced decisional conflict ($p$-values < 0.01). Improvements in the belief that one could find out about CCTs were observed in the CHOICES DA arm ($p$ < 0.001). Multivariable analyses controlling for educational attainment showed no significant differences in the magnitude of change in outcome variables between intervention arms, but did find that improvements in some variables in the NCI arm – but not CHOICES DA arm – were associated with previous educational attainment.
*Conclusions:* Interventions were feasible to implement and acceptable. Improvements in knowledge and decision-making outcomes were observed in both arms, supporting the view that interventions to improve CCT decision making are effective and feasible. Our results suggest that the CHOICES DA may be more effective than an informational website in improving decision-making outcomes regardless of participants' educational attainment.
*Practice implications:* CCT resources should support informed decision-making among all cancer survivors, regardless of educational attainment.



## 1. Introduction

Interventions to improve decision making about participation in cancer clinical trials – particularly ones developed with minority patient focus and participation – are needed. Although cancer clinical trials (CCTs) have the potential to advance cancer care through improvements in treatment and mortality, only a small percentage of cancer patients participate [1]. Indeed, a recent systematic review and meta-analysis found that only 8.1% of cancer patients participated in CCTs, with higher rates at academic centers compared to community treatment centers (i.e., 15.9% vs. 7.0%, respectively) [2]. Barriers to clinical trial participation include structural, clinical, financial, and practical barriers as well as those related to attitudes, lack of knowledge, mistrust, and navigating uncertainty about CCT participation and outcomes [2,3]. Given the unknowns and uncertainties inherent in CCT participation [3], as well as the fact that there are many unfamiliar and potentially confusing concepts related to CCT participation, it is essential that patients are provided with resources to help facilitate their ability to make an informed decision about whether or not to participate.

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Underrepresentation of racial/ethnic minority patients in CCT enrollment remains a significant concern as participant demographics often do not reflect the cancer burden experienced among various racial/ethnic groups, and thus, CCT findings are not always applicable and cannot be generalized to racial/ethnic minority patients [4–6]. In a telephone survey study conducted among 1100 Black, White, and Hispanic cancer survivors in Florida by our team, only 7.7% reported that they had participated in a CCT, with Hispanic participants being less likely to report participation compared to non-Hispanic White patients [7]. However, 36.5% of the study participants were *willing to participate* in a CCT, with no racial/ethnic differences observed [7].

We used information from that study as well as in-person semi-structured qualitative interviews with racially/ethnically diverse cancer survivors and an iterative process of development and usability testing to develop the CHOICES Decision Aid (DA) [8]. CHOICES DA is a patient-centered, web-based DA which has been tested among cancer survivors [9]. The overarching goal of CHOICES DA is to improve informed decision making about CCTs among newly diagnosed, racially and ethnically diverse cancer patients through increasing knowledge, values clarification, and improving empowerment.

Building upon the prior work [8], the current randomized controlled pilot study was designed to assess intervention implementation feasibility and acceptability, and to compare the preliminary effectiveness of the CHOICES DA versus the National Cancer Institute (NCI)'s CCT informational website in enhancing newly-diagnosed cancer patients' CCT knowledge and preparedness to make informed decisions about CCT participation. We examined potential changes in scores for subjective and objective knowledge and multiple decision-making and cognitive factors (e.g., decision readiness, clarity of opinions, decisional conflict, willingness to participate in a CCT, preparation for decision-making) from initial to second assessment overall and by study arm. In addition, we explored the role of intervention arm in changes in intervention decision-making variables while controlling for educational attainment.

## 2. Methods

### 2.1. Study sample

The University of Miami Institutional Review Board approved the study procedures (20140381) for this pilot 2-arm randomized controlled trial (1:1 allocation) featuring a pre-post longitudinal design. Data were collected at three time points: baseline (pre-intervention), immediately following the intervention, and 2 weeks post intervention. Between the dates of 10/15/2014 and 10/16/2015, newly-diagnosed cancer patients were recruited at the University of Miami Sylvester Comprehensive Cancer Center (SCCC). Recruitment was inclusive of all cancer patients who were: 1) 18 years or older, 2) scheduled for an upcoming visit during which treatment options were likely to be discussed, 3) diagnosed with a type and stage of cancer which matched the eligibility criteria for at least one clinical trial at SCCC open to enrollment during the study period, 4) not currently receiving treatment or pending treatment, 5) English speaking and comfortable having healthcare discussions in English, 6) physically and mentally capable of participating, and 7) willing to participate. Recruitment of minority patients was prioritized, but the participant pool was limited to SCCC patients which had a patient population (2008–2012) of 10.3% Black and 35.7% Hispanic.

Sample size for this pilot RCT was largely dictated by time and funding for participant recruitment. The statistical appropriateness of a sample size of 50 participants per arm was assessed using pre-post data from the previous development and beta-testing CHOICES DA study [8,9]. Specifically, post-hoc power calculations using previous data showed that a sample size of approximately 32 participants in the CHOICES DA arm would provide greater than 90% power to detect significant changes pre-post in the objective knowledge variable as well as several decision preparedness variables. Allocation was 1:1 to the two arms.

### 2.2. Interventions

*CHOICES DA.* Development of the CHOICES DA has been described previously [8]. Briefly, CHOICES DA builds on our Knowledge, Empowerment, Values Clarification (KEV) model for improving patient decision-making [8,10]. The three overarching content domains are: 1) knowledge, 2) empowerment, and 3) values clarification [8]. In addition, patient narratives were featured to illustrate the CCT decision-making process, with accounts of patients who consented to a CCT as well as those who declined CCT participation. The CHOICES DA was designed to be applicable across cancer types and cancer stages as well as trial phases, and was developed on the premise that improving decision-making requires more than just increasing knowledge. In addition to knowledge regarding clinical trials, good decision-making also necessitates consideration of the patient's values and empowering patients to take ownership of their decision-making. Thus, the CHOICES DA has components which explicitly were designed to: 1) provide understandable information to improve patients' knowledge of CCTs; 2) enhance empowerment so that patients are able to find out more about CCT participation, discuss CCT participation with their provider, and as necessary, to ask questions of their provider; and 3) help patients clarify and understand their own values with respect to CCT participation.

#### 2.2.1. NCI CCT website

The NCI website is an online resource which covered multiple CCT-related topics over the course of several webpages. Content included a definition of clinical trials, types of clinical trials, clinical trial phases, randomization, use of placebos, eligibility, potential risks and benefits, costs, and questions to ask one's provider about CCT participation, among other concepts. Thus, the NCI CCT website does provide extensive information on multiple CCT topics. Unlike the CHOICES DA, however, the NCI CCT website was not designed as a decision aid, and thus does not – and cannot be expected to – satisfy the International Patient Decision Aid Standards (IPDAS) gold standard criteria for decision aids [11,12].

### 2.3. Procedures

The study team prospectively identified potential participants through patient records prior to a scheduled appointment. Using information from previous visits and laboratory tests, we sought to identify visits where patients would be likely to discuss treatment options with their provider. Potential participants were approached by a Research Associate (RA) either prior to or following a provider visit. The RA briefly explained the study and asked if the patient was interested in learning more about the study. Patients who agreed were taken into a private room where the study was fully explained, and informed consent obtained for those agreeing to participate. Study activities were completed in accordance with the Declaration of Helsinki. Study flow is outlined in Fig. 1.

Following consent, demographic and contact information were collected for all participants. Next, participants were randomized to review either the CHOICES DA or the NCI website. A computer programmer had developed a randomization sequence (n = 120) using Excel, with no blocking or stratification, to allow for a final sample size of 100 participants after potential dropout. Randomization assignment was linked to the unique login passwords provided to each participant, which were constructed so that the participant was taken to either the CHOICES DA or NCI website after completing the

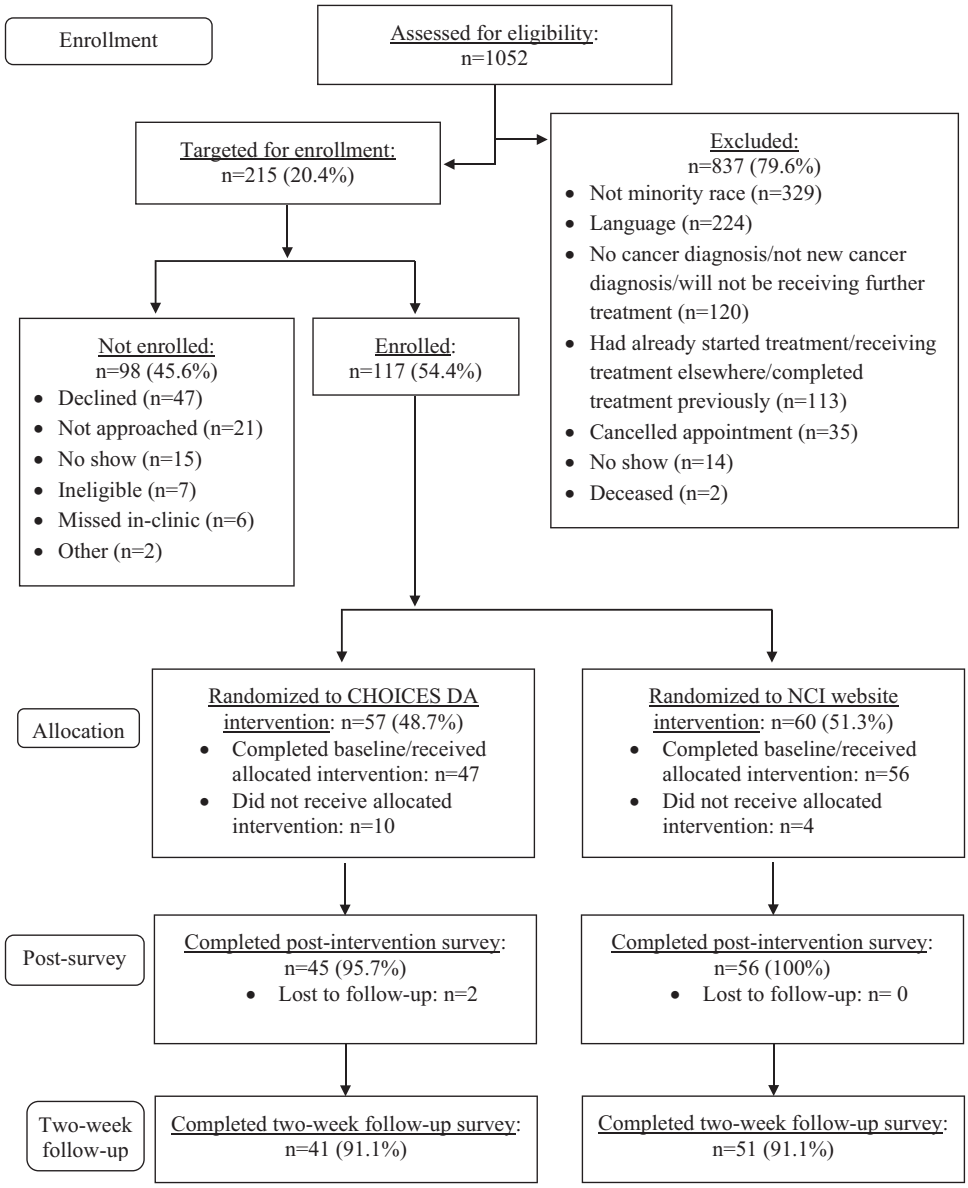


**Fig. 1.** CONSORT diagram.

pre-website viewing survey. Log in information, including password, was provided to participants after enrollment and completion of baseline demographic and contact information.

Upon log-in on the study computer (located in a private room adjacent to the SCCC waiting room), participants completed the baseline (pre-website viewing) survey. After completing baseline, participants were automatically taken to either the CHOICES DA or the NCI website. Participants could spend as much or as little time as desired reviewing the information, and could exit at any time. Upon exiting, a post-survey automatically opened. A 2-week follow-up telephone survey was also conducted. Participants received a $60 gift card following the in-clinic assessment and a $20 gift card via mail following the 2-week follow-up.

## 2.4. Measures

### 2.4.1. Participant characteristics

Sociodemographic characteristics assessed included age, gender, race/ethnicity, educational attainment, insurance status, income, marital/partner status, and cancer type.

### 2.4.2. Decision readiness

Decision readiness was measured with three separate items at baseline and post-survey addressing Decision Preparation, Subjective Knowledge, and Clarity of Opinions [7,13] on a 7-point scale (i.e., 1 = not at all prepared to 7 = completely prepared, 1 = not at all knowledgeable to 7 = completely knowledgeable, and 1 = not at all clear to 7 = completely clear, respectively).

### 2.4.3. Decisional conflict

Decisional conflict was measured with four items during the baseline and post-survey [14]. Response options included: *Yes*, *No*, or *Not sure*. Responses of "No" and "Not sure" were collapsed and coded as 0. "Yes" responses were coded as 1. Higher scores indicate lower decisional conflict. Cronbach's alpha was 0.85 (baseline) and 0.86 (post-survey).

### 2.4.4. Objective knowledge

Objective knowledge about CCTs was measured using eleven items at baseline and post-survey [15]. Response options were: *True*, *False*, or *I don't know*. Incorrect and "I don't know" responses were

collapsed. Correct responses were summed. Higher scores indicate higher levels of knowledge.

*2.4.5. Belief in one's ability to find out more about clinical research*

A six-item scale completed at baseline and post-survey assessed belief about whether one felt that they could successfully obtain more information about clinical research on a five-point scale (from strongly agree to strongly disagree) [16]. Lower scores indicate stronger beliefs in one's ability to find out more. Cronbach's alpha was 0.85 (baseline) and 0.92 (post-survey).

*2.4.6. Willingness to participate*

Willingness to participate in a CCT was assessed at baseline and post-survey with one item [7]. Response options ranged from 1 = extremely unlikely to 7 = extremely likely. Higher scores indicated greater likelihood of participating in a CCT if one was offered.

*2.4.7. Preparation for decision making*

A ten-item scale at post-survey and two week follow-up assessed perception of being prepared to make a decision about whether or not to participate in a CCT based upon interaction with the intervention [17]. Responses ranged from 1 = not at all to 5 = a great deal. Higher scores indicate better preparation for decision-making. Cronbach's alpha was 0.96 (post-survey) and 0.95 (two-week follow-up).

*2.5. Statistical analysis*

First, we summarized demographic characteristics for the entire sample and for each intervention arm. Second, we summarized survey response scores for the overall sample and by intervention arm for each time point. Paired *t*-tests were conducted to assess whether there were significant improvements in outcome measures from one time point to another. Next, we calculated participant-level change variables for all of the outcome measures. Finally, multivariable regression analyses were conducted with the change in outcome variable as the dependent variable, intervention arm as the explanatory variable, and baseline outcome variable and educational attainment as control variables. We controlled for educational attainment as this variable has been positively associated with being approached about a CCT and/or willingness to participate in CCT [18,19]. We also conducted multivariate analyses stratified by intervention arm to explore whether educational attainment had differential effects in the intervention arms. Analyses were conducted using Stata version 13.1 (Statacorp, Houston, Texas) in 2019 and 2020.

## 3. Results

Sociodemographic characteristics of the 103 participants completing baseline are displayed in Table 1. Implementation of the interventions into the clinic was judged feasible and did not disrupt clinic procedures. Of the 215 cancer patients identified as potential participants, 54% (117) were successfully enrolled, 22% (47) declined involvement, and only 3% (7) were found to be ineligible upon further screening (see Fig. 1). In addition, all in-person study steps (of which viewing the intervention websites was only one part) were completed during the clinic visit by 86.3% of the 117 enrolled participants (see Fig. 1). Participants assigned to the CHOICES DA arm spent on average significantly more time in minutes interacting with the website than those assigned to the NCI website arm: 24.1 (SD = 17.2) versus 15.1 (SD = 12.6), *t*-test = 3.047, p < 0.003. Among those completing the interventions, participants were asked if: a) the website was helpful; b) the information on the website was easy to follows; and c) they would recommend the website. On a scale of 1–5 (low to high), both intervention arms had average scores over 4 for all questions, and the CHOICES DA average was significantly higher for question b (4.5 vs 4.1, $p < 0.02$).

**Table 1**
Participant characteristics.

| | Overall (N = 103) | CHOICES DA (n = 47; 45.6%) | NCI Website (n = 56; 54.4%) | *p*-value comparing CHOICES DA vs. NCI website |
|---|---|---|---|---|
| | Number (%) or Mean (SD) | Number (%) or Mean (SD) | Number (%) or Mean (SD) | |
| Age (mean, SD) | 54.1 (13.7) | 54.3 (15.8) | 54.0 (11.8) | 0.91 |
| Female | 60 (58.3) | 24 (51.1) | 36 (64.3) | 0.18 |
| Race/Ethnicity | | | | |
| White (1) | 53 (55.2) | 25 (56.8) | 28 (53.9) | |
| Black (2) | 9 (9.4) | 5 (11.4) | 4 (7.7) | |
| Hispanic (3) | 34 (35.4) | 14 (31.8) | 20 (38.5) | 0.71 |
| Education | | | | |
| HS or less (1) | 15 (14.7) | 8 (17.0) | 7 (12.7) | |
| Some college (2) | 40 (39.2) | 18 (38.3) | 22 (40.0) | |
| 4-year Bachelors (3) | 23 (22.6) | 9 (19.2) | 14 (25.5) | |
| Postgraduate (4) | 24 (23.5) | 12 (25.5) | 12 (21.8) | 0.82 |
| Insurance | | | | |
| Private (1) | 80 (79.2) | 32 (69.6) | 48 (87.3) | |
| Medicaid (2) | 9 (8.9) | 6 (13.0) | 3 (5.5) | |
| Medicare (3) | 12 (11.9) | 8 (17.4) | 4 (7.3) | 0.09 |
| Income | | | | |
| ≤ $40,000 | 17 (20.2) | 6 (15.0) | 11 (25.0) | |
| $40,001–60,000 | 12 (14.3) | 6 (15.0) | 6 (13.6) | |
| $60,001–100,000 | 33 (39.3) | 16 (40.0) | 17 (38.6) | |
| ≥ $100,001 | 22 (26.2) | 12 (30.0) | 10 (22.7) | 0.68 |
| Live with a Partner | 70 (68.0) | 31 (66.0) | 39 (69.6) | 0.69 |
| Cancer type | | | | |
| Breast (1) | 31 (30.1) | 9 (19.2) | 22 (39.3) | |
| GI (2) | 19 (18.5) | 9 (19.2) | 10 (17.9) | |
| Melanoma (3) | 14 (13.6) | 8 (17.0) | 6 (10.7) | |
| Sarcoma (4) | 10 (9.7) | 4 (8.5) | 6 (10.7) | |
| Other (5) | 29 (28.2) | 17 (36.2) | 12 (21.4) | 0.18 |

Note. DA = decision aid; NCI = National Cancer Institute.

Scores on the various CCT decision-making scales (e.g., means, standard deviations) at each time point are displayed in Table 2, overall and by study arm. The following significant changes from pre to post overall were found: 1) increases in subjective and objective knowledge, clarity of opinions, and perceived ability to find out more about CCTs; and 2) decreases in decisional conflict and willingness to participate (all *p*-values < 0.01). In the CHOICES DA arm, mean scores for the following measures changed significantly from pre to post: 1) increases in subjective and objective knowledge, clarity of opinions, and perceived ability to find out more about CCTs; and 2) decreases in decisional conflict (all *p*-values < 0.001). In the NCI website arm, significant changes in the mean scores from pre to post included: 1) increases in subjective and objective knowledge and clarity of opinions; and 2) decreases in decisional conflict and willingness to participate (all *p*-values < 0.01). Therefore, the primary differences between CHOICES DA and NCI website were: 1) belief that one can find out about research studies increased significantly in the CHOICES DA arm ($p < 0.001$) and 2) willingness to participate scores decreased significantly in the NCI website arm ($p = 0.03$). Willingness to participate scores also decreased in the CHOICES DA website arm, but this was not a significant change ($p = 0.22$).

We calculated the magnitude of changes in decision-making scores between pre and post (Table 2), to explore whether there were differences in the arms in the change (data not shown). There were no significant differences in the magnitude of change in the decision-making scores between the intervention arms. However, the magnitude of score changes trended higher in the CHOICES DA intervention participants compared to the NCI website intervention

**Table 2**
Outcome variable scores overall and by intervention arm across the study period.

| | OVERALL | | | CHOICES DA | | | NCI WEBSITE | | |
|---|---|---|---|---|---|---|---|---|---|
| Outcome Variables | Baseline Mean (SD) | Post Mean (SD) | Change *p*-value | Baseline Mean (SD) | Post Mean (SD) | Change *p*-value | Baseline Mean (SD) | Post Mean (SD) | Change *p*-value |
| Perceived Decision Preparedness | 5.05 (1.77) | 5.27 (1.43) | 0.18 | 4.92 (1.83) | 5.29 (1.44) | 0.16 | 5.16 (1.72) | 5.25 (1.43) | 0.65 |
| Subjective Knowledge | 3.54 (1.58) | 4.98 (1.26) | **< 0.0001** | 3.47 (1.57) | 5.09 (1.43) | **< 0.0001** | 3.61 (1.60) | 4.89 (1.11) | **< 0.0001** |
| Clarity of Opinions | 3.97 (1.76) | 5.20 (1.24) | **< 0.0001** | 4.02 (1.78) | 5.18 (1.35) | **< 0.0001** | 3.93 (1.77) | 5.21 (1.16) | **< 0.0001** |
| Decisional Conflict | 1.84 (1.64) | 2.60 (1.60) | **< 0.0001** | 1.55 (1.50) | 2.6 (1.57) | **< 0.001** | 2.06 (1.72) | 2.57 (1.64) | **0.001** |
| Objective Knowledge | 4.60 (1.69) | 5.52 (1.75) | **< 0.0001** | 4.57 (1.77) | 5.79 (1.96) | **< 0.001** | 4.63 (1.65) | 5.29 (1.55) | **< 0.01** |
| Willingness to Participate | 5.30 (1.58) | 4.88 (1.57) | **< 0.01** | 5.23 (1.71) | 4.84 (1.49) | 0.11 | 5.36 (1.47) | 4.91 (1.64) | **0.03** |
| Belief that One can Find Out about Research Studies | 1.80 (0.66) | 1.64 (0.72) | **< 0.01** | 1.78 (0.70) | 1.57 (0.70) | **< 0.001** | 1.80 (0.62) | 1.70 (0.74) | 0.22 |
| ¥¥Preparation for Decision Making | 3.59 (0.97) | 3.60 (1.12) | 0.77 | 3.51 (1.08) | 3.75 (1.23) | 0.31 | 3.69 (0.85) | 3.49 (1.01) | 0.13 |

Note. SD = standard deviation; DA = Decision aid; NCI = National Cancer Institute. For the overall sample analyses, n's range from 92 to 103; for the DA sample analyses, n's range from 41 to 47; for the NCI website sample analyses, n's range from 51 to 56.
¥¥Preparation for Decision Making values were collected at POST and 2 week follow up rather than Baseline and post.

participants on two outcomes: decisional conflict ($p = 0.06$) and preparation for decision making ($p = 0.08$).

Findings from multivariable regression analyses examining change in outcome measures while controlling for educational attainment and baseline scores are shown in Table 3 (Table 3a overall; Table 3b by intervention arm). Baseline score on the outcome variables was a significant predictor of the decision-making outcome change scores overall and by intervention arm for all outcome variables with one exception. In addition, educational attainment was significantly associated with several outcome change measures overall and in the NCI website arm, but not in the CHOICES DA arm.

## 4. Discussion and conclusion

### 4.1. Discussion

The primary aims of the study were to evaluate intervention feasibility and acceptability, and to preliminarily evaluate and compare the effectiveness of the CHOICES DA and the NCI website to improve CCT knowledge and decision-making preparedness.

We found that the interventions were feasible and acceptable. Significant improvements in knowledge and decision preparedness overall and in both arms were found. However, the pilot nature of our study limited our ability to find significant differences between the intervention arms. For example, there were significant improvements in both intervention arms on subjective knowledge and objective knowledge as well as on improved clarity of opinions and decreased decisional conflict.

Although decision preparedness increased overall, stated willingness to participate in a clinical study significantly decreased overall and for participants in the NCI website arm and decreased slightly in the CHOICES DA arm. This is in contrast to previous work which found that decreases in decisional conflict were associated with increased CCT enrollment [20]. However, overall results from CCT interventions have been mixed with regard to changing participants' willingness to participate [21,22]. Although we emphasize that the role of decision aids is to improve decision making, not enrollment, we also believe that reductions in misconceptions and improved decision making will lead to improved retention in clinical trials at the least and may also improve actual (rather than stated willingness) participation in trials.

Findings from multivariable regression analyses examining the effect of intervention arm on the magnitude of change in scores showed that baseline variable score was almost universally a significant predictor overall and in both intervention arms. In contrast, educational attainment was only a significant predictor for the magnitude of change overall and in the NCI website arm, but not in the CHOICES arm. This suggests that the CHOICES DA may be more effective in improving decision-making outcomes regardless of participants' educational attainment.

In comparison to the results found here, a previous RCT [15] conducted at a different large cancer center compared the CHOICES DA to that cancer center's website (which provided information similar to that provided on the NCI CCT website). That study found that CHOICES DA arm participants demonstrated higher knowledge and were significantly more likely to report greater clarity of opinions and less uncertainty about participating in a CCT compared to those in the website arm [15]. However, there were no significant differences between intervention arms in intentions to participate in a CCT [15]. Also, a CHOICES DA targeted to rural cancer patients demonstrated improvements in choice certainty and knowledge, but no significant changes in self-efficacy, attitudes towards CCTs, or willingness to enroll in a CCT [23].

Strengths of the current study include the randomized controlled study design, the enrollment of racially and ethnically diverse cancer patients, and enrollment of newly diagnosed patients who were

**Table 3**
Multivariable analyses of change in outcome scores overall (3a) and stratified by intervention arm (3b). Coefficient (SE).

| **(3a) Overall** | | | | | |
|---|---|---|---|---|---|
| | **Intercept** | **Study Arm[#]** | **Education Level[##]** | | |
| | | **CHOICES DA** | **Some** | **College** | **Grad** |
| Perceived Decision Preparedness | ***-0.56 (0.07)*** | -0.14 (0.24) | 0.67 (0.08) | 0.57 (0.41) | 0.62 (0.41) |
| Subjective Knowledge | ***-0.74 (0.08)*** | -0.24 (0.24) | 0.46 (0.22) | 0.46 (0.40) | **0.87 (0.40)** |
| Clarity of Opinions | ***-0.50 (0.06)*** | 0.11 (0.21) | 0.28 (0.32) | 0.10 (0.35) | 0.53 (0.34) |
| Decisional Conflict | ***-0.42 (0.08)*** | -0.32 (0.27) | 0.64 (0.41) | 0.62 (0.45) | 0.62 (0.44) |
| Objective Knowledge | ***-0.72 (0.11)*** | -0.50 (0.33) | 0.38 (0.51) | 0.71 (0.59) | 0.84 (0.59) |
| Willingness to Participate | ***-0.55 (0.09)*** | 0.05 (0.28) | 0.44 (0.43) | 0.83 (0.47) | **01.05 (0.47)** |
| Belief that One can Find Out about Research Studies | **-0.22 (0.08)** | 0.12 (0.10) | -0.23 (0.16) | -0.28 (0.17) | -0.27 (0.17) |
| [¥¥]Preparation for Decision Making | ***-0.37 (0.11)*** | 0.33 (0.20) | -0.45 (0.31) | -0.28 (0.35) | -0.30 (0.33) |
| **(3b) By Intervention Arm** | | | | | |
| | **CHOICES DA** | | | | **NCI WEBSITE** |
| | **Intercept** | **Education Level[##]** | | | **Intercept** | **Education Level[##]** | | |
| | | **Some** | **College** | **Grad** | | **Some** | **College** | **Grad** |
| Perceived Decision Preparedness | ***-0.60 (0.11)*** | -0.22 (0.58) | -0.41 (0.65) | 0.10 (0.62) | ***-0.55 (0.09)*** | 1.49 (0.48) | 1.43 (0.52) | 1.11 (0.52) |
| Subjective Knowledge | ***-0.65 (0.13)*** | -0.04 (0.60) | 0.24 (0.67) | 0.70 (0.63) | ***-0.80 (0.09)*** | 0.90 (0.46) | 0.70 (0.49) | 1.04 (0.50) |
| Clarity of Opinions | ***-0.54 (0.09)*** | -0.29 (0.49) | -0.11 (0.54) | 0.45 (0.51) | ***-0.66 (0.08)*** | 0.87 (0.42) | 0.48 (0.47) | 0.73 (0.47) |
| Decisional Conflict | ***-0.65 (0.16)*** | 0.13 (0.70) | 0.43 (0.78) | 0.37 (0.74) | ***-0.31 (0.09)*** | 0.75 (0.50) | 0.70 (0.51) | 0.61 (0.51) |
| Objective Knowledge | ***-0.72 (0.18)*** | 0.79 (0.80) | 1.30 (0.96) | 1.20 (0.93) | ***-0.70 (0.14)*** | -0.11 (0.68) | 0.10 (0.77) | 0.38 (0.76) |
| Willingness to Participate | ***-0.67 (0.13)*** | -0.11 (0.63) | 0.26 (0.71) | 0.81 (0.67) | **-0.43 (0.13)** | 0.89 (0.60) | 1.28 (0.65) | 1.20 (0.66) |
| Belief that One can Find Out about Research Studies | -0.13 (0.08) | -0.11 (0.15) | -0.10 (0.17) | -0.05 (0.16) | **-0.29 (0.14)** | -0.35 (0.27) | -0.41 (0.28) | -0.45 (0.29) |
| [¥¥]Preparation for Decision Making | **-0.42 (0.16)** | -0.82 (0.48) | -0.41 (0.54) | -0.61 (0.52) | **-0.37 (0.15)** | -0.10 (0.42) | -0.09 (0.46) | 0.00 (0.45) |

[#]Study Arm reference group was NCI Website
[##]Education Level reference group was High School Education or Less
*Bolded values are significant at < 0.05, Italic-bolded values significant at < 0.001
[¥¥]Preparation for Decision Making values were collected at POST and 2 week follow up rather than Baseline and post.

likely to be making treatment decisions in the near future and who were diagnosed at a stage and disease site appropriate for an ongoing CCT at their treatment location. Also, although the use of decision aids is increasing in many areas of health care, to date there are few studies, and even fewer RCTs, in the area of clinical trials participation decisions. We deliberately chose to use the NCI CCT website as the comparator arm – rather than a "no-intervention" control – since it was developed by experts, and we believed that it would provide more than a "strawman" comparison. We found in this study that a decision aid developed on very different grounds is equally successful in improving knowledge and other measures as a well-established website on clinical trials such as the NCI. Indeed, participants rate the CHOICES DA as significantly better in ease of following the information than the NCI website. In addition, our decision aid includes components for empowerment and values clarification that are not present in the NCI website. Therefore, the fact that our longer and more involved DA is at least as effective in comparative areas, and would be highly recommended overall, is unique data in this area.

Study limitations include that this was a pilot study conducted among English-speaking patients at a single cancer center (potentially limiting generalizability). Although our participant demographics on race and ethnicity matched the SCCC patient population, we were not successful in oversampling Blacks and Hispanics. In addition, the relatively small number of patients diagnosed with the various cancer types (prohibiting us from examining whether there were differences in decision-making scores by cancer type). The CHOICES DA utilized in the current study was in English only, and eligible participants had to be comfortable having health discussions with their provider in English. However, a Spanish-language version of the CHOICES DA is now ready for implementation and assessment. In addition, participant follow up was limited to two weeks, and thus, we were not able to assess actual CCT participation.

A limitation of our survey is that it did not include measures of hope, psychological distress, financial concerns, or other factors that prior studies have suggested may impact clinical trial decision making [24–27]. Finally, the current study was designed as a pilot study to assess the feasibility and acceptability of the interventions, and to examine preliminary efficacy of the CHOICES DA intervention. Although sufficiently powered to detected overall changes in outcomes pre-post within the CHOICES DA group based on our beta testing, it was not powered to detect statistical differences between study arms, nor for differences among racial/ethnic patient groups. Future studies should consider assessing each of these important areas.

### 4.2. Conclusion

The CHOICES DA was designed to improve knowledge and clarification of personal values about the pros and cons of CCT participation and improve feelings of empowerment among racially and ethnically diverse patients. Both the CHOICES DA and NCI CCT website were effective in improving subjective knowledge, objective knowledge, and clarity of opinions and reducing decisional conflict related to CCT participation. Individuals in the CHOICES DA arm also demonstrated significant improvements in the belief that they could find out about research studies. Importantly, educational attainment was a significant predictor of scores for several outcome variables overall and in the NCI website arm, but not the CHOICES DA arm. Although participants in the NCI website arm demonstrated significant decreases in reported willingness to participate in a CCT, we believe that patients who are better prepared for CCT decision-making will at least be more likely to be retained through the duration of a CCT, and maybe more likely actually enroll. Future studies should examine whether this hypothesis is supported in a longitudinal RCT which follows patients through treatment decision-making and the course of treatment. In conclusion, providing cancer patients with the tools they need to make an informed decision about CCT participation should remain a priority, especially in order to increase CCT participation among racially and ethnically diverse patients.

### 4.3. Practice implications

Both online resources included in the current study which provided information about CCT participation have the potential to improve CCT knowledge among newly diagnosed cancer patients. However, decision aids focus on providing an opportunity for values clarification which resources that only provide information do not. Thus, cancer centers might consider use of decision aids to support

patients in the CCT participation decision-making process so that they make both an informed choice and one that takes into consideration their values.

Patient Details Statement: I confirm all patient/personal identifiers have been removed or disguised so the patient/person(s) described are not identifiable and cannot be identified through the details of the story.

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## CRediT authorship contribution statement

All authors confirm that they participated in sufficient aspects of the research and manuscript development to satisfy requirements for authorship. Specifically, acquisition of funding (MMB, ASL), design and conduct of research (MMB, ASL), data analysis and interpretation (MMB, SMC, ASL), drafting and revisions of manuscript (MMB, SMC, ASL).

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