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Short Communication

Improving knowledge and decision readiness to participate in cancer clinical trials: Effects of a plain language decision aid for minority cancer survivors

Aisha Langford[a], Jamie L. Studts[b,c], Margaret M Byrne[d,*]

[a] New York University Grossman School of Medicine, Department of Population Health, New York, NY 10016, United States
[b] Division of Medical Oncology, Department of Medicine, University of Colorado School of Medicine, Aurora, CO 80045, United States
[c] Cancer Prevention and Control Program, University of Colorado Cancer Center, Aurora, CO 80045, United States
[d] Department of Health Outcomes and Behavior, Moffitt Cancer Center, Tampa FL 33612, United States

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ABSTRACT

Objective: To evaluate the impact of a web-based, plain language decision aid (CHOICES DA) on minority cancer survivors' knowledge of cancer clinical trials (CCTs), readiness for making decisions about clinical trial participation, and willingness to participate in a clinical trial.
Methods: Participants were 64 Black and Hispanic cancer survivors from Miami, Florida. In a single arm intervention study, participants completed self-report assessments of CCT knowledge, decision readiness regarding clinical trial participation, and willingness to participate at three time points.
Results: Black and Hispanic participants did not differ on demographic characteristics. Post-test and follow-up measures of CCT knowledge and decision readiness were significantly greater than pre-test measures for the sample overall, and for Black and Hispanic participants separately. Few significant differences were observed between Black and Hispanic participant outcomes at each survey time point, and willingness to participate did not change overall and for either group independently.
Conclusions: Reviewing the CHOICES DA was associated with significantly improved knowledge and decision readiness to participate in a CCT immediately and at 2-week follow-up.
Practical Implications: These findings suggest that CHOICES DA may support informed decision making about CCT participation within an acute, yet clinically relevant window of time for minority cancer patients who are substantially under-represented in cancer research.

1. Introduction

Cancer clinical trials (CCTs) evaluate new methods of preventing, treating, and managing symptoms of cancer [1], and represent a viable treatment alternative for many cancer patients. Estimates of adult participation in cancer clinical trials range from 2% to 8.1 % and racial/ethnic minorities continue to be underrepresented [2]. Low enrollment (for minority and non-minority patients) in CCTs may be mitigated with the use of decision support tools designed specifically for clinical trial decision making, which incorporate health literacy and plain language principles into patient education materials [3].

Decision aids constitute a promising, yet underutilized strategy for increasing knowledge and decision readiness about CCTs [4,5]. In general, decision aids are designed to increase patients' knowledge about health care options and reduce decisional conflict and regret [6]. Although decision aids have generally been shown to be helpful for patients in aggregate [7,8], few studies have examined whether the acceptability, efficacy, or effectiveness of decision aids varies by race/ethnicity [9–11]. To address this gap, we developed CHOICES DA – a plain language, web-based decision aid about CCTs, specifically designed for Black and Hispanic cancer survivors. CHOICES DA was created in both English and Spanish, with the goal of providing Black and Hispanic cancer patients with balanced information about CCTs. In this pilot study, we assess the effects of CHOICES DA on the self-reported

* Corresponding author at: Department of Health Outcomes and Behavior, 12902 Magnolia Drive, MFC-EDU, Moffitt Cancer Center, Tampa, FL 33612, United States.
E-mail address: margaret.byrne@Moffitt.org (M.M. Byrne).

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outcome measures related to participation in CCT, such as objective knowledge, decision readiness, and willingness to participate or recommend participation in a CCT.

2. Methods

2.1. Study sample, recruitment, and procedure

As reported elsewhere [12], Black and Hispanic cancer survivors were recruited from the Miami, FL area. In partnership with several community cancer organizations, recruitment was conducted via flyers distributed in the community and by word of mouth. In the web-based DA, culture was reflected both in text and images, and field testing of materials was done to ensure that materials were well-received by the target audience. The website was designed to minimize complexity but allowed for a high-quality experience for participants with varying levels of computer literacy. Pre-test and post-test assessments happened on the same day (immediately before and after interacting with the website). Two weeks later, participants completed a follow-up telephone survey with the study coordinator. Each participant received a $60 gift certificate upon study completion.

2.2. Measures

We measured effects of CHOICES DA on three categories of outcomes based on measures used in our prior studies [5,13]. Acceptability and utility of the measures were demonstrated during CHOICES DA development.[12] Item wording and response options are listed in Table 1.

2.2.1. CCT knowledge

Objective knowledge of cancer clinical trials was assessed using an 11-item scale used previously to examine CT decision making [14–18]. Analyses examined changes in item-level and total correct scores over time.

2.2.2. Decision readiness

Readiness to make a CCT decision was measured with four items, evaluating perceived preparation, subjective knowledge, information-seeking skills, and decision clarity. Response options ranged from 1 [not at all] to 7 [completely] [19].

2.2.3. Willingness to participate in a clinical trial

Participation willingness was measured with two face valid questions using a 7-point Likert response set, ranging from extremely unlikely [1] to extremely likely [7] used in previous research. Parallel items asked about personal willingness and whether the participant would recommend others consider participating.18

As the primary goal of the CHOICES DA was to improve decision making, we hypothesized that participants would be more knowledgeable about CCTs, more prepared to make CCT decision, and more willing to participate in a future CCT following exposure to CHOICES DA and that these changes would be sustained at two-week follow-up.

2.3. Data analysis

We first calculated summary statistics for participant demographic characteristics and the main outcome measures at each survey time period (overall and by race/ethnicity). To examine differences across the three survey time points, we conducted paired *t*-tests comparing outcomes between: 1) pre-test and post-test and 2) pre-test and follow-up. Finally, we compared outcomes at each survey time point between Black and Hispanic participants using *t*-tests. All analyses were conducted using STATA SE 13.0 and use a $p < .05$ for determining statistical significance.

Table 1
Outcome Measures.

Concept	Item/Instrument	Measurement Scale
Knowledge		
	11-Item Scale	Sum of correct answers
F	Only very sick patients are asked to take part in a cancer research study.	
T	Cancer research studies are the best way to find out whether one treatment is better than another.	
F	Cancer research studies are only offered when the doctor thinks there are no other treatment options for a patient.	
T	A patient can choose to stop being in a cancer research study at any time, even after a patient has signed the consent form and the study has started.	
F	A patient can only be in a research study if his or her doctor recommends it.	
T	A cancer research study could not be offered to a patient unless the new drug has been tested for safety in animals.	
T	Cancer research studies almost never involve the use of a placebo or sugar pill.	
T	Cancer research studies follow strict guidelines that are described in the study protocol.	
F	A patient has to be in a research study if his or her doctor recommends it.	
F	Patients are asked to take part in cancer research studies only when all other treatment options have been exhausted.	
F	A phase III cancer research study focuses on finding the safety of new treatments	
Decision Readiness		
	How prepared do you feel you would be to make a decision about participating in a cancer research study?	1=Not at all prepared 7=Completely prepared
	How would you rate your current knowledge of cancer research studies?	1= Not at all knowledgeable 7=Completely knowledgeable
	How would you rate your ability to seek information about cancer research studies from health care providers or other sources?	1=Not at all able 7=Completely able
	Would you say that your opinions about cancer research studies are clear in your mind?	1=Not at all clear 7=Completely clear
Willingness to Participate		
	In general, if I was making a decision about cancer treatment, I would be willing to participate in a cancer research study if one was available for me and I was offered the chance to participate:	1=Extremely unlikely 7=Extremely likely
	In general, how likely would it be that you would encourage another cancer patient to participate in a cancer research study if one was available to him or her?	1=Extremely unlikely 7=Extremely likely

3. Results

3.1. Demographics

As shown in Table 2, participants were Black (70 %) or Hispanic (30 %), primarily female (92 %), most had private health insurance (59 %), and many had attended at least some college (45 %). The mean age was 56 (SD = 8.7). With regard to cancer diagnosis, breast cancer was the most common cancer represented (81 %), followed by prostate (5%), and lymphoma (3%). All other cancers were collapsed into one group (11 %).

3.2. Knowledge of CCT

With regard to objective CCT knowledge, Table 3 shows results from the 11-item knowledge of CCTs instrument, as measured by total correct responses for participants. Knowledge was significantly higher at both post-test and follow-up for the full sample when compared against the pre-test. These results were consistent for all participants, and for Black and Hispanic participants separately. There were no differences between Black and Hispanic participants in knowledge of CCTs on any of the three surveys.

3.3. Decision readiness

Table 4 shows outcomes related to decision readiness as measured at each time point. Significant increases in decision readiness were found for the whole sample, and for Black and Hispanic participants separately. However, there were fewer significant differences in decision readiness between Blacks and Hispanics at any specific time point. Preparedness for decision making was higher in Blacks than Hispanics at pre-test (P = 0.033) and follow-up (p = 0.028);

3.4. Willingness to participate

Table 5 shows outcomes for participant willingness to join a CCT and their likelihood of recommending participation to a friend of relative. For both of these measures, there were no differences across time, for outcomes overall, or for Black or Hispanic participants separately. There were no significant differences between Blacks and Hispanics at any of the three survey time points.

4. Discussion

We conducted a single-arm intervention trial examining the effects of the CHOICES DA on minority cancer survivors' objective knowledge, decision readiness, and willingness to participate or recommend CCTs. We found that participants' objective knowledge and decision readiness measures improved significantly from baseline when measured immediately after viewing the CHOICES DA and remained significantly different from baseline two weeks later. Thus, the effects of a single viewing of the CHOICES DA improved CCT decision-making measures over a time window that is likely to be relevant for newly diagnosed cancer patients making treatment decisions (i.e., two weeks).

Conversely, we found that there were no significant differences by race/ethnicity in willingness to participate or to recommend participation after respondents viewed the CHOICES DA. However, rather than being a limitation of the CHOICES DA, the lack of an impact is likely due to a ceiling effect, such that the vast majority of the sample were willing to participate in a CCT at baseline. We also found minimal differences by race/ethnicity in response to the information in the CHOICES DA during the development phase and thus, only developed a single version of the English language decision tool. This finding is consistent with a previous study which showed that no differences between White and Black patients in message framing perceptions and willingness to participate in a hypothetical diabetes prevention trial [18]. To date, the literature on minority participation in CCTs has primarily focused on barriers. Only a. few studies have focused on the decision-making *process* for CCT participation among minority cancer survivors, which includes knowledge, readiness, and willingness. Thus, our findings address an important gap in the field of decision science. Moving forward, decision aids like the CHOICES DA may help dispel myths about trial participation, while simultaneously providing minority cancer patients with accurate, digestible health information related to CCTs.

Some challenges to this project should be noted along with its strengths. First, CHOICES DA was a single-arm intervention study that evaluated the effect of a decision aid in a relatively small sample of Black and Hispanic cancer survivors in Miami, Florida. Second, patients considering or receiving active treatment were not included in the study. We made a deliberate decision not to conduct this initial test of CHOICES DA in vulnerable, newly diagnosed cancer patients without a better understanding of its plausible effects. Third, the majority of participants were breast cancer survivors and do not reflect the full range of cancer types. Fourth, we did not ask if survivors had participated in clinical trials in the past or if they had ever been offered a trial. Finally, although CHOICES DA was well-received by cancer survivors and was associated with improved knowledge and decision preparedness, we have not yet evaluated CHOICES DA's

Table 2
Demographics: Overall and by Race/Ethnicity* Mean (SD) and Count (%).

Race/Ethnicity	Overall	Black	Hispanic
Black	45 (70.3 %)		
Hispanic	19 (29.7 %)		
Age	55.0 (10.7)	55.1 (10.9)	54.9 (10.7)
Years since Dx	3.8 (3.1)	3.7 (3.1)	4.0 (3.2)
Female	59 (92.2 %)	42 (93.3 %)	17 (89.5 %)
Breast Cancer	52 (81.3 %)	39 (86.7 %)	13 (68.4 %)
Insurance			
Private	37 (58.7 %)	25 (56.8 %)	12 (63.2 %)
Medicare	14 (22.2 %)	9 (20.5 %)	5 (26.3 %)
Medicaid	7 (11.1 %)	6 (13.6 %)	1 (5.3 %)
Uninsured	5 (7.9 %)	4 (9.1 %)	1 (5.3 %)
Education			
High school or less	11 (17.2 %)	8 (17.8 %)	3 (15.8 %)
Some College	29 (45.3 %)	20 (44.4 %)	9 (47.4 %)
College degree or more	24 (37.5 %)	17 (37.8 %)	7 (36.8 %)

Table 3
Objective Knowledge of Clinical Trials: Comparison among time periods; Overall and for each Race/Ethnicity; p-values indicate significance of differences between the baseline (pre) survey measure, and the post and follow up measures (overall, and separately for Blacks and Hispanics).

Knowledge of Clinical Trials	Overall	Black	Hispanic
Pre	6.97 (1.83)	7.04 (1.82)	6.79 (1.87)
Post	8.79 (1.76); p < 0.0001	8.66 (1.83); p < 0.0001	9.11 (1.57); p = 0.0001
Follow up	9.11 (1.66); p < 0.0001	9.10 (1.81); p < 0.0001	9.14 (1.17); p = 0.0002

* No significant differences in demographic characteristics by Race/Ethnicity.

Table 4
Decision Readiness: Comparison among time periods; Overall and by Race/Ethnicity; 7-point Likert Scale; p-values indicate significance of differences between the baseline (pre) survey measure, and the post and follow up measures (overall, and separately for Blacks and Hispanics).

	Overall (n = 64)	Black (n = 45)	Hispanic (n = 19)
Feel prepared to make decision			
Pre	5.56 (1.62)	5.84 (1.33)	4.89 (2.05)
Post	6.43 (0.72); p = 0.0001	6.53 (0.66); p = 0.0016	6.17 (0.79); p = 0.0228
Follow up	6.40 (0.80); p = 0.0002	6.53 (0.74); p = 0.0002	6.00 (0.88); p = 0.1453
Feel know enough to make a decision			
Pre	4.25 (1.71)	4.49 (1.67)	3.68 (1.70)
Post	6.17 (0.98); p < 0.0001	6.18 (0.94); p < 0.0001	6.17 (1.10); p < 0.0001
Follow up	5.98 (0.92); p < 0.0001	6.14 (0.83); p < 0.0001	5.50 (1.02); p = 0.0110
Feel like they can seek information			
Pre	5.81 (1.41)	5.89 (1.50)	5.63 (1.21)
Post	6.62 (0.75); p < 0.0001	6.69 (0.67); p = 0.0012	6.44 (0.92); p = 0.0069
Follow up	6.63 (0.67); p < 0.0001	6.63 (0.69); p = 0.0012	6.64 (0.63); p = 0.0032
Firm opinion on trials			
Pre	5.26 (1.58)	5.45 (1.52)	4.89 (1.70)
Post	6.56 (0.64); p < 0.0001	6.58 (0.69); p < 0.0001	6.50 (0.51); p = 0.0005
Follow up	6.42 (0.78); p < 0.0001	6.37 (0.85); p = 0.0013	6.57 (0.51); p = 0.0077

Table 5
Willingness to Participate in Clinical Trials: Comparison among time periods; Overall and for each Race/Ethnicity. No significant differences between survey time points, either overall or by race/ethnicity.

	Overall	Black	Hispanic
Willingness to Participate			
Pre	6.08 (1.47)	6.16 (1.35)	5.89 (1.76)
Post	6.23 (1.22)	6.25 (1.04)	6.17 (1.62)
Follow up	6.09 (1.56)	6.16 (1.38)	5.86 (2.07)
Likely to Recommend Participation			
Pre	6.13 (1.43)	6.30 (1.15)	5.74 (1.91)
Post	6.23 (1.51)	6.18 (1.17)	6.33 (1.14)
Follow up	6.25 (1.19)	6.14 (1.20)	6.57 (1.16)

impact on actual enrollment in CCTs that are actively recruiting cancer patients. Future research needs to assess the efficacy and effectiveness of CHOICES DA and other similar instruments in newly diagnosed cancer patients who may be facing an immediate decision about CCT participation.

5. Conclusions

This trial of CHOICES DA was among the first studies to evaluate the impact of a plain language, CCT-focused decision aid developed specifically for Black and Hispanic cancer survivors. Decision aids may hold promise for improving minority readiness to make informed choices about participation in CCTs.

CRediT authorship contribution statement

Aisha Langford: Formal analysis, Methodology, Validation, Writing - original draft, Writing - review & editing. **Jamie L. Studts:** Conceptualization, Investigation, Methodology, Supervision, Validation, Visualization, Writing - review & editing. **Margaret M Byrne:** Conceptualization, Data curation, Formal analysis, Funding acquisition, Investigation, Methodology, Project administration, Supervision, Validation, Visualization, Writing - original draft, Writing - review & editing.

Appendix A. Supplementary data

Supplementary material related to this article can be found, in the online version, at doi:https://doi.org/10.1016/j.pec.2020.07.005.

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