HHS Public Access

Author manuscript

J Cancer Educ. Author manuscript; available in PMC 2020 August 01.

Published in final edited form as:

J Cancer Educ. 2019 August ; 34(4): 803–809. doi:10.1007/s13187-018-1377-x.

Evaluating Adaptation of a Cancer Clinical Trials Decision Aid for Rural Cancer Patients: A Mixed Methods Approach

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Abstract

Purpose: Rural-residing cancer patients often do not participate in clinical trials. Many patients misunderstand cancer clinical trials and their rights as participant. The purpose of this study is to modify a previously developed cancer clinical trials decision aid (DA), incorporating the unique needs of rural populations and test its impact on knowledge and decision outcomes.

Methods: The study was conducted in two phases. Phase I recruited 15 rural-residing cancer survivors in a qualitative usability study. Participants navigated the original DA and provided feedback regarding usability and implementation in rural settings. Phase II recruited 31 newly-diagnosed rural-residing cancer patients. Patients completed a survey before and after using the revised DA, R-CHOICES. Primary outcomes included decisional conflict, decision self-efficacy, knowledge, communication self-efficacy, attitudes towards and willingness to consider joining a trial.

Findings: In Phase I, the DA was viewed positively by rural-residing cancer survivors. Participants provided important feedback about factors rural-residing patients consider when thinking about trial participation. In Phase II, after using R-CHOICES, participants had higher certainty about their choice (mean post-test = 3.10 v. pre-test = 2.67; $P = 0.025$) and higher trial knowledge (mean percent correct at post-test = 73.58 v. pre-test = 57.77; $P < 0.001$). There was no significant change in decision self-efficacy, communication self-efficacy, attitudes towards or willingness to join trials.

Conclusion: The R-CHOICES improved rural-residing patients' knowledge of cancer clinical trials and reduced conflict about making a trial decision. More research is needed on ways to further support decisions about trial participation among this population.

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Disclosures-

Dr Politi has a research contract with Merck Pharmaceuticals unrelated to this manuscript. The other authors have indicated that they have no potential conflict of interest to disclose.

Keywords

decision aid; cancer clinical trial; rural health

BACKGROUND

Cancer clinical trials are essential for practice of evidence-based medicine. They answer specific questions and can lead to novel cancer treatments or help improve and gain more knowledge regarding known treatments or interventions. However, participation rate in cancer clinical trials is low, with only about 2–3% of adult cancer patients choosing to enroll in a trial [1, 2]. Many patients misunderstand the benefits of clinical trials and believe that standard treatment always leads to better outcomes than trials [1, 3, 4]. A recent meta-analysis conducted across three decades worth of studies found that patients continue to misunderstand key trial concepts, such as randomization and placebo use [3]. As many as 25% of participants do not understand their rights as a research participant, such as the right of refusal to participate and the right to withdraw at any time during the trial [5].

Rural-residing cancer patients, in particular, demonstrate even lower rates of clinical trial participation [6]. They may have limited health literacy and struggle to understand trial details [7]. They may face unique barriers to clinical trial participation such as travel time to and from cancer centers, transportation issues, the need to find accommodations near the hospital or cancer center, increased time off work and reduced earnings due to time demands of participating in a clinical trial [8, 9]. Rural-residing cancer patients may also hold long-standing fears and mistrust of physicians and the health care system [9, 10].

Previous interventions have sought to increase patients' knowledge of trials [11, 12] and facilitate informed decision-making [13] through patient decision aids [14]. However, most decision aids pertaining to cancer treatment revolve around helping patients decide between different forms of approved treatments, such as the decision between lumpectomy and mastectomy for breast cancer patients [15, 16] or the decision to use or forgo adjuvant chemotherapy for lymph-node negative breast cancer patients [17]. Alternatively, other cancer-focused decision aids help patients decide on whether or not to undergo cancer screening procedures, such as how to decide between the different types of colorectal screening procedures [18], and about genetic testing for hereditary breast cancer [19]. Only a few of these interventions were specifically tested with rural-residing cancer patients, and few if any focus on cancer clinical trials participation.

Patient decision aids [DAs] can facilitate shared decision making between patients and providers and can be used to support cancer clinical trial decisions [20]. In previous work, colleagues developed the Cancer Research CHOICES DA to facilitate shared decision making for cancer clinical trial decisions in minority populations [3, 13]. The tool was tested in urban cancer centers and improved knowledge, self-efficacy, and preparedness to make a decision about cancer clinical trial participation [3]. The aim of this study was to modify the Cancer Research CHOICES DA and pilot test the revised R-CHOICES for use with rural populations in order to broaden the use and scope of the tool and incorporate unique needs and preferences of rural-residing cancer patients.

METHODS

Decision aid development

The original Cancer Research Choices decision aid (CHOICES) was developed through feedback from semi structured interviews with Black and Hispanic cancer survivors and tested in a randomized trial with 200 participants [3]. The goal of the Cancer Research Choices tool was to educate and empower patients to have informed conversations with their physicians about cancer clinical trials, should the option be presented to them. It also allowed patients to clarify their values and make their decisions accordingly. The current study was conducted in two phases.

Phase I: Usability testing of the Choices Decision Aid among Rural-Residing Cancer Survivors

To modify this tool for rural-residing cancer patients, 15 English-speaking adults were recruited from a Midwestern cancer institute with satellite facilities in both urban and rural settings who met the following inclusion criteria: 1) Diagnosed with cancer within the past three years; 2) had not previously participated in a cancer clinical trial; 3) lived in a zip code with a Rural-Urban Commuting Code (RUCA) greater than or equal to 7.0, indicating their residence in a small rural town; 4) English-speaking; 5) did not have any medical or psychiatric illness that precluded providing informed consent or completing the study questions. The Human Research Protection Office at Washington University approved this phase of the study.

As part of the usability testing of the tool, after completing written informed consent, participants navigated the Cancer Research Choices website in a goal-oriented manner [21]. Individual semi-structured interviews were conducted where each participant was asked to use a “talk aloud” approach as they reviewed the tool page by page [22]. Participants discussed what they liked, disliked, and what they would change about the tool, as well as specific concerns and considerations rural-residing cancer patients have when seeking treatment or considering a cancer clinical trial. All interviews were conducted and audio-recorded by a member of the research team who had been trained in qualitative research methods and usability assessment. Participants received a $10 gift card for their participation.

At the completion of the interview, participants were also asked to complete a brief quantitative survey about their experience using the Cancer Research Choices decision aid, which aimed to measure the tool’s usability. Demographic variables such as age, gender, RUCA code and education level, type of cancer, race, and ethnicity were collected. Quantitative usability of the tool was measured by using items from the System Usability Scale (SUS) [23], the Computer System Usability Questionnaire (CSUQ) [24], and the Ottawa Decision Support Framework Acceptability Questionnaire [25]. Both the SUS and CSUQ measures were scored on a Likert scale, with 1 indicating *strongly disagree* and 5 indicating *strongly agree*. The Ottawa Decision Support Framework Acceptability Questionnaire items asked users to rate the comprehensibility, length, pace, balance of

information, and suitability of a decision aid using qualitative (poor to excellent; yes/no/unsure) descriptors.

Phase I – Data Analysis: Quantitative measures of the tool and participant characteristics were summarized using frequencies and percent distributions or means. SUS scores were converted to a range of 0–100 with scores above 68 considered adequate usability. An SUS score above 68 is considered above average percentile ranking and indicates adequate us ability of the tool. The Acceptability Questionnaire responses were reported descriptively in terms of responding positively or negatively for each item.

The interviews were transcribed, de-identified, and uploaded to QSR N Vivo 11 for coding. A codebook was developed to identify usability themes discussed by the participants. Two reviewers individually coded the first four transcripts, discussed discrepancies in coding, and revised the codebook. Any inconsistent codes (percent agreement less than 95% and/or kappa less than 0.80) were discussed between the reviewers. If consensus could not be reached, the principal investigator resolved the discrepancy. Once the coders reached consensus, they divided the remaining transcripts and coded separately.

Phase II: Pilot testing the modified decision aid among recently diagnosed rural-residing cancer patients

English-speaking adults who were diagnosed with cancer in the past 9 months, had no prior participation in a cancer treatment clinical trial, and who resided in a zip code with a RUCA code greater than or equal to 7.0 were recruited from a different cancer institute in the Midwest with satellite facilities in urban, suburban and rural settings. Eligible patients who agreed to join the study and provided written informed consent were asked to complete a pre-test survey before going through the R-CHOICES DA, and a post-test survey after they had used the tool. Participants were given the option to complete the study in-person at the hospital or at home. They were also given the choice to view the tool in an online format, such as on a tablet or computer screen, in a paper format, or a combination of the two modalities. Participants received a $10 gift card for completing the study. The IRB at Southern Illinois University School of Medicine approved this phase of the study.

Phase II Measures: Demographic variables such as age, gender, cancer type, education level, race, ethnicity, household income, and health literacy (measured using the Single Item Literacy Screener (SILS) [26] were collected from each participant. Our primary outcomes included decisional conflict (higher values indicate more certainty about choice) [27], decision self-efficacy (higher values indicate more confidence in one's decision-making ability) [28], patient communication self-efficacy (higher values indicate more confidence in one's ability to communicate with their provider) [29], knowledge of cancer clinical trials (scored as the percent correct out of the completed questions) [30], attitude toward cancer clinical trials (values 1–3 indicate a positive perception, 4 indicates a neutral perception, and 5–7 indicates a negative perception) [31], and willingness to consider a cancer clinical trial [3]. We also measured participants' decision-making preferences [32].

Phase II Data Analysis: Participant characteristics were summarized using frequencies and percent distributions or means. Pre and post-test descriptive statistics were compared using a paired t-test to determine statistical significance. The significance of $\alpha = 0.05$ was used and all tests performed were two-sided. All not answered/skipped questions were treated as missing. Statistical package SPSS version 25 was used for analyses.

RESULTS

Phase I Results

28 participants were approached, 4 were ineligible, and 15/24 of those eligible agreed to participate (63% response rate). One participant's interview was halted and not analyzed because comorbidities became apparent during the interview that inhibited the participant from properly seeing the computer screen and responding to the interviewer's questions. Our final sample included 14 individuals with an average age of 61.6 years, with 5 different cancer diagnoses represented in the sample. There was an even distribution of gender, age, cancer diagnosis, and education level among the participants (Table 1). While there were only non-Hispanic, Caucasian individuals in this part of the study, this may represent the demographics of the rural zip codes represented.

On the Acceptability Questionnaire, participants responded positively to the website. All (14/14) of the participants agreed that they would find the website useful if they were to consider joining a cancer research study. Most (12/14; 85.7%) felt the length of the website was just right, though two participants (14.3%) felt it was too long. Most (13/14; 92.9%) felt the tool was balanced between participating and not participating in a cancer clinical trial, though one person felt it was slightly slanted towards participating in a cancer clinical trial.

The mean CSUQ score was 4.5, indicating a high mean overall satisfaction with the decision aid. The mean SUS score across all 14 participants was 82.9 (SD= 12.4, range of 60 to 97.5) indicating an above average percentile and adequate usability of the tool.

In qualitative interviews, participants also reported positive impressions of the tool, while providing suggestions for ways to improve it for rural-residing patients:

> "...it's very helpful and...seems to me all the information that is needed to decide "do I want to participate in a study?" Because each person has to decide for themselves and that gives you the deeper information to make that decision."
>
> (P102, female, breast cancer, ≥ 65 yrs.)

> "I think it's very informative...you know, if I hadn't had my doctor already explain some of this ...this would give me a better overview of what was to come. So I do, I think it was good."
>
> (P115, female, ovarian cancer, ≥ 65 yrs.)

Once the data were collected and analyzed, the tool was modified based on participant feedback as well as stakeholder review from the two primary institutions leading the study (WUSM and SIUSM). An eight-page document was compiled with changes to modify the

tool and we worked with our programmer to address this feedback. Examples of participant quotes that helped us modify the tool:

> "Well I guess, one thing that pops into my mind right away is it doesn't say...where it would be located for people like us in rural areas, where we gotta travel to. It's like me coming in here now, it takes me 50 minutes to an hour to get here if there's no problems with traffic. So people wanna know how far they gotta go to do this."
>
> (P112, male, prostate cancer, ≥ 65 yrs.)

Information was added about location and transportation needs, and our values and preferences was modified to better reflect this concern.

> "...it would be helpful to have pages like this that broke down different types of cancers and kind of give people pinpoints. Even if it's other websites that they have found links to take them to, so it was all in one place, easier to find, 'cause when you're told you have cancer and you never would expect it, you're panicked to find information of what to expect..."
>
> (P101, female, cervical cancer, < 65 yrs.)

Information was added about links to information about different cancer types.

Phase II Results

Participants Characteristics—A total of 71 eligible individuals were approached: 41/71 (58% response rate) enrolled (Table 2). The most common reasons for nonparticipation were a lack of interest and/or time, lack of computer/tablet access at home, and/or a feeling that the study seemed too involved in addition to cancer treatment. The final sample of completed data included 31 participants with an average age of 64.6, with 13 different types of cancer diagnosis represented in the sample (Table 2). There was an even distribution of age, education level, and cancer diagnosis among the participants (Table 2). Twenty-nine percent had limited health literacy (Table 2). Most (13/31; 41.9%) participants chose to complete the study procedures via a paper-based modality. The remaining participants (9/31, 29%) chose to complete the online version of the study procedures via tablet or computer, or (9/31, 29%) a hybrid of both paper and online versions (completion of the pre-test survey and R-CHOICES in the clinic via online or paper format and complete the post-test survey via online or paper format at home).

Changes in Confidence in Choice, Knowledge, and Perspectives of Cancer Clinical Trials.—After using the R-CHOICES DA, participants had significantly higher certainty about their choice as measured by the SURE scale for decisional conflict (mean post-test = 3.10 v. pre-test = 2.67; t (29) = −2.359, $P = 0.025$) and higher cancer clinical trials knowledge (mean percent correct at post-test = 73.58 v. pre-test = 57.77; t (30) = −4.149, $P < 0.001$) (Table 3). There were no significant changes in decision self-efficacy, patient communication self-efficacy, attitude and willingness to consider a cancer clinical trial (Table 3).

DISCUSSION

Overall, the study found that rural-residing cancer survivors who participated in qualitative usability assessments viewed a cancer clinical trials decision aid positively. In a pre-post test pilot study, the Rural Cancer Choices (R-CHOICES) DA improved rural-residing patients' knowledge of cancer clinical trials and increased their certainty about making a choice about whether to enroll in a clinical trial or not. The R-CHOICES DA provided accurate information displayed in a way that helped individuals clarify their personal beliefs about participating in a cancer clinical trial. Increasing knowledge and reduced conflict about making a choice could help patients engage in informed conversations about cancer clinical trials with their clinicians.

However, in a pre-post test pilot study, there were no significant changes in participants' confidence making a decision about trials, talking to their providers about trials, their attitudes towards or willingness to participate in a cancer clinical trial. Many had high baseline levels of self-confidence in their ability to make decisions and communicate with their doctors prior to utilizing the R-CHOICES DA. Most participants reported taking an active or shared responsibility decision-making role prior to exposure to the intervention. Many also had positive attitudes towards cancer clinical trials prior to piloting R-CHOICES. Willingness to consider a cancer clinical trial may not have increased because R-CHOICES asks about trials in general, rather than focusing on a specific trial that might be a possible cancer treatment option for them.

Through our mixed-methods study, some barriers to using R-CHOICES were noted which may need to be addressed prior to implementing web-based DAs in general in rural cancer settings. Many rural residing cancer patients have low participation rates in cancer clinical trials due to multiple barriers such as travel time, cost of accommodation, time away from work, mistrust of the healthcare system, lack of understanding, and/or lack interest [8–10]. These challenges also persisted in our study. During recruitment, many patients declined participation in our study due to lack of time/interest, feeling overwhelmed with a new diagnosis and/or treatment decisions. Many participants felt the study procedures, consisting of viewing R-CHOICES and filling out surveys about it, were too involved. This may be a reflection of the participant's stress level at the time of approach. Some participants enrolled in the study, but withdrew. Many who consented were hard to reach to complete procedures after enrollment.

In addition, access to and comfort with the Internet presented challenges to enrollment. Many participants did not complete the study procedures online and preferred paper-based completion of materials. Although we made this option available to our study participants, additional ways to support using R-CHOICES or other web-based tools like it may need to be considered in rural settings such as incorporating it into routine clinic visits. A paper-based tool that is completed with clinical staff whom the patient trusts could be a better approach to attaining higher engagement levels with web-based tools.

Throughout recruitment, study staff observed that defining rural population based on RUCA codes was not accurately capturing all rural communities. RUCA codes might not be the best

way to assess rural residence although it is the most widely used criteria. The U.S Census Bureau and U.S. Office of Management and Budget (OMB) might provide broader definitions of rural which may be more applicable than RUCA codes [33].

Strengths of this study include a decision support tool that is specifically targeted to rural-residing individuals, the use of International Patient Decision Aids Standards guidelines and the Knowledge, Empowerment, Values Clarity framework for decision tool development [3], and the use of multiple facilities serving many communities to conduct this study. Limitations include a small sample size due to accrual difficulties, with mostly White, non-Hispanic participants. Due to our small sample size, we were unable to control for variables such as age or health literacy at the multivariate level. We were also unable to explore whether time since diagnosis may have affected our enrollment rates. Since a pre-post within-subjects design was conducted rather than a randomized trial, results should be interpreted as demonstrating the preliminary efficacy of the tool.

Future larger studies (e.g., prospective randomized controlled trials) can be done comparing the use of R-CHOICES DA to usual care counseling by providers. Future studies can also explore the use of R-CHOICES in various modalities (e.g., on paper, electronically, with or without using it with a trusted member of the care team). More research is needed on ways to further support decision making and empowerment to increase engagement and participation of rural population in clinical trials.

Acknowledgments-

Dr Margaret Byrne, PhD, Moffit Cancer Center

Rebecca Wolf, RN, BSN

Nageen Mir, MPH

Ali Davis, RN, BSN

Funding sources-

All phases of this study were supported by P20 grant: Addressing Rural Cancer Health Disparities: A SCCSIUSM Partnership. Grant number: 5P20CA192987–02.

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Table 1.

Phase I participant demographics (n=14)

Age, mean (range)	61.6 (30–73)
< 65 years, n (%)	6 (42.9%)
≥ 65 years, n (%)	8 (57.1%)
RUCA Code, mean (range)	7.6 (7–10.2)
Gender, n (%)	
Male	6 (42.9%)
Female	8 (57.1%)
Education level, n (%)	
Some high school	2 (14.3%)
High school diploma or GED	3 (21.4%)
Some college	3 (21.4%)
College degree	3 (21.4%)
Graduate or professional degree	3 (21.4%)
Type of cancer, n (%)	
Breast	3 (21.4%)
Cervical	1 (7.1%)
Endometrial	2 (14.3%)
Ovarian	2 (14.3%)
Prostate	6 (42.9%)
Race, n (%)	
Caucasian only	14 (100%)
Hispanic ethnicity: No, n (%)	14 (100%)

Table 2.
Phase II participant demographics (n=31)

Age, mean (range)	64.6 (44–83)
<65 years, n (%)	17 (54.8%)
≥ 65 years, n (%)	14 (45.2%)
Gender, n (%)	
Male	11 (35.5%)
Female	20 (64.5%)
Education level, n (%)	
Some high school	1 (3.2%)
High school diploma or GED	15 (48.4%)
Tech. Training or Certification	3 (9.7%)
Some college	6 (19.4%)
College degree or higher	6 (19.4%)
Type of cancer, n (%) *	
Bladder	1 (3.2%)
Breast	5 (16.1%)
Colorectal	3 (9.7%)
Gynecologic	10 (32.3%)
Head or Neck	5 (16.1%)
Liver	1 (3.2%)
Lung	1 (3.2%)
Lymphoma	1 (3.2%)
Melanoma	1 (3.2%)
Pancreatic	2 (6.4%)
Prostate	1 (3.2%)
Renal	2 (6.4%)
Skin	1 (3.2%)
Health Literacy	
Limited	9 (29%)
Adequate	22 (71%)
Race, n (%)	
Caucasian only	31 (100%)
Hispanic ethnicity: No, n (%)	31 (100%)

* = The percentages for cancer types will not add up to 100% due to some patients having more than one cancer type

Table 3.
Phase II –Bivariate Analysis of the Primary Outcomes

	Pre-test	Post-test	T	P-value
Decisional conflict (SURE)[1] **(n=30)**				
Mean (SD)	2.67 (1.40)	3.10 (1.35)	−2.359	0.025
Range	0–4	0–4		
Decision Self-efficacy (n=30)				
Mean (SD)	84.09 (19.61)	84.39 (23.04)	−0.104	0.918
Range (possible range 0–100)	18–100	18–100		
Patient Communication Self-efficacy (n=31)				
Mean (SD)	5.48 (1.03)	5.29 (1.40)	1.184	0.246
Range	2–6	1–6		
Knowledge of CCT (% correct out of completed)				
Mean (SD)	57.77 (19.85)	73.58 (17.59)	−4.149	<0.001
Range	0–100	0–100		
Perceptions towards CCT (n=31)[2]				
Mean (SD)	21.16 (8.99)	23.58 (11.19)	−1.359	0.184
Range (possible range 10–70)	10–46	10–50		
Willingness to consider a CCT (n=31)				
Mean (SD)	3.90 (0.87)	3.74 (0.97)	1.153	0.258
Range	1–5	1–5		

1. High SURE values indicate more confidence in choice.

2. Values 30 or below indicate a positive perception and above 30 indicates a negative perception towards CCT.