FOX CHASE CANCER CENTER
TEMPLE HEALTH

Protocol Title

mychoice: Testing an interactive mHealth tool to enhance communication and informed decision making about clinical trial participation in cancer patients

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1.0 Introduction

- Evidence shows that although clinical trials are aimed at producing new strategies for reducing cancer morbidity and mortality, participation remains suboptimal for all populations, especially those from racial and ethnic groups [1-3]. Although some interventions have been found to be effective at enhancing participation, few studies have tested tailored communication activities using innovative communication techniques (perceptual mapping) with aims to address barriers and facilitators for patients and facilitate more engaged discussions with their providers in real world settings. We therefore aim to fill that gap by testing a culturally diverse and patient guided mHealth decision tool called ***mychoice***, which allows patients to explore their concerns and questions related to clinical trial participation, as well as create a customized and personalized set of questions to enhance patient-provider communication and increase informed decision making. This study employs a mixed-methods approach using both qualitative and quantitative data to evaluate the effectiveness of the ***mychoice*** intervention for patients and to explore the provider and organizational factors that impact implementation. A randomized controlled trial will be performed with 270 participants in order to determine the acceptability and feasibility of the intervention, as well as its effects on self-efficacy in discussing clinical trial participation with providers, leading to enhanced informed decision-making. Results will also investigate whether the tool has enhanced effects on minority patients, particularly African Americans. A secondary aim of the study is to evaluate the implementation of the intervention in clinical settings. Implementation evaluation will occur using surveys of medical staff whose patients are participating in the study. These surveys will assess institutional facilitators and barriers to study implementation. We will also conduct cognitive de-briefing interviews after the intervention is completed with key stakeholders at the participating institutions, which will inform a larger implementation study in the future.

2.0 Objectives

- The ***primary objective*** of the study is to assess the effectiveness of the ***mychoice*** mHealth tool on perceived patient self-efficacy and decisional conflict, and whether these results are enhanced in minority patients.

- The ***secondary objective*** of the study is to describe the acceptability and feasibility of implementing ***mychoice*** in oncology services at three leading cancer centers in Philadelphia.

- **Purpose of the study**: ***mychoice*** was conceptualized and developed with a Fox Chase-Temple NODAL grant, using extensive formative research, including the use of commercial marketing techniques (perceptual mapping and vector modeling) and

patient engagement, and customized to address the significant barriers for African American patients to consider clinical trials. The tool went through user testing and received excellent reviews, and now is ready for an efficacy test. This study represents the next step in personalized clinical trial education research. It completes the ***mychoice*** communication tool to make it multi-cultural and thus appropriate for all patients, and tests its effectiveness with diverse cancer patients to improve knowledge and preparation to discuss clinical trials within real world settings. We will also explore organizational factors that impact implementation of a technology-based intervention, an innovative aspect that will provide critical understanding on feasibility to ensure scalability in a large medical setting. Results could inform how a tool like ***mychoice*** could be implemented in a cancer center and enhance communication about clinical trials between patients and doctors.

- **Specific Aims**:
  - **AIM 1**: Test the perceived usefulness and effectiveness of ***mychoice*** to increase patients' self-efficacy and decrease decisional conflict.
  - **AIM 2**: Describe the acceptability and feasibility of implementing ***mychoice*** in oncology services at three leading cancer centers in Philadelphia by identifying provider and organizational factors influencing its integration in the clinical space.

- The following **hypotheses** are proposed for Specific Aim 1:
  - ***H1***: Compared to a non-tailored education aid, ***mychoice*** will improve self-efficacy in making a decision about participating in clinical trials for all patients as well as a subsample of underrepresented patients (non-white).
  - ***H2:*** Compared to a non-tailored education aid, ***mychoice*** will reduce decisional conflict about clinical trial participation for all patients, as well as a subsample of underrepresented patients (non-white).

3.0 Background/Rationale

- **Background**: Evidence shows that ethnic and racial minorities are significantly underrepresented in clinical trials, which are critical to producing new strategies for reducing cancer morbidity and mortality for all populations [4-22]. Recognizing the complexity of barriers to participation in clinical trials, research has focused on potential strategies to enhance participation. Interventions have shown that provider referrals of minority patients, community outreach, acknowledging and addressing issues of trust, flexibility in intervention methods, and population targeted materials are effective [23-26]. Few studies, however, have tested tailored communication activities to address barriers and facilitators for patients using innovative communication techniques in real world settings – meaning ways these

activities can be integrated into the healthcare workflow - or addressed the unique needs of racial and ethnic minorities.

The ***mychoice*** communication tool begins to prepare patients to participate in a personal and tailored discussion with their provider about clinical trials as a potential treatment option. It is also customized to address the concerns of those least likely to participate, instead of providing a more general look at clinical trials- a common trait of other available tools. Previous research has shown that patient education before the first oncologist visit improves knowledge, attitudes, and preparation for decision making about clinical trials [27] and integrating these tools into the clinical encounter is critical. In addition, using innovative communication techniques (perceptual mapping and vector modeling) to validate and explore salient messages across diverse cancer patients provided new insights into tailoring messages and personalizing patient/provider communication. Insight gained from validation of the intervention will improve the decision making process, and inform a large scale integration of ***mychoice*** to affect patient perceptions and increase willingness to participate in clinical trials, especially in minority patients.

In addition, we will assess barriers to implementation when introducing the tool in diverse cancer centers, each with different protocols and patient populations, to inform a future proposal. Using the Consolidated Framework for Implementation Science (CFIR), one of the predominant implementation science research frameworks, we will focus on five domains: intervention characteristics, outer settings, inner setting, characteristics of individuals (patients and providers), and process [28]. Implementation science is becoming an important component of intervention implementation and we aim to use this framework to ensure success.

- **Preliminary Data**: To address the issue of clinical trial participation, we developed ***mychoice (IRB #14-811)*** to target unique barriers of underrepresented populations and prepare them for a discussion about clinical trials with their providers [29-38]. The intervention was developed with stakeholder (both patients and providers) involvement and includes real life stories of cancer patients. The intervention, initially focused on African American cancer patients, was based on mixed-methods formative research including in-depth interviews (Phase I), a survey of African American cancer patients using perceptual mapping and vector modeling to guide the development of the communication messages within the intervention (Phase 2), and message and user testing of the mHealth tool with African American cancer patients who had never participated in clinical trials (Phase 3).

  In Phase 1 we conducted in-depth interviews with 16 African American cancer patients. Investigators reviewed and developed themes/subthemes, which resulted in eight themes: knowledge, benefits, disadvantages, social support, decision influencers, provider beliefs, personal history, and value of clinical trials. Results from these interviews were used, along with a thorough literature

review, to inform the development of a quantitative survey that was used in Phase 2.

Phase 2 was completed with 41 African American adult cancer patients, just over half (53.7%) of whom indicated they had never participated in a clinical trial. Surveys occurred either in person or over the phone and participants were asked to report how much they agreed or disagreed on a 0-10 scale (0=strongly disagree, 10=strongly agree) with statements regarding clinical trials' helpfulness, benefits, barriers, value, support from those around them, and beliefs about healthcare providers. T-tests revealed significant perceptual differences between individuals who had participated in a clinical trial and those who had not. Based on the perceptual maps that were generated, the research team developed message strategies to address those issues found to be important in the maps**.**

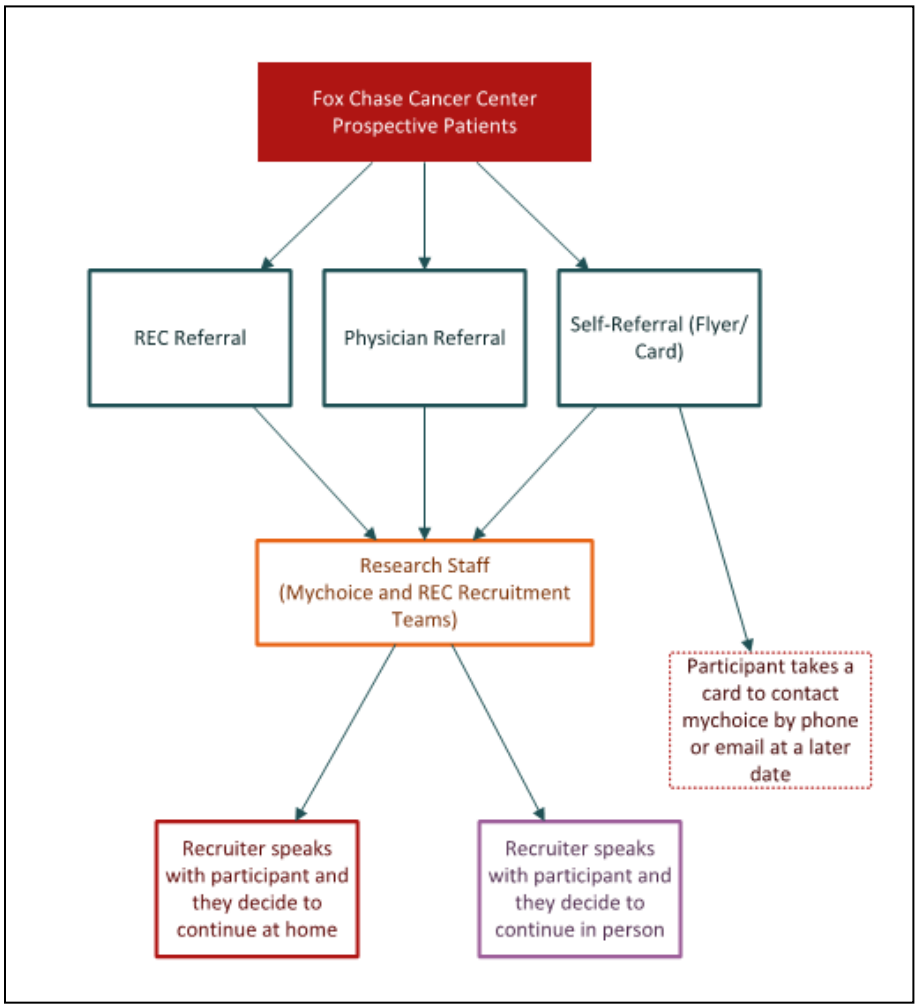
The resulting ***mychoice*** mHealth prototype was then developed, working with an app development company and in consultation with our research staff and oncologists. This iterative process included many changes to content, visuals and narrative. In addition, since patient-provider communication and informed decision making was a main theme, we chose to make the mHealth tool interactive to provide patients with an easy way to ask providers questions that were tailored to their interests. The tool combines text, animation, and videos of real patients discussing the identified themes. User testing of the ***mychoice*** prototype showed that the communication tool was easy to use and understand and was perceived to be very helpful in preparing patients to discuss clinical trials. Feedback from the user testing with predominately African American patients indicated that the patient videos should be more diverse showing a broad representation of races and ethnicities. In addition, a more culturally diverse, rather than a targeted intervention for only African Americans, would be more representative of real world settings. Therefore, the patient videos are being expanded for the current version.

- **Significance**: Participation in clinical trials is a serious and complex decision, and many patients of all races and backgrounds have limited knowledge and understanding of clinical trials as a treatment option. Although much research has been conducted to explore the barriers to participation, there has been a call for more intervention research to address these barriers [39]. A fundamental aspect of patient focused interventions is an exploration of their personal questions and concerns, without which it is difficult for patients to become empowered to participate in an informed or shared decision making process. However, there remains limited empirical research to suggest which messages are most salient to a diverse range of patients to improve decision making, and how decision tools can be tailored to enhance the patient-provider communication dyad. This research will provide insight into that process when the decision is participation in clinical trials.

4.0 Study Design

a) Recruitment methods

- We will recruit a total of 270 patients (~~100~~ 130 at FCCC via the medical oncology, radiation oncology, and surgery units and 100 at TUHS via the cancer center). The remaining 40 ~~70~~ patients will be recruited at Thomas Jefferson University Hospital and The University of Pennsylvania We anticipate that approximately 20% of the participant pool will be non-white which should provide sufficient number to perform sub-analyses of effects. We will monitor this during recruitment, however, and if we find that we are not reaching this number of non-white participants, we will change the protocol to focus on recruiting only non-white participants.
- There are three ways that patients will be recruited for the study at FCCC. This is shown in Figure 1.



- (1) First, at FCCC, Dr. Fleisher will collaborate with FCCC oncologists to identify patients who might be offered a clinical trial but who have not participated in a clinical trial previously. A patient information card and a flyer have been developed for oncologists to provide to patients (see

Appendices A and B). Oncologists will suggest the study to patients at regular visits and be instructed to either go to the Resource and Education Center at Fox Chase, or find a study representative in the waiting area at a table who is wearing a mychoice pin. Mychoice study staff will be in the waiting areas of participating oncologists on days/times that are busiest. If staff are not available that day, they can go to the REC. If the patient approaches a study staff, they will meet the patient in a designated private space, consent them, and give them the option of doing the study then on either a provided iPad or go to the REC to do the study on a computer.

- (2) Study staff will also be available in the common areas of FCCC at a table. Patients can come up to the table and ask about the study. We will also have a small "wheel" that is a game that patients can play to win small prizes (candy, umbrella, $5 gift cards). All patients who come up to the table can play and win a small prize; there is no requirement to enroll in the study to play. If they are interested in the study, we will provide an information card and answer any questions they have. They can then complete consent and do the study then (as above) or have the option to complete the study at home.
- (3) Another way for patients to participate is through a referral by REC staff. When patients go to the REC, staff will provide information to the patients about the study. If they are interested, REC staff will go through the above steps to consent a patient and provide them an iPad or computer to complete the study.
- (3) The last way for patients to participate will be by self-referral. Cards and posters will be available throughout the waiting areas. On this card are the study email and phone number. Patients could use these to contact study staff who will explain the study and verbally consent people over the phone and then provide the option to come to do the study at home or at the REC. Because this consent is occurring over the phone, staff will use a script (provided) to explain the study and screen for eligibility. A waiver of document of consent has been provided to assist with this process. After they have verbally been consented for the study, they will be sent a link to the study through the RedCAP system and provided information on how to complete the study. They will be directed to review the study consent and indicate their willingness to participate by entering their name as an e-signature. They then will be asked to do the same with the HIPAA waiver. Once they agree, they will be directed to the baseline survey.
- Patients recruited at TUH, Jefferson, and HUP will follow the same recruitment strategies, but will only be recruited by Physician Referral and Self-Referral. There are no REC staff at these institutions, so recruitment strategies will rely solely on study staff and physicians. Study staff will be in the waiting rooms prepared for any referrals during busy clinic days.

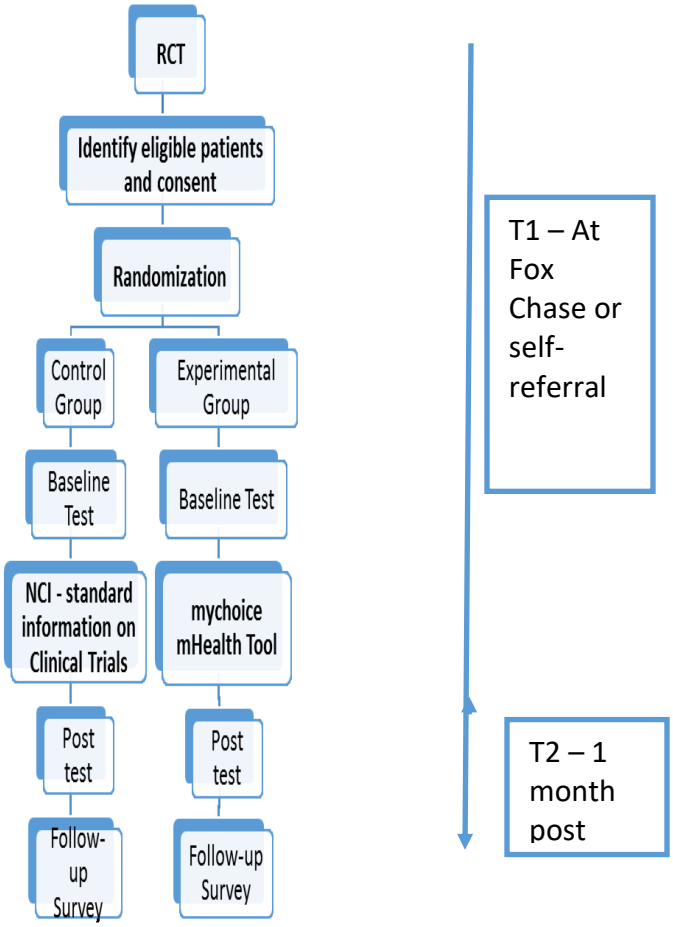
- All study materials, including the pre and posttest and the patient education materials, are programmed in REDCap. If completing the study in person, once the patient agrees to be in the study and is set up in the RedCAP system, study staff will explain this process and have them sign in the REDCap system to indicate they agree to participate (script for staff to follow in Appendix C) and to the HIPAA waiver. Study assignment will be random and programmed into the system
- The email link will provide a contact name, phone number, and email should the participant have any questions or concerns. If they choose to come to the REC because they do not want to do the study at home, we will make an appointment with them to meet them at a designated day/time.
- The REDCap link will include pre/post-tests (Appendices D and E) for all patients, and the appropriate patient education materials based on randomization. (**Note:** Baseline surveys take approximately 15 minutes and post-test surveys take approximately 5 minutes, based on testing.) The pre and posttests as well as the consent form will be integrated into the materials through REDCap. All patients will then be contacted by telephone or email one month post consult by the research staff to conduct a follow-up survey (Appendix F – Treatment Arm; Appendix G – Control Arm). In some cases (i.e. at TUH) follow-ups will be done in person when the patient has returned for an appointment.
- The experimental condition will receive the ***mychoice*** mHealth Tool (Screen shots (http://mychoice.sandstorm.notss.com) of the tool are provided in Appendix G.) The entire tool is available at the URL. The control condition will receive the NCI material on clinical trials: Taking Part in Cancer Treatment Research Studies (https://www.cancer.gov/publications/patient-education/CRS.pdf). Both will be provided on the device through the RedCAP system. Participants in the experimental condition will receive a pair of ear buds (which they can keep) to listen to audio/video segments and will receive a printed version of the questions they identify as important to them.
- Patient participants will receive a total of $50 compensation, provided as a $25 gift card at initial testing and an additional $25 upon follow-up survey. These will be provided in person if they choose to complete the study in person or via mail if they choose to complete the study at home. Recruiters and physicians interviewed about implementation will not receive compensation.

b) Inclusion and exclusion criteria

- **Eligibility criteria for participation in the RCT are:** 1. 18 years of age or over; 2. Active diagnosis of invasive cancer (any diagnoses); pre or post chemo/radiation/surgery; 3. Able to speak and read English
- **Exclusion**: Participated in a therapeutic trial in the past

c) Procedures involved in the human research

- **Study Design**: (**Figure 2**)



The primary outcomes are decision-related self-efficacy and decisional conflict. Secondary measures will include patient-related outcomes such as increased knowledge, use of ***mychoice,*** increased patient activation, and perceptions of the provider encounter. Table 1 on the following page describes the study measures.

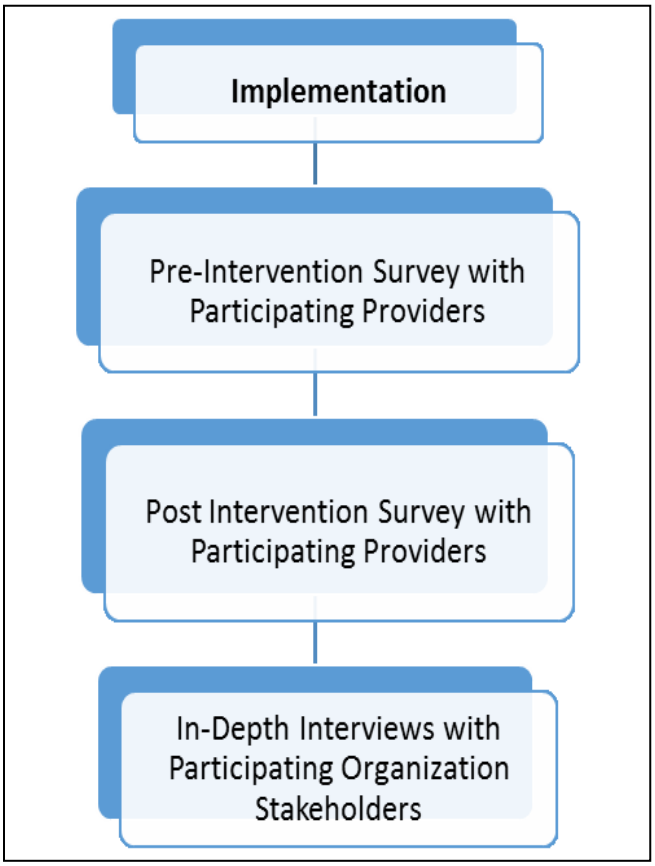
- **Randomization**. Upon completing the informed consent form, patients will be randomized to either ***mychoice*** group or control group by RedCAP at a 1:1 ratio. The system will randomly assign participants as they enter into the system after they have been consented to the study.

Table 1. RCT Study Measures

Measure	Source	Description	Pre	Post	1 month follow-up
Demographics	NIH	Age, education, insurance, income, race, ethnicity, gender, living situation (8 items)	X		
Cancer and Clinical Trial Experience (personal and family/friends)		Cancer type, stage (6 items)	X		
Technology Use	HINTS	Mobile, smartphone, computer, tablet (5 items)	X		
Health Literacy	SILS	1 item	X		
Clinical Trial Perceptions	Bass, Fleisher	Test perceptions over time using perceptual mapping – knowledge, benefits, concerns, perceptions/experiences with cancer treatment, beliefs about health care providers and your health (48 items pre; 31 post; 43 follow up)	X		X
Patient Activation (Decisional Engagement Scale)	Hoerger, et al (DES-10)	2- scales decision making preference (1 item), Comfort with interacting with physician (10 items)	X		X
Patient Self-Advocacy Scale	Brashers eta l.	Perceptions and self-reported behaviors about information seeking and provider relationship (12 items)	X		
Knowledge of Clinical Trials	Campbell	Knowledge of clinical trials (reduced items; 16)	X	X	X
Self-Efficacy	PEPPI	Confidence in communicating with Physician (10 items)	X	X	X
Decision preparation scale (PrepDM)	Bennett, et al	Value of mychoice in preparation to make a decision (10 items)		X	
Perceived Shared Decision Making (CollaboRATE)	Barr, et al	Patient perceptions of effort to discuss concerns			X
Shared Decision Making	SDM Q-9 Kriston et al	Patient perception of shared decision making with provider (12 items)			X
Decisional conflict	Ottawa	Decision conflict (revised; 13 items)	X	X	X
Clinical Trial Intention	Adapted from Ottawa Patient Decision Aid	If offered, would be considered (1 item)	X	X	X
Satisfaction with patient materials	CISRC adapted	Helpfulness and recommendations of materials (app or standard brochure) (3 items post; 13 items follow-up)		X	X
Experience with clinical trial discussions		Self-reported experience about clinical trial discussions with provider (6 items)			X
Satisfaction with Decision	Enswistle, et al	Satisfaction with decision about clinical trials (6 items)			X

To assess implementation issues and address Specific Aim 2, we will use the Consolidated Framework for Implementation Research (CFIR) to guide the implementation evaluation, focusing on the acceptability and feasibility of implementing the ***mychoice*** study as well as the integration of this tool in ongoing practice. This evaluation is descriptive in nature. To evaluate the acceptability and feasibility of the proposed ***mychoice*** study, we will collect data from the initial planning meetings, review of recruitment logs and files, as well as surveys from physicians who have patients that are participating in the study. Meeting notes will be kept and used to design the recruitment process, procedures, and logs. Prior to the start of recruitment (using REDCap; Appendix H) and at project end (will be developed based on how intervention is implemented in sites), an online survey will be conducted with each physician who has patients who are participating in the study. The survey will assess level of commitment to the project and potential barriers. The survey will include key constructs from CFIR, such as perceptions of intervention strength, relative advantage, trialability, patient needs, self-efficacy, and champions. During the recruitment period and throughout the study, recruiters will keep logs of the number of identified patients, number of consented patients, and notes regarding challenges and opportunities in the recruitment process. At the end of the recruitment, the PIs will conduct debriefing interviews with the stakeholders (guide to be developed based on implementation) at each site to more fully explore the challenges and opportunities for ongoing implementation and sustainability (Figure 3). Table 2 describes the measures for the implementation evaluation.

Figure 3. Implementation Process Study Design



	4/17-9/17	4/17-	1/18-	7/18-	8/19-

Table 2. Implementation Constructs

CFIR Constructs	Baseline Survey	End of Study	Debrief Interviews	Meeting Notes
I. Intervention Characteristics				
Source	X	X		
Evidence Strength & Quality	X	X	X	X
Relative Advantage	X	X	X	X
Complexity	X	X	X	X
II. Outer Setting				
Needs & Resources of Those Served by the Organization	X	X	X	X
III. Inner Setting				
Culture	X	X		
Implementation Climate	X	X	X	X
Tension for Change	X	X		
Readiness for Implementation	X	X		
Leadership Engagement	X	X		
Available Resources	X	X		
IV. Characteristics of Individuals				
Knowledge & Beliefs about the Innovation	X	X	X	X
Self-Efficacy	X	X	X	X
V. Process				
Planning			X	X
Engaging			X	X
Formally Appointed Internal Implementation Leaders			X	X
Champions			X	X
Key Stakeholders			X	X
Executing			X	X
Reflecting & Evaluating			X	X

- **Timeline: This is a 33 month project (4/2017-12/2019)**

		12/17	**6/18**	**7/19**	**12/19**
Months:	**1-6**	**1-9**	**10-15**	**16-28**	**29-33**
Revisions based on initial user testing	X	X			
Review by key stakeholders	X	X			
New patient testimonials to increase diversity	X				
Final Production	X	X			
Create Study Instruments		X			
Finalize data management system		X	X		
Recruitment process established at sites					
1. Fox Chase			X		
2. Temple			X		
3. Jefferson				X	
4. Penn				X	
IRB review and approval at study sites					
1. Fox Chase			X		
2. Temple			X		
3. Jefferson				X	
4. Penn				X	
Recruit 270 Patients				X	
Conduct pre-intervention implementation surveys with participating staff				X	
Conduct baseline, intervention, and post test				X	
Conduct one-month follow-up surveys				X	
Conduct post intervention implementation surveys				X	
Data Analysis – Patient Surveys					X
Tracking analysis-metrics in mychoice					X

In-depth implementation interviews with site stakeholders					X

5.0 Risks to Participants

- Participating in this study does not pose direct physical risk to patients. Participants may have questions about clinical trials after taking the surveys, in which case they will be instructed to talk with their oncologist about medical or eligibility questions related to clinical trials. Participants may also be directed to the Resource and Education Centers at TUHS for additional information about clinical trials.

6.0 Potential Benefits to Participants

- Participating in the study does not pose direct physical benefit to participants. This is not a therapeutic study, but rather an evaluation of an educational app. The results of the research will be used to modify the app thereby making it a more appropriate and useful decision-making tool to help African American, and other cancer patients, make better informed decisions concerning clinical trial participation.

7.0 Provisions to Maintain the Confidentiality of Data

- All information collected for this study will be kept confidential. Subjects will be told that all information will be kept in strict confidence. All deidentified survey data will be downloaded from RedCAP and stored on computer files or in locked filing cabinets to which only select members of the research staff will have access.
- RedCAP survey data and user data from the mHealth tool will be identified only by participant number and will be downloaded into SAS for analysis.
- ipads have been purchased for this study and will be used to implement the intervention, along with computers used either at the REC or in the participant's home. All ipads and REC computers are password protected with only study staff having that information. No files will be saved or downloaded on the ipads or computers, and no data will be accessible on the ipads or computers that would identify patients. Participants will go to a RedCAP study URL which will then randomize them to condition. All data from the surveys will be gathered by the RedCAP system and not on the ipad or computer itself.
- All participating sites will direct patients to the RedCAP URL to begin the study. No data will be shared with them and they will not have access to the data. Only study PIs and the study coordinator will have this access.
- For medical staff personnel, surveys will also be sent via email where they will be provided a RedCAP link. When conducting interviews, a digital recorder will be used to capture the interview. These will be transcribed and then destroyed. No identifying information will be recorded on the transcriptions.

- All data will be housed behind the firewall at Fox Chase Canacer Center using RedCAP. The PIs and study coordinator, will have access to this data and will download de-identified data for analysis to share with the biostatistician to be used in SAS. A special study ID and password will be required to enter into RedCAP. In addition, any additional files will be password protected and kept on secure, fire-wall protected servers at Temple University and Fox Chase Cancer Center .

8.0 Costs to Participants

- There are no costs to participants. The study will take approximately 1 hour initially (10 minutes consent, 15 minutes pre-test, 30 minutes education tool, 5 minutes post test). The one month follow survey will take approximately 30 minutes.
- For medical staff participants, surveys will take less than 5 minutes; post-intervention interviews will take approximately 30 minutes.

9.0 Consent Process

- The study coordinator will introduce the study and review the consent document either in person or over the phone. If providing consent over the phone, the staff member will read the consent to the participant (script provided). If they verbally agree, they will be directed to the link in their email for the study. The study consent document is then also embedded into the RedCAP baseline survey that will be on the iPad or computer. Participants will read through the consent and provide consent by entering their name and hitting a designated button. They then will be asked to do the same for the HIPAA consent. These consents will be recorded and the participant will be allowed to proceed to the baseline survey. If the participant has any questions about the study or consents, the site recruiter will be available in person or over the phone. Staff will have copies of the consent should the participant like to have a copy to take home; those doing at home can download a pdf of the consent to have a copy. The scripts for the staff person to explain this is included (App C). A telephone screening consent script is also provided.
- Participants will be able to decide to continue or discontinue at any time.
- All participants will be English speaking.

10.0 Off-Study Criteria

- Not applicable

11.0 Drugs and Devices

- Not applicable.

12.0 Multi-Site Research Study

- • Fox Chase Cancer Center serves as the primary site, with participating sites including sites Temple University Hospital, Thomas Jefferson University Hospital, and Hospital of the University of Pennsylvania. Dr. Fleisher serves as the PI at FCCC overseeing study recruitment at all coordinating sites. Each site will have their own IRB oversight and coordinating investigator as well as their own study documents (e-consent and protocol) to meet their institutions requirements. Dr. Fleisher and the study coordinator at FCCC will oversee the other sites regulatory by documenting the study team's Human Subjects training and expiration dates. They will also track all sites Continuing Reviews to ensure compliance across all 4 coordinating sites.
- Dr. Fleisher and the study coordinator at FCCC will also oversee protocol management by conducting monthly meetings and periodic review of each site's protocol. The study coordinator will conduct on-site visits monthly to review recruitment and study progress. All sites will participate in a monthly full team call to discuss updates and address any recruitment/implementation issues.
- Each site will be provided an Operations Manual that incorporates important protocol specific information to provide support onsite. Each member of the study staff will have 3 training sessions prior to their recruitment start date. We will also conduct periodic recruitment training to reinforce operations and protocol compliance.
- Data management will take place at FCCC via REDCap weekly by the Study Coordinator. The Study Coordinator will review quality and completeness of the data on a weekly basis and provide feedback to each site PI and recruitment staff.

13.0 Statistical Analysis

- ***General analyses:*** After screening for potential differences across sites on the key outcome variables, all data will be graphed and tabulated by group (i.e., ***mychoice*** vs. control) for review of distributional properties and anomalous values prior to the main analyses. Continuous and normally distributed variables will be summarized with means and standard deviations. All parameter estimates will be bound by 95% confidence intervals. Tests of significance will be based on adjustments for alpha to protect family-wise error rates at 5% using the method of Benjamini and Hochberg [40]. Data will be analyzed using an intent-to-treat (ITT) approach where subjects are analyzed according to their treatment assignment at randomization, regardless of level of participation or engagement. Because an ITT analysis is planned, we will evaluate models suitable for non-ignorable (missing not at random) data within a sensitivity analysis framework in order to determine the extent to which analysis conclusions depend on the assumptions being made about unobserved values. We will perform model-based analyses with direct maximum likelihood methods, including those for data missing not at random (MNAR) if necessary. We will screen for violations of assumptions for all statistical tests involved. All analyses for specific aims will be conducted using SAS 9.4.

- ***H1 Analysis***: The principle endpoint will be 1-month follow-up, i.e., one month after completion of either the ***mychoice*** or control education. We will conduct a mixed-effect regression models for each repeatedly measured continuous outcome (i.e., self-efficacy and decisional conflict at post intervention and 1-month follow-up) on a dummy grouping variable (***mychoice***, as compared to Control), adjusting for baseline level of this outcome and covariates discovered to be unbalanced between the two groups, and moderators of interest. In these models, we will treat time as a categorical variable and examine the fixed effects for time, intervention group, and their interactions. We will specify the covariance structure within patients using an unstructured model to account for the in-patient correlation over time.

  In addition, the dichotomous race (White vs. non-White) variable and the non-White-Treatment interaction will be entered in each regression model as predictors, to understand possible different effects of ***mychoice*** for non-White vs. White participants. A significant, positive regression coefficient of the non-White Treatment interaction indicates non-white participants' benefits more from the treatment than their White counterparts.
- **Power:** Power analyses were performed using G*Power 3.1, with 2-sided tests and an adjusted alpha level of .025 (= .05/2) for multiple group comparisons. We performed power analyses for comparisons on primary and secondary outcomes for Aim 1. Effect size (mean difference between groups divided by the pooled standard deviation) is a common measure for assessing the magnitude of a treatment effect on continuous outcomes. The number of participants needed for Aim 1 is selected to sufficiently power the detection of a difference between groups on the outcomes adjusting for covariates and moderators at 1-month follow-up.

  To detect a moderate treatment effect size of 0.47 SD on either the self-efficacy and decisional conflict scales, our trial would need 88 patients per group, presuming alpha = .025 and beta = .20 (power = 80%). Of note, this effect size is comparable to prior studies (please cite some papers). Including a 20% adjustment for dropout and loss of degrees of freedom when adjusting for possible additional confounding variables, a total of 220 patients are needed. By using mixed-effects repeated measures regression analysis, our power is likely to be even higher. Therefore our estimated power provides a conservative lower-bound of the likely actual power of our sample size. Also, we will need an additional 50 patients to do exploratory analysis on potential differences in effect by recruitment type, bringing the total needed to 270.
- ***H2 Analysis***: Descriptive statistics will be employed for the analysis of the quantitative feasibility and acceptability data. All qualitative data collected through the meeting notes and debriefing interviews will analyzed the Krueger method of analyzing narrative data will be used; familiarization, identifying a thematic framework indexing, charting, mapping and interpretation [80]. Recordings will be listened to and transcriptions read to become familiar with what participants said. A

thematic framework, based on the CFIR constructs will be developed to create categories and quotes will be indexed according to categories to reduce data. Major themes of the analysis will be reviewed across institutions. Recruitment logs will be reviewed and compared against study recruitment goals to determine potential barriers.

14.0 Data Safety Monitoring Plan

- This is a minimal risk study. We will monitor the study and any participant complaints or issues. In general, we believe data will be accurate based on self-reported attitudes.

15.0 Adverse Event Reporting

- In accordance with FCCC guidelines, this protocol will employ the following mechanisms for adverse event reporting: 1) alert the FCCC review committees of any and all reports of adverse events; 2) inform all members of the study team of any all reports of adverse events. If 3 or more adverse events are reported, the study team will assess potential causes of the adverse events and, if events are clearly linked to study participation, discontinue the study.

16.0 Quality Assurance Procedures and Participant Confidentiality

- Information about study subjects will be kept confidential and managed according to the requirements of the Health Insurance Portability and Accountability Act of 1996 (HIPAA). Those regulations require a signed subject authorization informing the subject of the following: The protected health information (PHI) that will be collected from patient; who will have access to that information and why; who will use or disclose that information; the rights of a research subject to revoke their authorization or use their PHI. In the event that a participant revokes authorization to collect or use PHI, the investigator, by regulation, retains the ability to use all information prior to the revocation of subject authorization. To ensure confidentiality, only a participant identifier will be recorded and used with collected electronic data. All records will be secured in a locked location.
- While we will not access private health information during the study accrual, but may access information on their participation in a clinical trial when we are analyzing data while the IRB is still open. As a result we will maintain the HIPAA waiver in the consent process.

17.0 Participant Informed Consent

- See separate informed consent document

18.0 References

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19.0 Appendices

A: Patient Card
B: Flyer
C. Script for electronic informed consent
D: Baseline Survey
E: Post Test Survey
F: Follow-up Survey – Treatment Arm
G: Follow-up Survey – Control Arm
H: Physician Survey – Pre Intervention