Physical activity (PA) can ameliorate many long term side effects and the increased risk of primary cancer recurrence (i.e., colon and breast), second neoplasm, and chronic non-cancer medical comorbidities experienced by cancer survivors. Because the majority of cancer survivors do not engage in regular PA, it is critical to increase the translation of efficacious PA behavior change interventions (BCIs) from research into cancer survivorship care, especially for rural cancer survivors who suffer poorer physical and mental health compared with urban counterparts. Our BEAT Cancer (Better Exercise Adherence after Treatment for Cancer) PA BCI for breast cancer survivors significantly improved PA behavior in a multicenter randomized controlled efficacy trial with the odds of meeting PA recommendations being double that reported by any previous BCI in cancer survivors, to date. A next translational step for the BEAT Cancer intervention is preparation for implementation within a Cancer Community Network (CCN). An implementation toolkit integrating planned adaptations for cancer types other than breast and a rural CCN site is needed before submitting an R01 application proposing an effectiveness-implementation hybrid type 1 trial (i.e., tests clinical effectiveness in a real world setting such as the CCN while also improving understanding of the implementation context). Such a trial is anticipated to occur within the University of Alabama at Birmingham (UAB) CCN which includes multiple community hospitals and cancer centers including those in rural settings. Therefore, we propose the following specific aims with the overall objective of improving implementation of the BEAT Cancer PA BCI within a CCN*:* 1) develop an implementation toolkit that adapts the intervention *to a rural CCN site and cancer types other than breast,* 2) test feasibility of implementing the toolkit, and 3) evaluate the toolkit's acceptability, adoption, appropriateness, fidelity, cost, and impact on service and client outcomes. Our proposal is based on the Consolidated Framework for Implementation Research and Rogers' Diffusion of Innovations theory. Qualitative and quantitative input will be obtained from three organizational levels in the targeted rural Alabama county (i.e., potential intervention participants, community-level stakeholders, and potential intervention delivery staff). Qualitative data (i.e., focus groups, nominal group technique groups, photovoice, ground truthing) will be used for planned adaptation and creation of the implementation toolkit. After development, the implementation toolkit will be pilot tested at the CCN site with 20 women cancer survivors. Feasibility measures will be obtained by survey and administrative data. Acceptability, adoption, appropriateness, and implementation cost will be assessed by survey, focus groups, and administrative data. Fidelity will be assessed with direct observation and survey. Outcomes (i.e., service and client) important to stakeholders and PA (self-report and accelerometer) will also be assessed. *Improving the implementation of this efficacious PA BCI within a CCN serving rural populations will increase the reach of the intervention and its beneficial effects on PA and health.*

2. Specific aims

Cancer survivors often experience poorer health and quality of life due to long term detrimental side effects and increased risk of primary cancer recurrence and mortality, secondary neoplasm, and non-cancer medical comorbidities (2-7). Based on evidence from exercise outcomes trials, physical activity (PA) can ameliorate the physical and psychological burden of suffering caused by cancer (8-12). Because only 13% of cancer survivors engage in the recommended amount of PA (i.e., 150 weekly minutes of moderate intensity PA), it is critical to increase the translation of efficacious PA behavior change interventions (BCIs) from research into cancer survivorship care (13, 14). BCI trials differ from exercise outcomes trials because their primary aim is changing PA behavior rather than testing effects of a specific exercise dose (15). Translation of PA BCIs from research to practice is particularly important among rural cancer survivors given their poorer physical and mental health (8-10, 16) and the higher rates of chronic disease and mortality in rural populations (17-21).The translational research continuum moves interventions from efficacy testing to research facilitating dissemination and implementation (D&I) in real world settings. D&I related translational research after efficacy testing of PA BCIs is rare, especially for rural cancer survivors (13, 22-24). Also, efficacy studies testing PA BCIs for cancer survivors have rarely reported significant BCI effects on PA behavior several months after intervention completion and/or documented benefit with an objective PA measure (25, 26). In contrast, our Better Exercise Adherence after Treatment for Cancer (BEAT Cancer) PA BCI for breast cancer survivors has significantly improved PA behavior immediately post-intervention and 3 months later (27-29). In our multicenter randomized controlled efficacy trial, the odds of meeting PA recommendations was double that reported by any previous BCI in cancer survivors to date (28). Also, our continued health and quality of life benefits 3 months after intervention completion have rarely been reported by other BCIs (28).

A next translational step for the BEAT Cancer intervention is preparation for implementation within a Cancer Community Network (CCN). Implementation can be enhanced by combining adaptation with implementation science to improve the fit for the local context (e.g., rural CCN) and broader population (women with any cancer type) (24, 30, 31). An implementation toolkit integrating planned adaptations (32) that increase appropriateness for other cancer types and a rural CCN site is needed in preparation for an R01 application proposing an effectiveness-implementation hybrid type 1 trial (i.e., tests clinical effectiveness in a real world setting such as the CCN while also improving understanding of the implementation context)(33). Such a trial is anticipated to occur within the University of Alabama at Birmingham (UAB) CCN which builds collaborative relationships between UAB faculty and multiple community hospitals and cancer centers across the Southeastern U.S. including those in rural settings. UAB CCN's infrastructure is well-suited for an eventual large-scale *effectiveness-implementation hybrid study. Such a study is best done after completing adaptation, implementation toolkit development, and proof of concept pilot testing proposed in this R21.*

Therefore, we propose the following <u>specific aims</u> with the overall objective of improving implementation of the BEAT Cancer PA BCI within a CCN site: 1) develop an implementation toolkit that adapts the intervention *to a rural CCN site and cancer types other than breast (toolkit contents described in Approach and Appendix)*, 2) test feasibility of implementing the toolkit, 3) evaluate the toolkit's acceptability, adoption, appropriateness, fidelity, implementation costs, and impact on service and client outcomes. Our proposal is based on Damschroder's Consolidated Framework for Implementation Research (34) and Rogers' Diffusion of Innovations theory (35). *As done previously by our Washington University D&I Core consultants, the Cultural Adaptation Process (36) model will guide planned adaptation.* Using the UAB CCN, qualitative and quantitative input will be obtained from three organizational levels: potential intervention participants, community-level (& CCN) stakeholders, and potential intervention delivery staff. Qualitative data from focus groups, nominal group technique groups, photovoice, and ground truthing will be used to create and refine the implementation toolkit. After development, the implementation toolkit will be pilot tested at the CCN site with 20 women cancer survivors. Feasibility measures will be obtained by survey (all three organizational levels) and administrative data (37). Acceptability, adoption, appropriateness, and *implementation cost* will be assessed by self-administered survey (all organizational levels), focus groups (all organizational levels), and administrative data (37). *Implementation costs will be identified and collected from the perspective of the entity implementing the intervention (e.g., CCN site and/or community center) and participants.* Fidelity will be assessed with direct observation (research staff, during implementation) and survey (all organizational levels, post-intervention). In addition to these implementation outcomes, pre/post intervention self-report and accelerometer PA (women cancer survivors) and outcomes important to stakeholders (e.g., quality of life, etc.) will be assessed.

This proposal's multidisciplinary team will combine adaptation and implementation science to optimize implementation of an efficacious PA BCI within a CCN infrastructure (30, 31) and improve intervention translation to women with all cancer types and CCNs caring for rural populations.

3. Research strategy

3.a. Significance - *Physical activity (PA) can break the cycle of poor health and economic burden in cancer survivors: The nearly 14.5 million Americans living with a history of cancer face an increased risk for long term detrimental effects (e.g., chronic fatigue, osteoporosis, poorer physical functioning, cardiovascular disease, etc.), cancer recurrence, secondary neoplasm, and non-cancer comorbidities (2, 4-7). This contributes to poorer overall health status (fair or poor health reported by 34% of survivors diagnosed ≤ 1 year prior, 26% of those diagnosed > 1 year prior, and 10.5% of controls, p < .001)(3) and increased financial burden (e.g., $16,213 annual excess economic burden for cancer survivors diagnosed ≤ 1 year prior and $4,427 if diagnosed > 1 year prior) (3). Cancer survivors (especially rural residents) are more likely to forgo medical care for financial reasons (38) and quality of life is negatively impacted by poorer health and greater financial burden (39, 40). Therefore, a cancer diagnosis may initiate a cycle of poor health, financial burden, and reduced quality of life. This cycle is potentially magnified in rural cancer survivors who suffer from poorer physical and mental health, quality of life, and functional well-being and greater cancer-specific symptoms, depression, anxiety, and fatigue when compared with urban counterparts (8-10, 16). Engaging in regular PA is one strategy for interrupting this cycle by ameliorating long term side effects (41), primary cancer recurrence (i.e., colon and breast) (11, 12), and risk of second neoplasm and chronic diseases (6, 42).*

Efficacious PA behavior change interventions (BCIs) for rural cancer survivors are needed: Given the benefits (8-12) and low prevalence (14, 43) of regular PA among cancer survivors, PA BCI studies that focus on testing programs that change behavior and increase regular PA are needed. Such studies are differentiated from the multiple published exercise and cancer outcomes trials that have confirmed exercise benefits (15, 41). Rural populations report less PA than urban populations (44-46) and PA BCIs can potentially reduce health disparities in rural cancer survivors (e.g., related to quality of life, physical functioning, and psychosocial outcomes) (41, 47, 48). Therefore, efficacious PA BCIs targeting cancer survivors that are not limited to urban implementation are needed. Although interventions for non-cancer rural groups have been tested in randomized controlled efficacy trials (49-51), focusing on cancer survivors is warranted because of the unique PA barriers faced by cancer survivors (52-54). Only one randomized controlled trial has tested a PA BCI in non-urban cancer survivors (55). The 8-month telephone intervention did not increase aerobic PA (52% of intervention participants versus 40% of usual care were meeting recommendations after intervention completion) and no objective PA measure was obtained (55). Most randomized trials of PA BCIs for cancer survivors (any type, not specifically rural) have failed to measure or confirm statistically significant PA behavior increases months after intervention completion. Even fewer have included an objective measure of PA.

Efficacy data: Our multicenter randomized controlled efficacy trial testing the Better Exercise Adherence after Treatment for Cancer PA BCI (BEAT Cancer) randomized 222 post-treatment breast cancer survivors to BEAT Cancer or usual care (28). Significant improvements in accelerometer and self-report weekly minutes of ≥ moderate intensity PA were noted immediately post-intervention (i.e., 3 months after baseline) using adjusted linear mixed-model analyses [mean between group difference (M) for accelerometer = +41; 95% confidence interval (CI) = 10 - 73; p = .010; self-report M = +93; CI = 62 - 123; p < .001]. BEAT Cancer participants continued to be more than twice as likely to meet PA recommendations (i.e., ≥ 150 weekly minutes of ≥ moderate intensity activity) 3 months after intervention completion [accelerometer odds ratio (OR) = 2.4; CI = 1.1 - 5.3; p = .024 ; self-report OR = 4.8; CI = 2.3 – 10.0; p< .001]. Multiple BEAT Cancer benefits noted immediately post-intervention remained statistically significant 3 months post-intervention (e.g., aerobic fitness, quality of life, fatigue, depressive symptoms, anxiety, et al). Post-randomization retention was 96%; adherence rates were 98% for supervised exercise, 96% for individual counseling, and 91% for discussion groups. Participants were paid for study assessments but not for intervention session attendance. Manuscripts reporting efficacy data are under review (i.e., Breast Cancer Research and Treatment (28)) and in preparation. Efficacy study participants lived in counties with a rural-urban continuum code (RUCC) (56) of 1, 3, or 6. Intervention effect did not vary based on RUCC (non-significant interaction term; unpublished data). Program acceptability was excellent [mean rating of BEAT Cancer = 4.6 ± .6 using a Likert scale (1= poor and 5 = excellent); no difference based on RUCC (p = .22; manuscript in preparation)]. Creating an implementation toolkit is critical to improving the implementation potential and public health impact of this efficacious intervention (57, 58). Also, focusing this proposal on women of any cancer type (rather than breast cancer alone) who live in rural regions will extend intervention reach and potential to reduce health disparities.

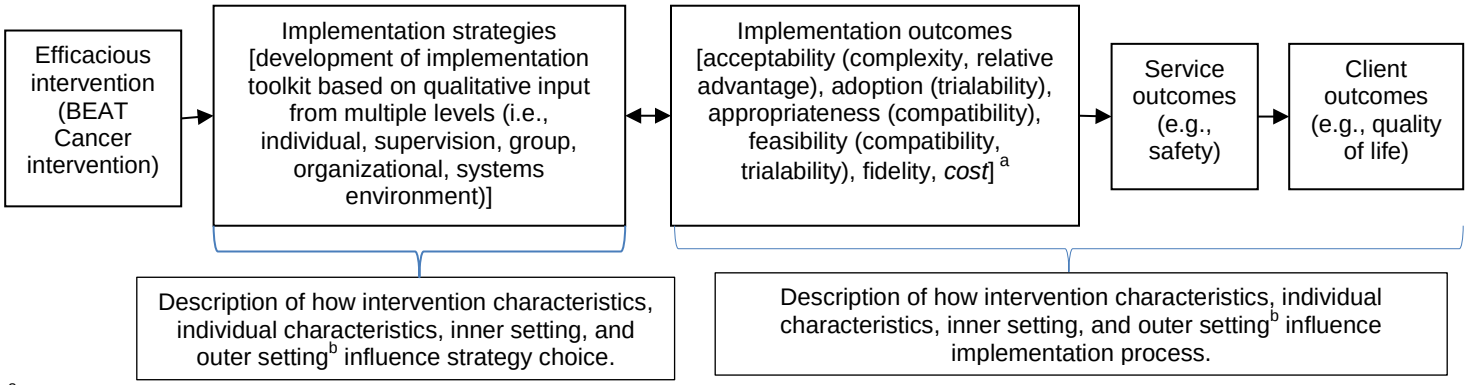
BEAT Cancer description: The 3-month social cognitive theory-based BEAT Cancer PA BCI includes 12 supervised exercise sessions with an exercise specialist (treadmill walking; three times weekly in weeks 1 & 2, twice weekly in weeks 3 & 4, and once weekly in weeks 5 & 6) (59). As supervised sessions are tapered, participants increase their home-based exercise (exercise type chosen by participant). During the final six

weeks, participants complete all exercise at home and attend face-to-face ("update") counseling sessions with the exercise specialists every two weeks. Throughout the intervention, participants attend six discussion group sessions covering topics such as stress management, time management, cognitive reframing, personal behavioral modification plan, etc. Details regarding the intervention and social cognitive theory targets have been published (59). Core components identified with qualitative assessment are summarized in the Approach.

Preparing for a future hybrid type 1 trial within a Cancer Community Network (CCN): The next step in the translational research continuum for our efficacious BCI is an effectiveness-implementation hybrid type 1 trial (i.e., tests effectiveness while also gathering data on implementation), as supported by meeting the following criteria: 1) strong face validity supporting applicability to new setting (e.g., one efficacy testing site implemented intervention in a clinic building with oncologists referring patients), 2) strong base of data from different but associated population (efficacy data, no difference in acceptability or intervention effect based on RUCC), and 3) minimal risk associated with the intervention. (33). The UAB CCN is a collaboration between UAB faculty and community hospitals that optimizes community-based oncology patient services and access to cancer-related clinical trials. *Because the UAB CCN includes multiple community hospitals and cancer centers across the Southeastern U.S., its infrastructure has the potential to increase the number of women benefiting from BEAT Cancer. The current members of the UAB CCN reside in metropolitan and non-metropolitan counties as classified by RUCC (56). CCN counties range from RUCC of 1 (metro areas of ≥ 1 million population) to 6 (2,500 to 19,999 population) with several being adjacent to counties with RUCC of 8 or 9 (completely rural or < 2,500 population). In preparation for a hybrid type 1 trial within the UAB CCN, an implementation toolkit that includes planned adaptations to improve the fit for the more rural CCN sites and women with any cancer type is needed (24, 30-32). For this R21 resubmission, we considered all CCN affiliates within a 75 minute drive from Birmingham, AL (UAB campus) in an effort to limit logistical and budgetary burden related to travel distance. Russell Medical Center in Tallapoosa County, AL was chosen because it is among the most rural CCN sites (RUCC = 6), adjacent to RUCC counties = 8 and 9, and located in a county with Caucasian (70%) and minority (30%) representation. Russell Medical Center is enthusiastic about facilitating this proposal (letter of support). Although 75% of our efficacy study participants were from a RUCC of 3, we chose a CCN site in RUCC of 6 for the following reasons: 1) strong evidence from associated population as described previously, 2) will provide new knowledge about implementation processes and options in a more rural site not available in the efficacy study that will increase toolkit generalizability to a broader range of sites, and 3) if proof of concept phase is successful in this most rural county then the likelihood of success throughout the UAB CCN is increased.*

Our proposal is based on Damschroder's Consolidated Framework for Implementation Research (CFIR) (34) and Rogers' Diffusion of Innovations (DI) Theory (35) (Figure 1). Within taxonomy suggested by Proctor (60), this proposal includes input from multiple levels (i.e., participants, intervention delivery staff, community stakeholders) and implementation, service, and client outcomes. We will use the CFIR to interpret the influences of multiple domains on implementation strategy choice, process, and outcomes. Outcomes include characteristics that improve diffusion potential according to Rogers' DI theory (Figure 1) (35, 37).

Figure 1. Proposal activities and outcomes; integration of the Consolidated Framework for Implementation Research and Rogers' Diffusion of Innovation theory (34, 35, 60)



[a]As described by Proctor, et al (37), Rogers' Diffusion of Innovation constructs in parentheses (35)
[b]Domains described in the Consolidated Framework For Implementation Research (CFIR) described by Damschroder, et al (34)

Applicability to PAR-13-054: This R21 resubmission will advance implementation science by using traditional and innovative methods to develop and evaluate an implementation toolkit for a PA BCI. Our proposal will increase the understanding of the following as they relate to implementing a PA intervention in

CCNs serving rural areas: 1) processes that inform an implementation toolkit to be used as an implementation strategy, 2) processes for carrying out planned adaptation of the intervention, and 3) implementation strategies related to multi-component health interventions in a potentially low resource setting. Our proposal includes key characteristics requested by PAR-13-054 (e.g., D&I theoretical framework, multi-component intervention in a low resource setting, multi-level context and environment, outcomes consistent with models used).

3.b. Innovation - *Although PA BCIs have been developed for rural populations other than cancer survivors (49, 51), these interventions have not been widely used and a better understanding of how to improve implementation of such interventions in rural organizations is needed (22). One critical implementation strategy is a well-designed implementation toolkit (57, 58).* This proposal will develop an implementation toolkit for a PA BCI for women cancer survivors throughout a CCN which includes rural sites. A similar toolkit does not currently exist for any previously tested PA BCI for cancer survivors. Such a toolkit can be used to *improve the health and well-being of women cancer survivors in rural populations through the BEAT Cancer beneficial effects on PA behavior, health, and quality of life. The goal of improving cancer survivorship* is consistent with NIH research priorities (61), PAR-13-054, and emphasis on prevention in the Affordable Care Act (62). Also, our proposal will fill a knowledge gap related to the lack of "type 3 evidence" (i.e., information needed for the adaptation and implementation of an intervention) in general (24) and for PA interventions specifically (63). *This proposal will lay the foundation for a future translational proposal testing the intervention effectiveness when implemented in all CCN sites (hybrid 1). Our intervention is unique among BCIs for breast cancer survivors in its effect on PA and health outcomes. As noted earlier, our intervention's ability to significantly increase the odds of meeting PA recommendations exceeds any previously reported BCI. This is of significant clinical value given the 27% reduction in all-cause mortality and 25% reduction in breast cancer mortality reported for breast cancer survivors who meet PA recommendations (64). Moreover, our intervention is the only BCI for cancer survivors, to date, reporting continued significant improvements in quality of life months after intervention completion. Inclusion of cost measures is particularly important given the impact of cost on rural cancer survivors' access to care (38) and dearth of cost data currently available for implementation strategies and PA interventions (24, 65, 66).* Lastly, our inclusion of photovoice and ground truthing, methods previously underutilized in research related to health intervention implementation (67), will provide innovative information and a better understanding of the usefulness of these methods in future implementation research.

3.c. Approach - This study will occur at the University of Alabama at Birmingham (UAB) in collaboration with a UAB CCN site (Russell Medical Center, Tallapoosa County, AL). Russell Medical Center will facilitate access to required infrastructure (e.g., meeting rooms for groups, etc.) and assist the investigative team with participant recruitment for all three organizational levels (Table 1). Recruitment will be by personal invitation, flyers in physician waiting rooms, support groups, and media advertisements. Study inclusion/exclusion criteria include: Potential intervention participants: 1) woman ≥19 years old with history of any cancer type except cancer limited to skin (any stage; any number of years since diagnosis), 2) resides in Tallapoosa County, AL or adjacent county 3) ambulates without assistance, 4) English speaking, 5) intact hearing, 6) no contraindication to moderate intensity exercise, 7) post-primary cancer treatment, 8) anticipates physician clearance for participation in a moderate-intensity exercise program, 9) no history of dementia or organic brain syndrome and 10) no medical, psychological, or social characteristic that would interfere with ability to fully participate. Community stakeholders: 1) community stakeholder who is ≥19 years old [no gender restrictions; examples include, but are not limited to CCN hospital administrators, cancer survivor advocates, oncologists, etc.], 2) resides in Tallapoosa County, AL or adjacent county, 3) English speaking, 4) intact hearing, 5) no history of dementia or organic brain syndrome and 6) no medical, psychological, or social characteristic that would interfere with ability to fully participate. Potential intervention delivery staff: 1) possesses qualifications related to at least one of the intervention activities (i.e., exercise specialist, discussion group leader, or administrative staff) who is ≥19 years old (no gender restrictions), 2) resides in Tallapoosa County, AL or adjacent county, 3) English speaking, 4) intact hearing, 5) no history of dementia or organic brain syndrome and 6) no medical, psychological, or social characteristic that would interfere with ability to fully participate.

BEAT Cancer is based on the social cognitive theory (68) and we have reported that exercise barriers, self-efficacy, and social support mediate the largest proportion of intervention effects on PA behavior 3 months after intervention completion (69). Based on participants' evaluations *during pilot and efficacy testing, intervention aspects most helpful in changing their exercise habits include interactions with exercise specialists, experiencing exercise benefits, exercise log, developing a routine, beginning slowly, supervised exercise sessions, group sessions (topics, materials, interaction), exercise prescription, accountability, program encouragement, and involvement of cancer patients only [unpublished data and (29, 70)]. Consistent responses existed across the RUCC represented in the efficacy study (i.e., 1, 3, and 6).* Taken as a whole,

these data suggest the following intervention core components (and social cognitive theory targets): 1) interactions with exercise specialists [barriers self-efficacy, barriers, benefits (outcome expectations)], 2) exercise prescription and log (self-efficacy, goal-setting), 3) educational materials [barriers self-efficacy, barriers, benefits (outcome expectations)], and 4) group interaction (social support).

Mixed-methods approach combining qualitative with quantitative data in a simultaneous and sequential manner will be used to achieve the development and evaluation activities of this proposal (Figure 2) (24, 71).

Figure 2. Timeline of mixed-methods assessments during development and evaluation of implementation toolkit

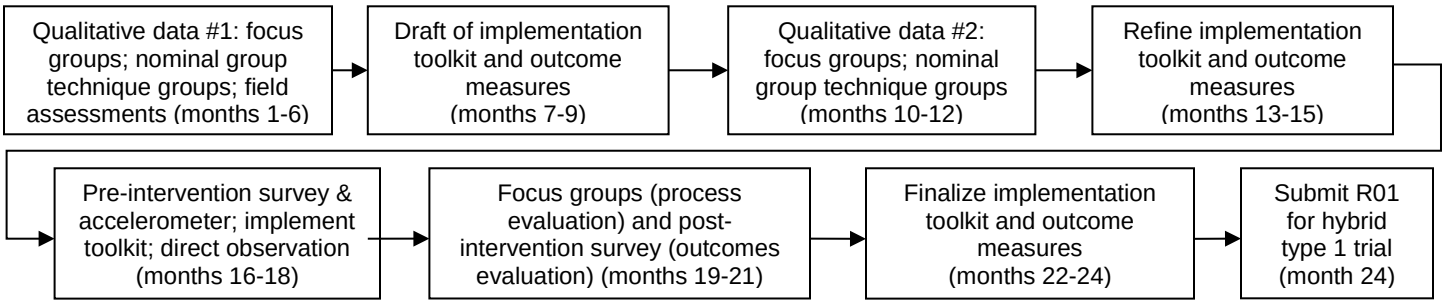


Table 1. Study activities for each study phase completed by each individual in an organizational level or on the investigative team *(i.e., some of the participants may participate in all study phases within a level)*

	Initial qualitative data for toolkit development	Qualitative data for toolkit refinement	Pilot test toolkit in proof of concept mini-trial	Toolkit evaluation
20 potential intervention participants (women cancer survivors)	Nominal group technique session, focus group session, and photovoice data collection with debriefing[a]	Nominal group technique session and focus group session[a]	Obtain physician clearance and then participate in intervention during toolkit implementation	Focus group[a], pre/post self-administered survey, self-report physical activity, and accelerometer
20 community stakeholders (hospital administrators, cancer patient advocates, etc.)	Nominal group technique session, focus group session, and photovoice data collection with debriefing[a]	Nominal group technique session and focus group session[a]	Assist with implementation and/or evaluation depending on toolkit design	Focus group[a] and pre/post self-administered survey
20 potential intervention delivery staff (Exercise specialists, group leaders, administrative staff, etc.)	Nominal group technique session, focus group session, and photovoice data collection with debriefing[a]	Nominal group technique session and focus group session[a]	Implement toolkit	Focus group[a] and pre/post self-administered survey
Research staff	Ground truthing		Direct observation (standardized data collection sheets; process evaluation); administrative records (cost, adverse events)	Cost data
Research staff and investigators	Prospective record of barriers, solutions, priorities, contextual influences, etc.			

[a]*Anticipate three of each type required to obtain input from 20 participants.*

At least 60 individuals [20 from each organizational level (Table 1)] will be enrolled [e.g., during the initial qualitative data collection, each participant will attend one nominal group technique (NGT) and one focus group (6-7 attending each session) resulting in data from three NGT and three focus groups]. *If participants choose to opt out of an activity, additional individuals will be enrolled to ensure that 20 provide input for each level during each data collection activity. Drs. Rogers and Shewchuk carried out three NGT groups with efficacy study participants to evaluate the intervention (manuscript in preparation); as with Dr. Shewchuk's prior experience with NGT groups, three groups of 6-7 individuals was sufficient for eliciting a comprehensive array of non-redundant responses.* Qualitative data will be collected in the following order: 1) potential intervention participants, 2) community level stakeholders, and 3) potential intervention staff. Each organizational level will build on information obtained from previously assessed levels. For example, during initial qualitative data collection, potential participants will express their preferences for exercise location and/or facilities then community level stakeholders will provide information on local resources for accessing these resources and/or facilities followed by potential intervention delivery staff determining how to operationalize intervention implementation within the framework of identified preferences and resources. *The Cultural Adaptation Process (CAP) model will guide planned adaptation similar to that previously done by our*

consultants at the Washington University D&I Core (30, 31, 72).

Focus group participants will be given a description of BEAT Cancer and core components. Group questions will be designed to elicit implementation strategies within the CFIR domains of intervention characteristics, individual characteristics, inner setting, and outer setting for each core component (Figure 1). For example, supervised exercise session with an exercise specialist is a core component. Participants will be asked how well this component can be adapted to their location (e.g., outcome = compatibility; domain = intervention characteristics), strategies for increasing willingness to meet with an exercise specialist (e.g., outcome = acceptability; domain = individual characteristics), cultural appropriateness of materials related to the session (e.g., outcome = compatibility; domain = inner context), and barriers with solutions related to access to facilities (e.g., outcome = compatibility; domain = outer context). *Participants will be asked what they anticipate the costs and benefits of participating in the BEAT intervention will be in terms of monetary expenditures, time, and savings (e.g., due to fewer doctor visits because of better health achieved with PA). CCN site and community stakeholders will be asked similar questions about their anticipated costs and benefits of implementing the BEAT intervention.* Focus groups will be led by Dr. Martin (co-investigator). Data will be analyzed employing content analysis (73, 74). Two raters (Drs. Rogers and Martin) will independently read the group transcripts and identify common themes. Any Cohen's kappa < .70 (intercoder reliability) (75) will be discussed by the two raters who will jointly decide upon a final coding scheme of relevant themes (76). Data will then by summarized including but not limited to how themes interrelate. Nominal group technique (NGT) is an alternative to traditional focus groups with the advantage of insuring that all participants voice their opinion and no single individual dominates the discussion (77). Whether NGT is used will depend on the information being sought. NGT will be used to determine preferred strategies for more discrete and focused topics (e.g., delivery channel, exercise location) but not when seeking input on broader topics (e.g., global critique of intervention materials for acceptability and cultural appropriateness). Dr. Shewchuk (co-investigator) will lead the NGT groups using a structured discussion format eliciting responses to a central question posed to participants who are then offered the opportunity to organize and prioritize their responses (78, 79). A description of BEAT Cancer and its core components will be provided after which group members will be asked a question similar to the following: "What can be done to help BEAT Cancer be successful in your community and for you?" The individually rank-ordered responses will be aggregated across all group members with results presented to the group for final comments before ending the session.

Photovoice and ground truthing will collect qualitative data for toolkit development. Photovoice enhances health interventions, community involvement, individual empowerment, and public health research (67, 80). Adapting published methodology, we will: 1) introduce photovoice (e.g., purpose, ethics, etc.), 2) describe the theme for taking pictures (e.g., places to exercise), 3) distribute cameras with review of use, 4) provide time for taking pictures, 5) print images, and 6) meet with participants to choose, contextualize, and codify the pictures as they relate to intervention implementation (81, 82). Ground truthing (including windshield tours) will augment data related to community resources (83) and will be performed (by research staff) after collection of the other initial qualitative data. To standardize data collection, research staff will develop field documents based on the data collected up until that point. Tallapoosa County will be divided into quadrants and staff will drive the main roads in each quadrant. *Photovoice and ground truthing data will be used to describe options for adapting each core component delivery in the implementation toolkit. For example, group interaction facilitated by an engaging and knowledgeable group leader is a core component but the setting for this interaction will vary by location (e.g., community center, etc.). Similarly, the setting for supervised exercise can occur in any location where a single treadmill can be placed (e.g., church, clinic, etc.). Photovoice and ground truthing will identify planned adaptation for the core components that will improve the fit for that site and provide information on options (and processes for identifying options) when implementing within other CCN sites. Systems environment data (Figure 1; implementation strategies) and individual perspectives regarding implementation within the environment obtained from photovoice will be combined with ground truthing for integration into the implementation toolkit (e.g., inform design of a barriers checklist, provide suggestions that help toolkit users identify local resources, provide implementation options for each intervention activity, etc.).*

Once developed, the toolkit will be evaluated in a "proof of concept" mini-trial (see Table 1 for mini-trial participants and roles; Figure 2 for relationship to other proposal activities). *To minimize potential negative effects on efficacy, we will emphasize the five elements of fidelity (i.e., intervention adherence, intervention dose or exposure, quality of delivery, participant responsiveness, core intervention components) (24). Although efficacy testing after planned adaptations is not feasible due to timeline and budgetary constraints of the R21 mechanism, the magnitude of pre/post intervention change in PA during the mini-trial (compared to the original efficacy study) and cost assessments are essential for planning a hybrid type 1 trial. Measurement of self-*

report [Godin Leisure-time Exercise Questionnaire (84-86)] and accelerometer PA will be similar to that used during efficacy testing (27, 29). The toolkit will be finalized after the mini-trial; content will include training and implementation manual, quick reference guides, group session materials, technical assistance contact information, slideshow for educating community stakeholders, etc. (additional detail in Appendix)].

Fidelity will be assessed with direct observation (research staff, during implementation, using standardized data collection sheets) and survey (all organizational levels, pre/post intervention). Service and client outcomes determined during toolkit development as being important to stakeholders will be assessed [possibilities include safety and quality of life such as SF-36 (87)] (Figure 1). A self-administered survey adapted from Steckler, et al (88), Moore and Benbasat (89), and Cook, et al (90) will assess acceptability (complexity, relative advantage), adoption (trialability), appropriateness (compatibility), and feasibility (compatibility, trialability). *The survey will also include questions regarding costs as informed by the qualitative work above. From the perspective of the implementing organization/s, we will identify all resources (labor, materials, facilities, etc.) used in the toolkit implementation, amount used, and unit cost of each resource (91-93). These resources include those for training, community awareness, screening and enrolling participants, and intervention delivery. From the participants, we will collect data on out of pocket costs related to, and time spent on, the intervention. Time effort will be valued using hourly wages of personnel and participants. Other resources will be valued using expenditures reported by implementing organizations or participants. As guided by the qualitative work, we will include survey questions about potential savings associated with the intervention (e.g., health care utilization).*

Data analysis: The majority of data will be qualitative with related data management described previously in the Approach section. The majority of the quantitative data analyses will be descriptive [e.g., safety (adverse events), adherence, intervention activities implemented as planned, etc.]. *The proof of concept phase will provide effect size estimates for comparison with the efficacy study (as discussed previously).* Assessing pre/post intervention PA in the 20 women cancer survivors (a budgetary and logistically feasible number sufficient for the grant's formative focus) will provide 80% power to detect a mean change of 76.4 minutes per week of ≥ moderate intensity PA as being statistically significant based on a standard deviation of 115.6 minutes, two-sided paired t-test, significance level of 5%. This is sufficient for detecting the pre/post change from baseline to 3 months of 128.9 weekly minutes (self-report) noted during efficacy testing (28). With regard to acceptability, adoption potential, and appropriateness, the mean of responses to Likert scale items developed will be analyzed pre/post intervention with participants combined (n=60)(paired t-test) and stratified by organizational level (participants, community stakeholders, and delivery staff)(analysis of covariance). We *will summarize costs from the perspective of implementing organization/s as average fixed [i.e., incurred regardless of the number of participants (e.g., training)], variable [i.e., vary depending on the number of participants (intervention sessions)], and total costs per participant* (91-93). *From the perspective of participants, we will also obtain a mean participation cost per person. We will also compare costs for PA and health care utilization incurred before and after participation using the data from the pre-post surveys. These analyses will inform implementation of BEAT Cancer on a larger scale as well as future analyses that compare costs and benefits of implementing the toolkit.*

Anticipated problems: Strategies will be used to facilitate recruiting and retaining participants representative of the stakeholders targeted in this proposal (e.g., ethnic/racial enrollment as noted in the targeted enrollment table, variety of ages, stakeholders from different organizational units, etc.). Possible approaches include: 1) recruitment activities developed based on input from the community partner, 2) "customer friendly" staff and scheduling, 3) expressions of appreciation, and 4) participant incentives. Including all cancer types increases the population of possible participants, facilitates diverse viewpoints, and improves intervention reach. Although we anticipate that intervention adaptation will minimize cost in an effort to improve intervention implementation, we will randomly select a subsample of the cancer survivors enrolled and/or seek funding from local philanthropic entities if the cost of the adapted intervention exceeds the amount budgeted.

Feasibility: The PI has demonstrated the ability to collaborate across disciplines and study sites (28, 59, 94, 95). BEAT Cancer was designed based on focus groups (96), clinic-based surveys (97-99), and population-based surveys (48, 100-103) demonstrating the PI's ability to collect and apply qualitative and quantitative data to intervention design. *The feasibility of carrying out a project within the UAB CCN is supported by Dr. Pisu and Dr. Martin's collaboration on a Healthcare Innovations Challenge Grant [e.g., involves a variety of patient interactions (in person, telephone, email, etc.); has enrolled almost 6,000 cancer survivors from 12 sites in five Southeastern states by working within the UAB CCN]. Therefore, this proposal has significant potential to reduce the burden of suffering in women cancer survivors by enhancing the implementation potential of an efficacious intervention that increases PA behavior and improves health.*

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