Clinic-to-Community Physical Activity Referrals for Cardiovascular Disease Risk Reduction in Cancer Survivors.

May 22nd, 2022

NCT05216380

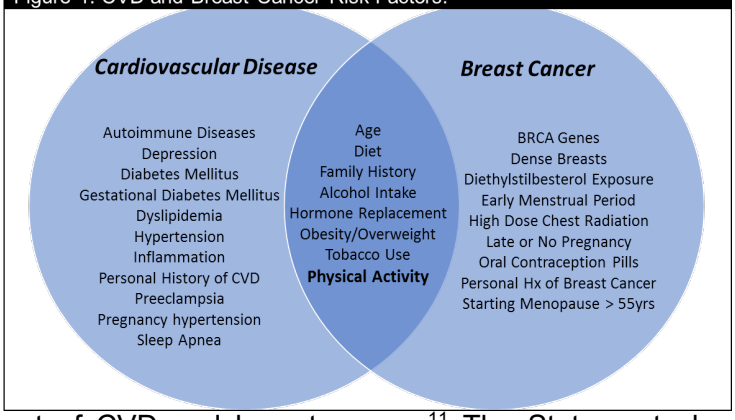
3. RESEARCH STRATEGY

3.1. Significance

3.1a. Cardiovascular Disease (CVD) - the leading cause of death among women.[28] CVD affects 47.8 US million women annually.[28] Though mortality from CVD has been declining overall, the decline has been significantly greater in men compared to women.[29] Studies show women are less aware of CVD risk than men.[30] Gender disparities are propagated by physicians as well. Physicians are more likely to assign a lower-risk category despite a similar calculated risk as compared to men.[31] Women are less likely to receive preventive treatment or guidance for CVD compared to men with a similar risk.[32]

3.1b. Breast cancer survivors (survivors) are at a higher risk of CVD,[33] as much as 30% more than their age-matched controls.[10] Over 3.8 million U.S. women have been diagnosed with breast cancer[34] and an estimated 280,000 new cases will be diagnosed in 2020.[35] CVD is a leading cause of non-relapse related mortality in women diagnosed with breast cancer.[36,37] This has been attributed to two main factors: **1)** The coinciding risk factors (e.g. advanced age, smoking, obesity and physical inactivity) associated with CVD and cancer (Figure 1),[8,12] and **2)** Survivors undergo toxic treatment that places them at an increased risk.[9] Racial disparities exist in those affected by CVD[38] and mortality from breast cancer.[39] To address these issues, the American Heart Association issued the first Scientific Statement in 2018 discussing prevention and treatment of CVD and breast cancer.[11] The Statement also suggests the fields of cardiology and oncology have long been working in silos.[11] This project addresses a major public health concern in a newly emerging cardio-oncology field receiving little attention to date.

Figure 1. CVD and Breast Cancer Risk Factors.



3.1c. Physical Activity reduces CVD Risk. Over 75% of deaths due to CVD could be prevented with adequate lifestyle changes.[38] Decades of research show physical activity has a cardioprotective effect on lowering CVD risk.[40] In addition to treating risk factors,[12] physical activity also mediates cardiotoxic effects of cancer treatments[13,14] and is associated with improved health outcomes after breast cancer diagnosis.[41,42]

3.1d. Though safe and effective, few survivors are physically active. Physical activity has been deemed safe and efficacious for survivors by the American College of Sports Medicine[43] and supported by the American Cancer Society.[44] Though the direct effect of exercise on CVD prevention in patients with breast cancer has yet to be evaluated in long-term randomized trials,[11] achieving physical activity guidelines is highly recommended. Due to the increased number of survivors, researchers have placed an emphasis on lifestyle interventions, including physical activity promotion to improve quality of life and counter disease progression[10] and other comorbidities.[11] However, less than 10% of patients will be physically active during treatment and only 20-30% physically active after treatment.[15,45] Survivor-reported barriers include program accessibility, affordability[12] and parking[46], while facilitators included convenient and survivor friendly environments.[47-49]

3.1e. The Institute of Medicine has recommended that cancer survivorship care plans be provided to all patients and include information on physical activity prescriptions and referrals.[16] Receiving a cancer diagnosis often presents a teachable time for behavior change, as patients are often motivated to improve their prognosis and survival.[50,51] Previous evidence[50,52] and my prior work (Section 3.3a.iii) shows providers are rarely giving survivors physical activity guidance and referrals. Providers often cite difficulty in referring patients to available behavior change programs.[53] Often, there is much uncertainty around referral pathways, including issues surrounding who refers the patient, where they refer them and who performs the follow-up.[54] There is a critical need for innovative implementation programs to increase physical activity referrals for these survivors.

3.1f. Our implementation program will focus on facilitating referrals to LIVESTRONG at the Y – an evidence-based community program. LIVESTRONG at the Y is an evidence-based, 12-week community physical activity program free of cost for survivors.[2-5] It is offered in over 10,000 communities and 42 US states at YMCA facilities.[55] It has proven efficacious at increasing survivor's physical activity levels (71% exercising at ≥ 150 minutes/week vs 26% of controls; $P<.05$), improvements in aerobic function (6-minute walk test, group difference: 28.9 meters [95% CI, 0.3-49.0; $P = .004$])[5] and physical function (balance, flexibility and strength).[4] Increases in both activity levels and fitness are related to decreases in one's CVD risk, thus showing promising results for health-related outcomes. Despite this potential for high reach and impact, my preliminary studies show that LIVESTRONG programs have trouble enrolling participants, especially from minority and underserved groups (Section 3.3a.ii). In order to offer LIVESTRONG, YMCA's must apply and undergo a 6-month needs assessment and training process to ensure they can meet the survivor's needs. Community-clinic integrated models can address health disparities in chronic disease treatment and care.[56] Drawing on components of the Chronic Care Model,[57] connecting patients to community resources improves management of chronic disease.

3.1g. Patient navigators are well-suited to referring survivors to LIVESTRONG but need to be supported. Patient Navigators, care coordinators linking patients to resources,[58] are well-suited to link patients to community physical activity programs. Navigators may be nurses, social workers or lay health workers who have received training in referring patients to programs that fit their logistical, geographic, cultural and economic preferences.[7] Navigators are essential both during and after cancer treatment and play a critical role in overcoming reported barriers of fragmented care, poor communication and lack of awareness of late effects and how to maximize health outcomes.[20] In my preliminary work with navigators (Section 3.3a.iii), they reported wanting more information on local lifestyle intervention programs. They also reported there was no formal system for referrals, though if they did refer, it was mainly by word of mouth.

3.1h. Adapting an electronic referral (e-referral) program for referring survivors to LIVESTRONG. Evidence has shown that oncologists providing a recommendation + referral compared with a recommendation only was associated with increased physical activity program participation in survivors.[59-61] However, providers lack time and program knowledge for referrals.[19] My proposal addresses these barriers through an electronic referral. My mentors' prior work found that an electronic referral compared to a paper referral was three times more effective in patient registration in a web-assisted tobacco intervention (Section 3.3a.iv).[22,23] E-referrals allow providers to refer and enroll patients in automated programs which can then send messages to the patient while providing real-time feedback to the provider. Using texting will allow for more traditional referral methods (e.g. paper, telephone) to be adapted to meet the rapidly evolving everyday use of patient digital technology and navigator's clinical workflow. Since the use of texting is almost ubiquitous including among minority and disadvantaged groups,[62] it will also increase reach of the referral.

3.2 Innovation

1. ActivityLink will be the first comprehensive implementation program developed to support patient navigator e-referrals of survivors with CVD risk factors of physical inactivity to a community-based program. Physical activity screening and subsequent referrals as a means of reducing CVD risk factors in cancer survivorship is vastly underdeveloped. As noted above, although survivors would greatly benefit from physical activity, few are physically active. Providers face many barriers to referring these survivors. I will adapt a novel, previously tested e-referral implementation program that was created for referring smokers from community medical and dental practices to a web-assisted tobacco intervention. Adaptation is needed to increase the efficiency and effectiveness of the program to the targeted population.[24] As I adapt the program, I anticipate creating additional innovations in each component of the e-referral program (such as the sample progress report in Figure 7). ActivityLink uses technology un-tethered to the electronic health record (EHR) system, allowing adaptations and increasing potential for dissemination. While the tethered (to the EHR) approach has some advantages, it may not be always amenable to adaptations in different settings. Further, it is not always accessible by community partners to communicate back to navigators.[63] Bi-directional feedback with community-based programs can be achieved with an untethered system.

2. I will use a participatory-stakeholder co-design and iterative approach to develop and beta-test ActivityLink, including the use of the PDSA cycle that was originally used by business for the control and continuous improvement of processes and products. Designing programs linking clinics and communities using technology requires both user and community feedback. As noted in Section 3.3c, the Clinic and Community Advisory Board (CAB) will be an integral part of each aim. Further in Aim 2, we will use the PDSA cycle to beta-test ActivityLink in two waves. In the healthcare arena, the PDSA cycle has been used to develop an interspecialty inpatient referral system,[64] test ideas on a small scale prior to full implementation[65] and used to implement projects into clinical workflow.[66] The conduct of the PDSA cycle while using a participatory-stakeholder co-design approach[67] is another innovation of our project. Co-design approaches take into account the viewpoints of patients, clinicians and stakeholders and actively involve them in all aspects of the design.

3.3 Approach

3.3a. Preliminary Data: **As a T32 Implementation Science Fellow, I have conducted a series of research projects that have informed the proposed K12 project.** In addition, this proposal builds on lessons learned from my mentor's research in e-referrals to smoking cessation programs.

i. LIVESTRONG has capacity to reach more survivors, though barriers exist. In my first study I examined data collected by YMCA-USA for all LIVESTRONG programs between 2010-2018 (manuscript under review). I used the RE-AIM framework[68] to assess reach, adoption, implementation and variables associated with participant-level maintenance, or membership conversion rate. Since 2010, LIVESTRONG has reached 62,044 survivors and 245 YMCA Associations (29.17%) adopted the program. However, 60,000 is just a fraction of the 16.9 million cancer survivors, with that number projected to increase to 20.3 million in the year 2026 [69], suggesting the need to reach additional survivors. I also found disparities exist. The mean membership conversion rate was significantly greater in higher household income areas as compared to lower household income areas (48.5 vs. 44.3; p=0.01). Similar disparities in accessing physical activity programs have been documented by other researchers.[70] These data suggest LIVESTRONG has the capacity to increase its reach to more survivors, though disparities exist amongst socioeconomic status levels.

ii. LIVESTRONG at the Y has difficulty enrolling survivors. In my second study, I performed semi-structured interviews with LIVESTRONG Program Directors (n=13), Instructors (n=7) and graduates (n=8) from 9 U.S. states to identify barriers and facilitators to participant enrollment. **Barriers: 1)** Limited resources to market and recruit, **2)** Lack of physician knowledge/awareness and lack of formal referral system, **3)** Lack of patient knowledge about the program, and **4)** Lack of patient follow-up on program attendance or activity. **Facilitators: 1)** Most programs had the capacity to serve additional survivors, **2)** Strong relationships with cancer clinic staff and providers, **3)** Referrals embedded in electronic medical records, **4)** Provider feedback on patient progress in the program, and **5)** Patient referral and follow-up from cancer clinic staff. These data suggest the need to integrate an e-referral system into the clinic to increase patient referrals to LIVESTRONG programs.

iii. Providers may have limitations to making referrals to physical activity programs, including LIVESTRONG. In my 3rd study, I performed interviews with UMass Memorial Health Care (UMMHC) Cancer Clinic administrators (n=2), oncologists (n=2), nurses (n=3) and patient navigators (n=8) to understand barriers to physical activity education and referrals. They reported lacking knowledge of available physical activity programs and/or a lack of standard operating procedures for physical activity referrals (timing in care, type of cancer, pre- or post-surgery etc.), having no place to document referrals and no follow-up with patients. All feedback suggested patient navigators may be best-suited to educate and refer to programs during their care coordination meetings. When discussing integrating a system into the EHR, navigators did not feel strongly about this, as EHR presents its own challenges, particularly when working with community-partners. These data suggest integration of referrals into standard practice may be best delivered by patient navigators.

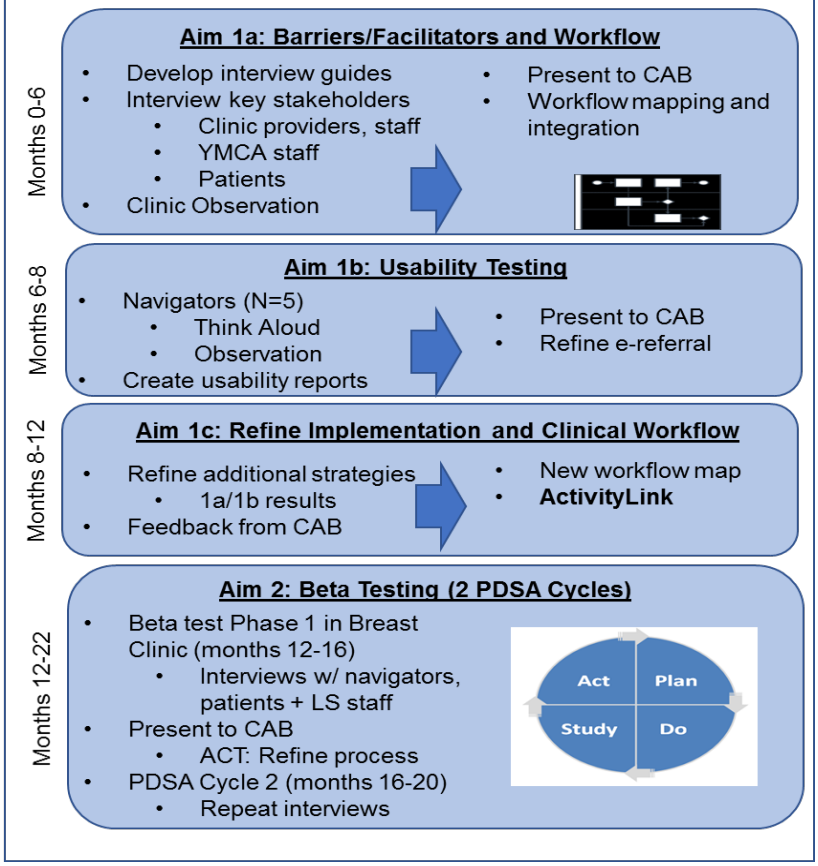
iv. Integrating e-referrals into clinical practice. I will build off my mentors' prior work testing an e-referral process (implementation strategy) in community-based medical practices to increase patient access to an evidence-based tobacco cessation intervention.[22,23,71] Using the Chronic Care Model[57], they connected medical and dental practices to a community-based tobacco cessation intervention using a secure e-referral system. The system used motivational messaging, email reminders, cues and follow-up to increase participation and adherence in the intervention (Section 3.3g.). Providers and staff were supported with training, toolkits and strategies to deliver referrals, monitor enrollment and provide follow-up. 93% of practices used the e-referral system and providers who viewed the practice feedback reports were significantly more likely to refer patients compared to those who did not. The e-referral process resulted in greater smoker referrals (33%) compared to the comparison paper referral (11%).[22,23]

In conclusion, my preliminary data demonstrates: 1) Survivors face clinic barriers to physical activity guidance and referrals, 2) LIVESTRONG programs that are successful in recruiting have referral and feedback methods established with providers, and 3) My ability to establish relationships and work with clinic, community and patient stakeholders, making this project feasible.

3.3b. Study Overview: I will develop ActivityLink, an adapted e-referral implementation program to increase participation in an evidence-based physical activity program (LIVESTRONG at the Y). ActivityLink will be adapted to a new setting and population from a previously used e-referral implementation program (Aim 1) and then beta tested (Aim 2) to set the stage for a future large feasibility pilot trial (Figure 2). In Aim 1, I will conduct formative work (1a), usability testing with navigators (1b) and refinement of ActivityLink to be integrated into clinical workflow (1c). Lastly, I will use 2 process cycles to beta test and refine ActivityLink for navigators to deliver to survivors with a CVD risk factor of physical inactivity (Aim 2). My formative work with clinical partners supports the navigator's delivery of the ActivityLink.

3.3c. The Clinic and Community Advisory Board (CAB): First I will finalize the partially established CAB. The CAB will bring together constituents from the clinic and community to provide feedback on the overall project,

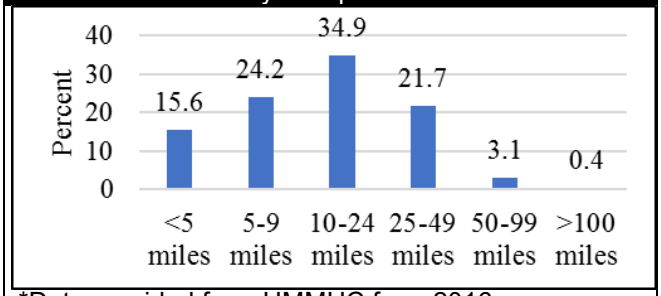
Figure 2. Study overview and timeline by aim.



including interview questions, workflow mapping, usability and refinement of the implementation program and adaptations during beta testing. The CAB will meet bi-monthly in year 1. In year 2, we will frontload the 6 meetings to match to the timing of our PDSA cycles. The CAB will consist of key stakeholders with whom I have already established relationships: UMMHC patient navigators, cardiology and oncology providers, YMCA-USA, LIVESTRONG staff and participants. I will include 1 member of the UMMS Center for Clinical and Translational Science, Science Participation Recourse Center's Community Advisory Board will (increase engagement of special populations in translational research through tailored, culturally responsive strategies).

3.3d. Setting: I will conduct the study in the Breast Clinic at UMMHC University Campus. The clinic is situated in Worcester, MA, with a population of 57.1% White, 20.9% Hispanic or Latino, and 11.8% Black or African American. The median household income is $45,869; 35.8% of the people speak a non-English language. The clinic employs 10 patient navigators who we will work with throughout the entirety of the study. In 2016 the clinic treated 461 women, with ~40% (n=184) of women living <9 miles from the Clinic (Figure 3). Breast Clinic data from 2016 showed that ~89% of the patients were White, though data on ethnicity and socioeconomic status are lacking. I will work with three YMCA branches within a 6-mile radius of the clinic: 1) Boroughs Family Branch YMCA (Westborough, MA), 2) Central Community Branch YMCA (Worcester, MA), and 3) Greendale YMCA (Worcester, MA). Though the Breast Clinic and YMCA sites have lower proportions of minority and underserved survivors, I chose them for convenience for this K12. I plan to work with more diverse sites in future.

Figure 3. Distance traveled to UMMHC Breast Clinic at UMMHC University Campus

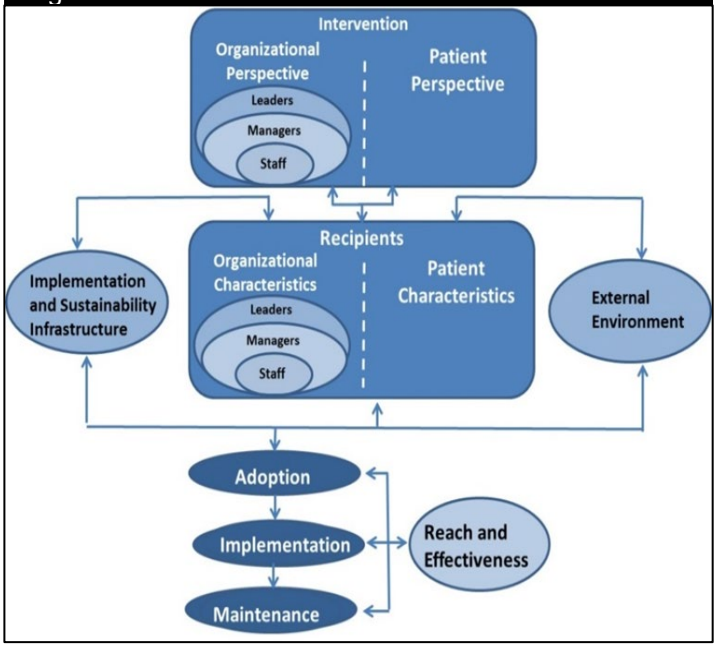


*Data provided from UMMHC from 2016.

3.3e. LIVESTRONG at the Y – an evidence-based community-based physical activity program designed for survivors: The evidence-based intervention to which navigators will refer patients is LIVESTRONG at the Y.[72] As previously stated, LIVESTRONG is an evidence-based 12-week physical activity program free of cost to survivors. The program has shown increases in physical activity levels, aerobic fitness and physical function.[4,5] Survivors are able to participate at any point following a cancer diagnoses with physicians' clearance. Enrolled participants will attend 2 sessions/week for 12 weeks. Sessions focus on aerobic, strength, balance and flexibility exercises and participants are tested at baseline and again at the end of the 12-week program. LIVESTRONG is offered in over 800 communities across the U.S.

3.3f. Theoretical Framework: After discussing with my mentors, I chose the Practical, Robust Implementation and Sustainability Model (PRISM) as an overarching framework to guide future larger, multi-site trials.[1] PRISM is an ideal fit because it spans the development spectrum – from the planning to the implementation and evaluation stages of the program.[73] PRISM is an explanatory-prescriptive mode and translates research to practice using concepts from quality improvement, chronic care, the diffusions of innovations and measures of the population-based effectiveness of translation.[1] Elements include: 1) program or intervention, 2) external environment, 3) sustainability and infrastructure, and 4) recipients. It focuses on examining key contextual factors at multiple levels to determine their effect on RE-AIM[68] outcome measures. The PRISM domains will guide my pre-implementation work in Aim 1 and examination of qualitative RE- AIM measures[74] in Aim 2. These assessments will guide the refinement of ActivityLink for future feasibility testing of the program in my K01 proposal.

Figure 4. PRISM Framework.[1]



3.3g. Developing and Beta-testing ActivityLink: As noted, I will use a co-design approach to adapt an existing e-referral program for ActivityLink. Below, I will first describe the existing e-referral program followed the anticipated adaptations. I will then describe my approach for Aims 1 and 2.

The Existing e-referral Implementation Program (ActivityLink): To develop ActivityLink, I will adapt an existing e-referral implementation program developed for facilitating referrals of smokers from community medical and dental practices to an web-assisted tobacco intervention.[22,23] Below, I describe the technology and supporting implementation components of the existing e-referral program. I will then discuss anticipated adaptations, followed by describing my steps to adapt this program for ActivityLink in the Aims.

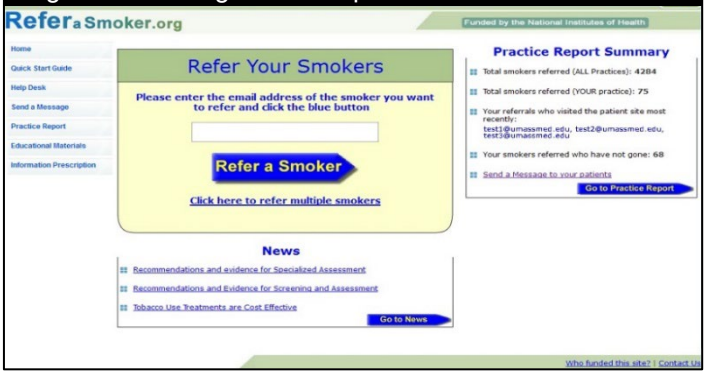
Technology-assisted components of the existing referral program included:

A. The secure Web-form for e-referral where providers could securely refer patients by entering their emails or mobile phone numbers into the system if they agree to be referred (Figure 5). Once entered, the system sent motivational emails/texts to encourage participation in the intervention.
B. Messaging templates that providers could customize to send messages to their patients reinforcing their participation in the web-assisted tobacco intervention and progress towards their cessation goals.
C. Feedback: The system provided real-time feedback to providers about smokers use of the web-assisted tobacco intervention. This was displayed as part of the practice report summary on the website.

Additional supporting components included:

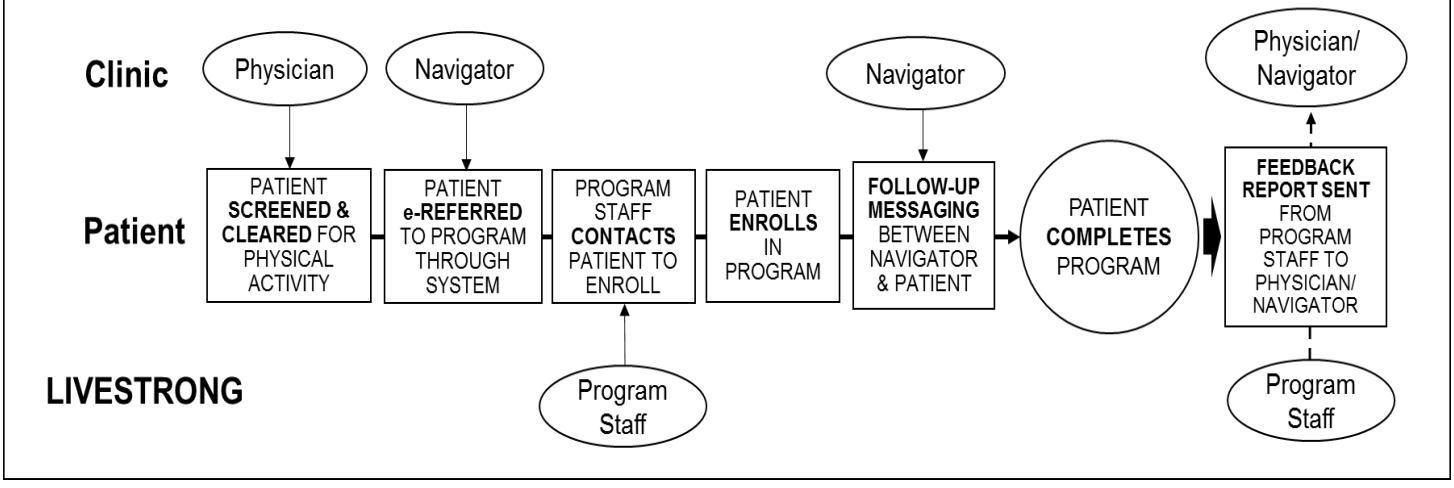
A. Paper prescription form: In my mentor's beta testing of the e-referral system,[71] they discovered that practices simply forgot to refer patients in the Web-based form. Thus, for the main study, they included printed information prescription pads as part of the program. Practices used the pad to write the name and email of the smokers who wished to be referred. The champions used the pad to refer the smokers on the secure e-referral Web-form at a convenient time. As noted above, this process was successful in the main study.[27]
B. Training: Individualized telephone/Internet trainings using an academic detailing approach were provided to implementation champions (physicians, nurses, dentist, hygienist, or other staff) at each practice. Training included hands-on demonstrations of the technology-assisted components described above, including practicing e-referring a "test" smoker. As a guide, a detailed training script was developed.
C. Booster sessions: To support implementation, a series of 4 motivational emails were sent and 15-30-minute calls made over a 6-week period.
D. Visual cues: Workflow support materials to aid referrals, such as fliers, were provided as cues to remind providers to refer smokers to the study.

Figure 5. Existing e-referral provider dashboard



Anticipated Adaptations of the e-referral and Implementation Program for ActivityLink: The design of the original trial was based on the "5A's" of counseling for behavior change: ASK (Current smoker), ADVISE (Recommendations on cessation), ASSESS (Readiness to begin program), ASSIST (Program referral, additional resources needed) and ARRANGE (Schedule follow-up call with patient). I will use a similar design adapted to a Breast cancer clinic setting and referral to an in-person community program (LIVESTRONG). Figure 6 shows my initial concept of the workflow for referrals in ActivityLink. Anticipated adaptations to the technology-assisted components, include: a) the e-referral system to include zip code entering, triggering an automated notification to LIVESTRONG program staff at the nearest site, b) motivational messaging templates to prompt patients to complete their program enrollment, and c) feedback on participants' attendance to and performance in LIVESTRONG (proposed in Figure 7). Anticipated adaptations to additional supporting components may include: a) training of navigators to include motivational interviewing on overcoming barriers to program attendance and, b) systematic protocol for screening patients, providing medical clearance and transmitting information to navigators for subsequent referral to LIVESTRONG.

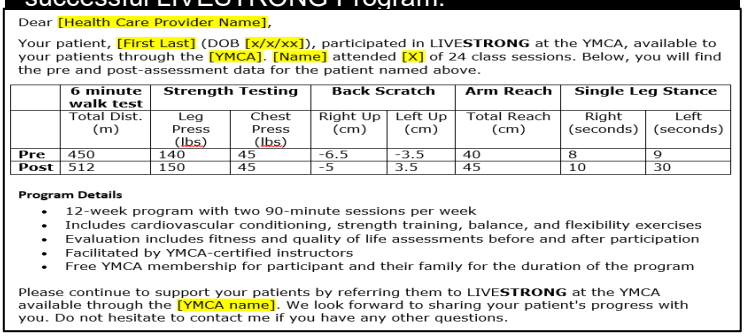
Figure 6. Proposed steps of ActivityLink



3.3h. Specific Aim 1 (Months 1-12): Develop ActivityLink implementation program to increase e-referrals to an evidence-based physical activity program (LIVESTRONG at the Y).

Sub-Aim 1a (Months 1-6): Understand the clinical workflow, barriers and preferences to referrals of survivors to LIVESTRONG (protocol, screening, triaging, and follow-up) by conducting qualitative interviews with key stakeholders (UMMHC patient navigators, oncology and cardiology providers, clinic staff, patients and LIVESTRONG staff). Participants will provide informed consent prior to interviews.

Figure 7. Sample patient progress report used by a successful LIVESTRONG Program.



Dear [Health Care Provider Name],

Your patient, [First Last] (DOB [x/x/xx]), participated in LIVE**STRONG** at the YMCA, available to your patients through the [YMCA]. [Name] attended [X] of 24 class sessions. Below, you will find the pre and post-assessment data for the patient named above.

	6 minute walk test	Strength Testing		Back Scratch		Arm Reach	Single Leg Stance	
	Total Dist. (m)	Leg Press (lbs)	Chest Press (lbs)	Right Up (cm)	Left Up (cm)	Total Reach (cm)	Right (seconds)	Left (seconds)
Pre	450	140	45	-6.5	-3.5	40	8	9
Post	512	150	45	-5	3.5	45	10	30

Program Details

- 12-week program with two 90-minute sessions per week
- Includes cardiovascular conditioning, strength training, balance, and flexibility exercises
- Evaluation includes fitness and quality of life assessments before and after participation
- Facilitated by YMCA-certified instructors
- Free YMCA membership for participant and their family for the duration of the program

Please continue to support your patients by referring them to LIVE**STRONG** at the YMCA available through the [YMCA name]. We look forward to sharing your patient's progress with you. Do not hesitate to contact me if you have any other questions.

1. Develop interview guides informed by PRISM domains and implementation prototypes (Table 1). Using PRISM domains, interview guides will be developed with iterative feedback from the CAB. I will examine topics including those affecting implementation of the program and participation in LIVESTRONG and implementation strategy prototype screenshots for feedback.
    a. I will create screenshot prototypes of implementation strategies to be adapted, including the referral webform (Figure 5) and a patient progress report (Figure 7).

Table 1. Examples of interview questions mapped on to PRISM[1] domains.

PRISM Domain	Example of Key Questions Relevant to ActivityLink
Program (Intervention) Organizational perspective Patient perspective	• What steps are needed to prepare key staff to identify and screen patients? To conduct the program? How can the system best be embedded into workflow? • How can the program be more patient-centered and less complex for patients? Does it address important patient barriers to response?
External Environment	• Are there community/outside resources that can enhance intervention?
Implementation & Sustainability Infrastructure	• How can existing infrastructure be used to handle key implementation/sustainability tasks? • Can implementation/sustainability tasks be part of key staff/Navigator job descriptions?
Recipients Organizational characteristics Patient characteristics	• Which available systems can best support implementing the program? Do key staff expect the program to be sustainable? • What are common knowledge, beliefs and perceived risk patterns among patient recipients? (modifiable factors regarding patient perceived net benefit)

2. Obtain feedback from key stakeholders. I will conduct semi-structured phone interviews (30-minutes) with UMMHC breast patient navigators (n=2), oncologists/radiologists (n=2), cardiologists (n=2), and patients (n=2) who are not part of the CAB. I will ask clinical stakeholders about current workflow for physical activity counseling/referrals or anticipated changes in workflow that need to be made using use-cases, often used by software engineers, to elicit workflow depiction.[75] Use cases describe how a user completed a task in a sequence of simple steps, beginning with a user's goal and ending when that goal is fulfilled. Thus, it is easier for the user to understand the workflow and highlight issues/provide additional details about the use-case. Under Dr. Sadasivam's guidance (a software engineer), I will use my clinical shadowing experience and field notes (see Training Plan) to develop initial use-cases as prompts for the discussion. Recruitment: I will use established partnerships and snowball sampling to recruit clinic staff and physicians and information extracted from EHR to identify patients for recruitment (HIPAA waiver). Navigators will aid in this effort.

Sub-Aim 1a Data Analysis: Under the direction of the qualitative advisor, Dr. Kristin Mattocks, I will transcribe interviews verbatim and use a coding start-list based on protocol content (deductive) followed by open coding driven by immersion in the data (inductive).[76] Myself and one other research team member with experience analyzing qualitative data will each code >10% of transcripts and coding checks will be completed to ensure inter-rater reliability. Disputes in coding decisions will be discussed within the research and mentor team until resolved and a kappa > 0.75 is attained, at which point the entire dataset will be coded. Based on the use-cases, I will also create a workflow map using swimlanes (Lucid software) to document what the actual workflow of the patient navigator is surrounding physical activity counseling/referrals. This will include their communication and interactions with oncologists, cardiologists and other clinic staff.[66] I will then present these results to the CAB to refine the program as discussed in Aim 1c.

Sub-Aim 1b (Months 6-8): Refine the e-referral Web form using think aloud usability testing with Navigators. I will perform usability testing with our users, present feedback to the research team and the CAB and make iterative refinements to the protocol as needed.

1. Conduct usability testing. I will use "Think Aloud"[77] protocols as follows: While users are reviewing the content, they will be asked to vocalize thoughts, feelings, and opinions while interacting with the system. Think Aloud allows you to understand how the user approaches the interface and what considerations they keep in mind while using. Participants will complete a rating instrument including questions addressing the

acceptability, accuracy, ease of use and satisfaction with the system. Since the recommendation indicates that the majority of issues can be identified with 4±1 users,[78] I will test the system with up-to 5 navigators.

a. **Analysis:** Testing sessions will be transcribed, data segmented and codes applied to identify themes in the data.[77] I will combine these themes with field notes to design usability reports.

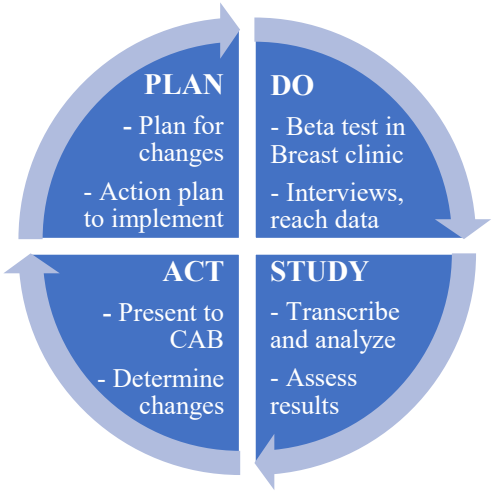
2. Systematically compare users' feedback.[79] To determine the need for refinements and additional testing, we will present reports to the CAB. If 50% or more of participants have difficulty achieving a task within the system, I will consider this problematic and revise that feature with iterative feedback from users'.[80] I will use this iterative process until less than 50% of participants are having issues with completing the tasks.

Sub-Aim 1c (Months 8-12): Refine the e-referral additional components to support integration into the clinical workflow (paper prescription form, reminders, training and booster program and feedback) for navigators using feedback from aims 1a and 1b. I will work iteratively with the CAB. Specifically, I will:

1. Create feedback summary reports based on aims 1a and 1b.
   a. Barriers and facilitators, implementation strategies, clinical workflow and usability reports.
2. Create new clinical workflow swimlane mapping and protocol including strategies and e-referral.
3. Meet with the CAB, present feedback reports, swimlane mapping and protocol.
4. Based on feedback, refine clinical workflow and protocol. Re-distribute to CAB for approval.
5. Develop final version of protocol and swimlane workflow mapping to be beta tested in Aim 2.

3.3i. Specific Aim 2 (Months 12-22): Beta test in UMMHC Breast Clinic and refine based on user feedback. This Aim will provide insight into feasibility and acceptability of ActivityLink delivered by navigators to survivors at rick of CVD. I will beta test the program in 1 clinic and at 3 YMCAs (3.3d. Setting). Beta testing is commonly conducted in iterative cycles and used to verify program readiness and user satisfaction prior to a full-scale launch.[81] Results from beta testing will inform a larger, multi-site feasibility pilot trial resulting in randomization at the level of the clinic mirroring my mentors' prior work.[82]

Figure 8. PDSA Cycle (2 cycles).



Design: I will beta test ActivityLink in two waves using Plan, Do, Study, Act (PDSA) Cycles.[25] PDSA cycles are best used to test ideas on a small scale prior to full implementation[65] and are commonly used for implementation of projects into clinical workflow.[66] As detailed below, the initial wave will be 8-weeks in length and used to refine ActivityLink for the second wave (8 weeks). Waves will be timed with the LIVESTRONG program calendar (new sessions begin in January, April, July and October). Thus, I plan to conduct the first wave for the October 2021 session and the second wave for the January 2022 (Figure 8).

Recruitment, Screening, Informed Consent and Data Collection: The Breast clinic employs 10 patient navigators. Inclusion Criteria: Navigators in the UMMHC Breast Clinic will be eligible to participate if they: 1) are employed as a navigator of the clinic and 2) provide written informed consent. Navigator Recruitment: I have already developed relationships with clinic navigators and will provide information on the study enrollment at their monthly in-service meeting. Interested navigators will complete an informed consent prior to enrolling in the study. Patient Recruitment: I will use an opt-out strategy for recruiting patients for the follow-up interview. Based on the workflow designed, eligible patients will be screened and referred to the program by the navigator. For those who agree to be referred, the navigator will enter their information to the e-referral system. For these patients and those who do not want to be referred, navigators will also document their contact information and reasons for not joining the program/refusing referrals as part of their clinical workflow. Navigators will also provide a brochure that will include information about the research study and that someone may contact them for a follow-up interview. The brochure will include contact information (email, text, and mailing information) for them to use to opt out of the follow-up interview if they wish to do so. I, or my research staff will then contact patients who have not opted out to schedule an interview. Data Collection: Follow-up phone calls with navigators, a sub-sample of patients and LIVESTRONG staff will be done to conduct qualitative assessments (verbal informed consent prior to the interview). I will also collect quantitative measures to assess number of referrals.

PDSA Cycle 1: Plan - Using feedback from Aim 1, ActivityLink wave 1 will go live 8 weeks prior to the start of the 3rd quarterly LIVESTRONG session (October 2021). I will use the plan designed and informed by the CAB in Aim1c for the program implementation. Navigators will undergo training on implementing ActivityLink and receive detailed protocol and workflow mapping prior to the start.

Do **–** During the implementation of ActivityLink navigators will receive booster phone calls and emails weekly (8 each) to encourage implementation and troubleshoot any issues. Measures: Throughout the implementation period, I will interview navigators using ActivityLink, patients who have been referred (accepted and declined) and LIVESTRONG site Program Directors. Navigator interviews will examine RE-AIM measures

(see Table 2) associated with the ActivityLink and any additional questions identified from the CAB. I will conduct at least 1 navigator interview every 2 weeks. Patient and LIVESTRONG staff interviews will examine barriers, facilitators and preferences of the ActivityLink referral process. I will interview patients (n=2-3) who were referred to the program (identified by our e-referral system), patients who declined (n=2-3) and LIVESTRONG Program Directors (n=3) starting 2 weeks after each wave launches. I will collect data navigators recorded from patients who refused the referral. Number of referred patients (from e-referral system) and number refused (from navigator documentation) will be collected during the 8 weeks.

Study - For qualitative analysis**,** I will use a similar protocol to Aim 1a (deductive followed by inductive approach.[76] Transcripts will be coded by myself and 1 other research team member using coding checks (10% transcripts) to ensure inter-rater reliability. We will resolve disputes in coding (> 0.75 Kappa) and then the entire dataset will be coded. Quantitative data will not be analyzed due to the small sample size, though I will present descriptive statistics of number of referrals, number of declined referrals and proportion of eligible patients referred (based on number of survivors treated in the clinic during the wave) and present to the CAB.

Act – I will organize results and present them to the CAB to help determine the need for adaptations to the system. Using the CABs feedback, we will develop action-items for changes to be made in Cycle 2.

PDSA Cycle 2: The CAB will help to determine adaptations needed to the new implementation plan. The second ActivityLink wave will go live 8 weeks prior to the January 2022 session and navigators will be trained on the newly adapted system. I will collect the same qualitative and quantitative measures as identified in PDSA Cycle 1. At the conclusion of wave 2 (Act), I will work with the CAB to refine and package ActivityLink to be ready for testing in pilot feasibility trial (see section 3.4).

Table 2. Qualitative sample navigator interview questions mapped on to RE-AIM measures.[74]

RE-AIM Measures	Sample Questions
Reach	• What factors contribute to the participation/non-participation of the participants? • What might have been done to get more of the target audience to participate?
Adoption	• What factors contributed to the organization and its individuals taking up ActivityLink? • What barriers interacted with the ActivityLink to prevent adoption? • Was there partial or complete adoption? • Why did some staff members in these organizations participate and others did not?
Implementation	• How was the ActivityLink implemented? By whom and when? • What influenced implementation or lack of implementation? • What combination of implementation effects affected the outcome results? • How and why was the program adapted or modified over time?
Maintenance	• Do you foresee ActivityLink being implemented after the program core period? • What is needed to maintain this program?

3.4 Impact and Future Directions

If funded, this project will help to advance my career as an implementation scientist and inform the development of a sustainable integrated community-clinical program that can impact the heart health and longevity of breast cancer survivors. I will end this award period with a refined version of ActivityLink to be further tested in a multi-clinic feasibility pilot trial. I have devoted time to manuscript preparation and grant writing which I will take place throughout the duration of the award. I will write-up and submit 3 manuscripts involving the project planning/design, protocol and final outcomes to Implementation Science and Public Health journals. During the second year of this K-award, I will write and submit a K01 (NHLBI) to test the feasibility of ActivityLink. The NHBLI K01 mechanism has specifically called for innovative research in the area of: “Implementation (T4 translation) research that addresses strategies for sustained adoption of proven, effective interventions in communities, health systems, clinicians, patients and families for heart, lung, and blood diseases and sleep disorders”. Thus, my project will be an apt fit for this mechanism. To further disseminate my work, I will present at annual conferences for Dissemination and Implementation Science, Society of Behavioral Medicine and UMMCCTS Community Engagement and Research Symposium. Quarterly reports will be distributed to the UMMHC Cancer Center, Cardiology Department and YMCA partners.

Table 3. Research timeline.

	Months of Project											
Task	2	4	6	8	10	12	14	16	18	20	22	24
Aim 1: Develop ActivityLink implementation program												
Protocol finalization/IRB approval	■											
Stakeholder interviews (1a)		■	■									
Usability testing/refinement (1b)			■	■								
Refine implementation/workflow (1c)				■	■	■						
Finalize ActivityLink						■						
Aim 2: Beta test implementation program												
Patient referrals and interviews						■	■	■				
Program completion and interviews							■	■	■	■	■	

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